OMB Number: 4040-0001
Expiration Date: 06/30/2011

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE	State Application Identifier

1. * TYPE OF SUBMISSION
☐ Pre-application ☐ Application ☒ Changed/Corrected Application

2. DATE SUBMITTED | **Applicant Identifier**

4. a. Federal Identifier: GRANT10782520

b. Agency Routing Identifier:

5. APPLICANT INFORMATION

*** Organizational DUNS:** 806345617

* Legal Name: Arizona Board of Regents, University of Arizona
Department: | Division:
* Street1: P.O. Box 3308
Street2:
* City: Tucson | County / Parish: Pima
* State: AZ: Arizona | Province:
* Country: USA: UNITED STATES | * ZIP / Postal Code: 85722-3308

Person to be contacted on matters involving this application
Prefix: Ms. | * First Name: Sherry | Middle Name: L
* Last Name: Esham | Suffix:
* Phone Number: 520-626-6000 | Fax Number: 520-626-4137
Email: sponsor@email.arizona.edu

6. * EMPLOYER IDENTIFICATION *(EIN) or (TIN):* 1742652689A1

7. * TYPE OF APPLICANT: H: Public/State Controlled Institution of Higher Education
Other (Specify):
Small Business Organization Type ☐ Women Owned ☐ Socially and Economically Disadvantaged

8. * TYPE OF APPLICATION:
☒ New ☐ Resubmission
☐ Renewal ☐ Continuation ☐ Revision

If Revision, mark appropriate box(es).
☐ A. Increase Award ☐ B. Decrease Award ☐ C. Increase Duration ☐ D. Decrease Duration
☐ E. Other (specify):

* Is this application being submitted to other agencies? Yes ☐ No ☒ What other Agencies?

9. * NAME OF FEDERAL AGENCY: National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:
TITLE:

11. * DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:
The Cost Effectiveness of School-Based Supervised Asthma Therapy

12. PROPOSED PROJECT:
* Start Date: 12/01/2011 | * Ending Date: 05/31/2015

*** 13. CONGRESSIONAL DISTRICT OF APPLICANT:** AZ-007

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION
Prefix: | * First Name: Lynn | Middle Name: B
* Last Name: Gerald | Suffix: Ph.D.
Position/Title: Professor
* Organization Name: Arizona Board of Regents, University of Arizona
Department: Health Promotion Sciences | Division: College of Public Health
* Street1: Post Office Box 245163
Street2:
* City: Tucson | County / Parish: Pima
* State: AZ: Arizona | Province:
* Country: USA: UNITED STATES | * ZIP / Postal Code: 85724-5163
* Phone Number: (520) 626-3243 | Fax Number: (520) 626-1660
* Email: lgerald@email.arizona.edu

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested	3,929,227.00
b. Total Non-Federal Funds	0.00
c. Total Federal & Non-Federal Funds	3,929,227.00
d. Estimated Program Income	0.00

16. * IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES ☐ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE:

b. NO ☐ PROGRAM IS NOT COVERED BY E.O. 12372; OR

☒ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious. or fraudulent statements or claims may subject me to criminal, civil, or administrative penalities. (U.S. Code, Title 18, Section 1001)

☒ *** I agree**

**** The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.***

18. SFLLL or other Explanatory Documentation

Add Attachment | Delete Attachment | View Attachment

19. Authorized Representative

Prefix: * First Name: Leslie Middle Name: P

* Last Name: Tolbert Suffix: Ph.D.

* Position/Title: Vice-President for Research

* Organization: Arizona Board of Regents, University of Arizona

Department: Division:

* Street1: P.O. Box 3308

Street2:

* City: Tucson County / Parish: Pima

* State: AZ: Arizona Province:

* Country: USA: UNITED STATES * ZIP / Postal Code: 85722-3308

* Phone Number: 520-626-6000 Fax Number: 520-626-4137

* Email: sponsor@email.arizona.edu

*** Signature of Authorized Representative**: Sean Armstrong

*** Date Signed**: 01/25/2011

20. Pre-application Add Attachment | Delete Attachment | View Attachment

424 R&R and PHS-398 Specific Table Of Contents

Appendix

Number of Attachments in Appendix: 1

OMB Number: 4040-0010
Expiration Date: 08/31/2011

Project/Performance Site Location(s)

Project/Performance Site Primary Location ☐ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: Arizona Board of Regents, University of Arizona
DUNS Number: 8063456170000
* Street1: P.O. Box 3308
Street2:
* City: Tucson County: Pima
* State: AZ: Arizona
Province:
* Country: USA: UNITED STATES
* ZIP / Postal Code: 85722-3308 * Project/ Performance Site Congressional District: AZ-007

Project/Performance Site Location a ☐ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: The Board of Trustees at University of Illinois
DUNS Number: 0989872170000
* Street1: 304 AOB, M/C672
Street2: 1737 West Polk Street
* City: Chicago County:
* State: IL: Illinois
Province:
* Country: USA: UNITED STATES
* ZIP / Postal Code: 60612-7227 * Project/ Performance Site Congressional District: IL-007

Project/Performance Site Location 2 ☐ I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: American Lung Association of Arizona
DUNS Number: 0201417760000
* Street1: 102 West McDowell Road
Street2:
* City: Phoenix County:
* State: AZ: Arizona
Province:
* Country: USA: UNITED STATES
* ZIP / Postal Code: 85003-0000 * Project/ Performance Site Congressional District: AZ-008

Performance Sites

Additional Location(s) Add Attachment | Delete Attachment | View Attachment

RESEARCH & RELATED Other Project Information

1. * Are Human Subjects Involved? ☒ Yes ☐ No

1.a If YES to Human Subjects

Is the Project Exempt from Federal regulations? ☐ Yes ☒ No

If yes, check appropriate exemption number. ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

If no, is the IRB review Pending? ☒ Yes ☐ No

IRB Approval Date:

Human Subject Assurance Number:

2. * Are Vertebrate Animals Used? ☐ Yes ☒ No

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ☐ Yes ☐ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. * Is proprietary/privileged information included in the application? ☐ Yes ☒ No

4.a. * Does this project have an actual or potential impact on the environment? ☐ Yes ☒ No

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ☐ Yes ☐ No

4.d. If yes, please explain:

5. * Is the research performance site designated, or eligible to be designated, as a historic place? ☐ Yes ☒ No

5.a. If yes, please explain:

6. * Does this project involve activities outside of the United States or partnerships with international collaborators? ☐ Yes ☒ No

6.a. If yes, identify countries:

6.b. Optional Explanation:

7. * Project Summary/Abstract 1244-abstract.pdf Add Attachment Delete Attachment View Attachment

8. * Project Narrative 1245-Narrative.pdf Add Attachment Delete Attachment View Attachment

9. Bibliography & References Cited 1246-BIBLIOGRAPHY & REFERENCES.pdf Add Attachment Delete Attachment View Attachment

10. Facilities & Other Resources 1247-Facilities & Other Resources.pdf Add Attachment Delete Attachment View Attachment

11. Equipment Add Attachment Delete Attachment View Attachment

12. Other Attachments Add Attachments Delete Attachments View Attachments

Abstract

Asthma is a common chronic condition among children that is associated with significant morbidity. Because medication non-adherence is an important cause of excess morbidity, the National Asthma Education and Prevention Program guidelines have called for the development of more effective adherence programs. Schools represent a logical setting where adherence programs could reach the inner-city, low-income, and ethnically diverse populations that have the highest morbidity and lowest adherence. A recent clinical trial demonstrated that supervised therapy of daily controller medication at school increased medication adherence and asthma control among primarily African-American students in urban, low-income elementary schools.

This study aims to evaluate: (1) the effectiveness of supervised therapy when administered by the community under real world conditions via a randomized controlled trial of 500 children with asthma in a large urban, predominantly Hispanic school system; (2) the cost-effectiveness of supervised therapy from the societal perspective using dollars per quality-adjusted life year (QALY) gained; and 3) the program's implementation fidelity, optimal delivery mechanisms, and construct validity via a comprehensive process evaluation. Supervised therapy is hypothesized to be both an effective and cost-effective mechanism to improve population-level asthma control among students with asthma.

This project will provide critical information regarding the program's value, feasibility, and sustainability within communities with large asthma burden. In addition, it will provide important recommendations to accelerate the adoption of guideline-based care for students with asthma in urban, low-income, and ethnically diverse populations. With this information, policy makers can optimize the use of scarce public health resources by adopting programs that efficiently maximize child health.

Narrative

The proposed project will evaluate the effectiveness and cost-effectiveness of a comprehensive school-based asthma program including supervision of daily asthma medicine. The information gained will help communities determine if such a program could be implemented in their schools to help children with asthma achieve better asthma control.

FACILITIES & OTHER RESOURCES

Investigators and staff involved in this project will rely on the resources of the Mel and Enid Zuckerman College of Public Health (MEZCOPH) and the Arizona Respiratory Center (ARC) at the University of Arizona.

The University of Arizona (UA). UA is the leading public research university in the American Southwest and is an ideal interdisciplinary academic community for the proposed project. UA is a land grant public university and has a 387 acre campus in Tucson, Arizona. The campus includes 159 buildings on the main campus and 25 buildings at the adjacent Health Sciences Center. The University's commitment to research was recognized by its ranking in 2007 from the National Science Foundation as 15th among public and 23rd among all universities in the United States for research and development expenditures with over $530 million in annual research funding.

The Arizona Health Sciences Center (AHSC). The AHSC is a 48 acre complex adjacent to the UA. It includes the Colleges of Medicine, Nursing, Pharmacy, Public Health, the University Medical Center and 11 other specialty centers officially recognized by the Arizona Board of Regents. During fiscal year 2008, AHSC generated almost 128 million dollars in grants and contracts for research, patient care, and education. The AHSC Library, located within the University Medical Center, contains the state's largest collection of health information resources and is open 24 hours a day to UA employees and students. The library provides electronic full text access to almost 10,000 journals and there is a librarian at each AHSC College dedicated to aiding faculty in research.

The Mel and Enid Zuckerman College of Public Health (MEZCOPH) and the Arizona Respiratory Center) ARC). The MEZCOPH and ARC are both located on the AHSC campus within 100 yards of each other. The MEZCOPH is dedicated to promoting the health of communities in the southwest and has extensive experience in community based research and translating research findings into community programs. The ARC is an internationally renowned, comprehensive Center of Excellence that combines the highest caliber of research, clinical care, and teaching. The ARC has state of the art clinical facilities and laboratories for the diagnosis and treatment of respiratory diseases. The unique collaboration between the MEZCOPH and the ARC provides an excellent scientific environment for dissemination and evaluation of a community based asthma program. The research team on the proposed project is part of these two organizations. The team has extensive experience in conducting community based clinical trials and the scientific environment at the University of Arizona will facilitate the successful completion of the proposed work.

Laboratory: N/A

Clinical: The clinical aspects of this proposal will rely on resources at the Clinical Research Unit, Arizona Respiratory Center. This unit (~5,000 sq feet) is adjacent to the administrative offices of the Center, and thus in close proximity to the physician and investigator offices. It is also 100 yards away from the Emergency Department at Unviversity Medical Center. It has 5 visit rooms, 3 special procedure rooms, offices for data input and confidential document storage, a waiting room for patients and parents. The Unit has all the instruments and equipment (spirometers, drug delivery systems, etc.) to perform all the proposed procedures. The Unit also has the capacity and experience to conduct off-site mobile clinics at schools or community locations.

Animal: N/A

Computer: The Mel and Enid Zuckerman College of Public Health (MEZCOPH) computing infrastructure consists of 10 servers running Windows 2003 and Windows 2008. These servers are used for a variety of purposes including web hosting, database management, file sharing, authentication, virtual private networking (VPN), network printing, and other special project specific applications. Servers used for production use are housed in the Computer Center building. These are monitored and backed up by the staff of the university's central information technology unit, University Information Technology Services (UITS). Business continuity support is provided via a replicated data center approximately seven miles from the main campus location. Development and test servers are located in Drachman Hall, home of MEZCOPH.

The College's faculty and staff use approximately 250 personal computers acquired through the division, college or research-funded resources. These are mostly Windows based systems, with a few Macintoshes, connected to the network in a variety of ways depending on location. On-campus locations have network speeds of 10 or 100 megabits/sec. Within Drachman hall, which is on the campus backbone network, voice over IP (VoIP) technology is used, which allows for both telephone and data service over the same set of wires. Secure wireless data networking is also being utilized in and around the building, complementing the wired data connection points within the building.

Every investigator involved in this proposal has one (and most often several) PC-compatible computer connected to laser and/or ink-jet color printers. Computer work is performed using hardware and software available at either MEZCOPH or the Arizona Respiratory Center.

The Stat Lab offices and computing facilities that will house the data for this project are part of the Arizona Respiratory Center and are located in the BIO5 Institute's Thomas W. Keating Bioresearch Building at the UA (~400 sq.ft.). This building is where Dr. Billheimer (statistician) and his staff's offices are located and is approximately 100 yards from the PI's and the other investigators' offices. The Stat Lab maintains a modern desktop computing environment via networked Unix-based and Apple computers. Data integrity is maintained by hourly incremental back-up. Internet access is provided by campus-wide 100base TX Ethernet. Software available on SCL computers includes the R statistical software environment, python and Perl scripting languages, TeX document preparation system, as well as other Unix-based computing tools and programming languages (e.g., C++, Fortran). In addition, there is a full line of Microsoft products including Access, Excel, Word, and PowerPoint. Other statistical software available includes Ggobi, SAS, Stata, and WinBUGS, among others. The Stat Lab makes extensive use of reproducible research computing tools, such as StatWeave, whereby statistical analysis code (e.g., R, SAS, Stata, etc.) is embedded into a LaTeX or Open Office document. Thus, analysis results can be computed dynamically, and automatically included in an executable document.

In addition to a modern desktop computing environment, the Stat Lab has dedicated access to the HPC resources on the UA campus, including the following:

- Shared Memory—SGI Altix 4700 (1.6 GHz Itanium2 "Montecito")
  - Marin—Interactive Front End, Altix 4700, 100-core Itanium2, 160 GB memory
  - Bora—Batch System, Altix 4700, 512-core Itanium2, 1024 GB memory
  - Solano—FPGA subsystem, 4 Xilinx Virtex 4 LX200, Altix 4700, 16-core Itanium2, 16GB memory
- Cluster—SGI Altix ICE 8200 (2.83 GHZ quad-core Xeon, "Harpertown")
  - Ice—Interactive Front End, 3 "round-robin" login nodes

- cluster—1392-core, quad-core Xeon (Harpertown), 2 GB memory/core

For tasks requiring additional HPC resources, the Stat Lab may utilize capacity offered by the national centers and the Open Science Grid with seamless transition of jobs between local, regional and national resources. Statistics personnel also have access to remote collaboration tools to enable virtual organizations and remote team science activities, via the ARL's Biotechnology Computing Facility. These collaboration tools allow multiple research teams to conduct web-based meetings and seminars and share applications and data analysis tools from their desktop. These tools also allow audio/video-based interactions without the need of any specialized hardware on either end.

Office: Researchers involved in this proposal have offices located either at the MEZCOPH or at the ARC, which are located only 100 yards away. The MEZCOPH has committed office space for the TBA Project Coordinator, Graduate Assistant, and Research Specialists in the same building as the PI and Investigators. The MEZCOPH is housed in the 103,000 square foot Drachman Hall. This space houses the College's administrative and support office, information technology, divisions, educational programs as well as faculty and staff offices.

Other: Local meeting spaces are available at the MEZCOPH and the ARC. University vehicles are available for UA investigators, students, and staff to travel to community partner sites and partner meetings.

OMB Number: 4040-0001
Expiration Date: 06/30/2011

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: | * First Name: Lynn | Middle Name: B
* Last Name: Gerald | Suffix: Ph.D.
Position/Title: Professor | Department: Health Promotion Sciences
Organization Name: Arizona Board of Regents, University of Arizona | Division: College of Public Health
* Street1: Post Office Box 245163
Street2:
* City: Tucson | County/ Parish: Pima
* State: AZ: Arizona | Province:
* Country: USA: UNITED STATES | * Zip / Postal Code: 85724-5163
* Phone Number: (520) 626-3243 | Fax Number: (520) 626-1660
* E-Mail: lgerald@email.arizona.edu

Credential, e.g., agency login: geraldl

*** Project Role:** PD/PI | **Other Project Role Category:**

Degree Type:
Degree Year:

***Attach Biographical Sketch** 1236-LBG biosketch.pdf [Add Attachment] [Delete Attachment] [View Attachment]
Attach Current & Pending Support [Add Attachment] [Delete Attachment] [View Attachment]

PROFILE - Senior/Key Person 1

Prefix: | * First Name: Joe | Middle Name: K
* Last Name: Gerald | Suffix: Ph.D
Position/Title: Assistant Professor | Department:
Organization Name: Arizona Board of Regents, University of Arizona | Division: Public Policy and Management
* Street1: Post Office Box 245210
Street2:
* City: Tucson | County/ Parish: Pima
* State: AZ: Arizona | Province:
* Country: USA: UNITED STATES | * Zip / Postal Code: 85724-5163
* Phone Number: 520-626-4678 | Fax Number: 520-626-1660
* E-Mail: geraldj@email.arizona.edu

Credential, e.g., agency login: geraldj

*** Project Role:** Co-Investigator | **Other Project Role Category:**

Degree Type:
Degree Year:

***Attach Biographical Sketch** 1237-Joe Gerald Biosketch.pdf [Add Attachment] [Delete Attachment] [View Attachment]
Attach Current & Pending Support [Add Attachment] [Delete Attachment] [View Attachment]

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Senior/Key Person 2

Prefix: | * First Name: Roni | Middle Name:

* Last Name: Grad | Suffix: M.D.

Position/Title: Associate Professor | Department: Pediatrics

Organization Name: Arizona Board of Regents, University of Arizona | Division: Medicine

* Street1: Post Office Box 245073

Street2:

* City: Tucson | County/ Parish: Pima

* State: AZ: Arizona | Province:

* Country: USA: UNITED STATES | * Zip / Postal Code: 85724-5163

* Phone Number: 520-626-7780 | Fax Number: 520-626-1660

* E-Mail: gradr@email.arizona.edu

Credential, e.g., agency login:

*** Project Role:** Co-Investigator | **Other Project Role Category:**

Degree Type:

Degree Year:

***Attach Biographical Sketch** 1238-Grad Biosketch Final.pdf | Add Attachment | Delete Attachment | View Attachment

Attach Current & Pending Support | Add Attachment | Delete Attachment | View Attachment

PROFILE - Senior/Key Person 3

Prefix: | * First Name: Scott | Middle Name:

* Last Name: Carvajal | Suffix: Ph.D

Position/Title: Associate Professor | Department: Health Promotion Sciences

Organization Name: Arizona Board of Regents, University of Arizona | Division: Public Health

* Street1: Post Office Box 245209

Street2:

* City: Tucson | County/ Parish: Pima

* State: AZ: Arizona | Province:

* Country: USA: UNITED STATES | * Zip / Postal Code: 85724-5163

* Phone Number: 520-626-9026 | Fax Number: 520-626-1660

* E-Mail: scott.carvajal@arizona.edu

Credential, e.g., agency login: carvajal

*** Project Role:** Co-Investigator | **Other Project Role Category:**

Degree Type:

Degree Year:

***Attach Biographical Sketch** 1239-Carvajal Bio.pdf | Add Attachment | Delete Attachment | View Attachment

Attach Current & Pending Support | Add Attachment | Delete Attachment | View Attachment

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Senior/Key Person 4

Prefix: | * First Name: Conrad | Middle Name: J

* Last Name: Clemens | Suffix: M.D.

Position/Title: Associate Professor | Department: Pediatrics

Organization Name: Arizona Board of Regents, University of Arizona | Division: Medicine

* Street1: Post Office Box 245073

Street2:

* City: Tucson | County/ Parish: Pima

* State: AZ: Arizona | Province:

* Country: USA: UNITED STATES | * Zip / Postal Code: 85724-5163

* Phone Number: 520-626-0923 | Fax Number: 520-626-1660

* E-Mail: cclemen1@email.arizona.edu

Credential, e.g., agency login:

*** Project Role:** Co-Investigator | **Other Project Role Category:**

Degree Type:

Degree Year:

***Attach Biographical Sketch** 1240-biosketch-clemens.pdf | Add Attachment | Delete Attachment | View Attachment

Attach Current & Pending Support | Add Attachment | Delete Attachment | View Attachment

PROFILE - Senior/Key Person 5

Prefix: | * First Name: David | Middle Name: D

* Last Name: Billheimer | Suffix: Ph.D

Position/Title: Associate Professor | Department: Agric/Biosystems ENG-RES

Organization Name: Arizona Board of Regents, University of Arizona | Division: Nutritional Sciences

* Street1: Post Office Box 210038

Street2:

* City: Tucson | County/ Parish: Pima

* State: AZ: Arizona | Province:

* Country: USA: UNITED STATES | * Zip / Postal Code: 85724-5163

* Phone Number: 520-626-9902 | Fax Number: 520-626-1660

* E-Mail: dean.billheimer@arizona.edu

Credential, e.g., agency login: dbillheimber

*** Project Role:** Co-Investigator | **Other Project Role Category:**

Degree Type:

Degree Year:

***Attach Biographical Sketch** 1241-Billheimer.pdf | Add Attachment | Delete Attachment | View Attachment

Attach Current & Pending Support | Add Attachment | Delete Attachment | View Attachment

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Senior/Key Person 6

Prefix: | * First Name: James | Middle Name: L

* Last Name: Goodwin | Suffix: Ph.D

Position/Title: Associate Scientific Investigator | Department: Arizona Respiratory Center

Organization Name: Arizona Board of Regents, University of Arizona | Division: Medicine

* Street1: Post Office Box 245030

Street2:

* City: Tucson | County/ Parish: Pima

* State: AZ: Arizona | Province:

* Country: USA: UNITED STATES | * Zip / Postal Code: 85724-5163

* Phone Number: 520-626-5001 | Fax Number: 520-626-1660

* E-Mail: jamieg@arc.arizona.edu

Credential, e.g., agency login: jamiegoodwin

*** Project Role:** Co-Investigator | **Other Project Role Category:**

Degree Type:

Degree Year:

***Attach Biographical Sketch** 1242-Goodwin 121310.pdf [Add Attachment] [Delete Attachment] [View Attachment]

Attach Current & Pending Support [Add Attachment] [Delete Attachment] [View Attachment]

PROFILE - Senior/Key Person 7

Prefix: | * First Name: Todd | Middle Name: A

* Last Name: Lee | Suffix: Ph.D

Position/Title: Associate Professor | Department:

Organization Name: University of Illinois at Chicago | Division:

* Street1: 1737 West Polk Street

Street2: 310 AOB M/C 672

* City: Chicago | County/ Parish:

* State: IL: Illinois | Province:

* Country: USA: UNITED STATES | * Zip / Postal Code: 60612-0000

* Phone Number: 708-202-5869 | Fax Number: 520-626-1660

* E-Mail: todd.lee@va.gov

Credential, e.g., agency login: toddlee

*** Project Role:** Co-Investigator | **Other Project Role Category:**

Degree Type:

Degree Year:

***Attach Biographical Sketch** 1243-Lee bio.pdf [Add Attachment] [Delete Attachment] [View Attachment]

Attach Current & Pending Support [Add Attachment] [Delete Attachment] [View Attachment]

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Lynn B. Gerald, PhD, MSPH	Canyon Ranch Endowed Chair for Lifestyle and Behavioral Science/Professor
eRA COMMONS USER NAME (credential, e.g., agency login) geraldl	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of Alabama at Birmingham	BS	1990	Psychology/Gerontology
University of South Alabama	MA	1992	Sociology/Gerontology
University of Alabama at Birmingham	MSPH	1997	Epidemiology
University of Alabama at Birmingham	PhD	1997	Medical Sociology

A. Personal Statement

I have extensive experience and expertise in the development and implementation of community based clinical trials in children with asthma. My previous funding from NIH/NHLBI has included three R01s which focused on school based asthma interventions and I also served as a Co-Investigator on the original NHLBI funded contracts to examine the effectiveness of asthma self-management programs in the schools. I have also served as PI on an NHLBI funded community based trial related tuberculosis as well as PI of an ALA Asthma Clinical Research Center. These Centers have conducted numerous NIH and industry sponsored clinical trials. I served as the PI for the efficacy trial on which the current proposal is based. In summary, I have a demonstrated record of successful and productive research projects in the area of investigation and have the expertise necessary to ensure that we achieve our stated research goals.

B. Positions and Honors

Positions

1992-1994	Instructor, Department of Sociology, University of South Alabama, Mobile, AL
1996-1997	Instructor, Department of Sociology, University of Alabama at Birmingham, Birmingham, AL
1997-2002	Assistant Professor, Department of Critical and Diagnostic Care, School of Health Related Professions, University of Alabama at Birmingham, Birmingham, AL
1997-2008	Scientist, Lung Health Center, University of Alabama at Birmingham, Birmingham, AL
1999-2004	Assistant Professor, Division of Pulmonary, Allergy & Critical Care Medicine, School of Medicine, University of Alabama at Birmingham, Birmingham, AL
1999-2007	Assistant Director, Lung Health Center, University of Alabama at Birmingham, Birmingham, AL
2000-2004	Associate Scientist, Center for Health Promotion, University of Alabama at Birmingham, Birmingham, AL
2001-2004	Assistant Professor, UAB Graduate School, University of Alabama at Birmingham, Birmingham, AL
2004-2007	Associate Professor, Division of Pulmonary, Allergy & Critical Care Medicine, University of Alabama at Birmingham, Birmingham, AL
2007-2008	Director, Lung Health Center, University of Alabama at Birmingham, Birmingham, AL
2007-2008	Professor, Division of Pulmonary, Allergy & Critical Care Medicine, University of Alabama at Birmingham, Birmingham, AL
2009-Present	Canyon Ranch Endowed Chair for Lifestyle and Behavioral Health, Mel and Enid Zuckerman College of Public Health, University of Arizona, Tucson, AZ
2009-Present	Professor, Health Promotion Sciences, Mel and Enid Zuckerman, College of Public Health, University of Arizona, Tucson, AZ
2009-Present	Scientist, Arizona Respiratory Center, University of Arizona.

Selected Honors

2007 Nominated (1 of 6 women) for the **American Thoracic Society's Elizabeth A. Rich Award** for outstanding scientific achievement among female scientists in pulmonary disease.
2007 Jefferson County American Federation of Teachers, **JCAFT Partners in Health Award.**
2006 **Max Cooper Award for Research Excellence**. University of Alabama at Birmingham, School of Medicine.
2005 Nominated (1 of 15 candidates) for the CHEST Foundation's **Alfred Soffer Research Award**.
2004 Featured as a "**Lung Disease Champion**" in the American Lung Association's *How We Help Today Annual Report 2004.*
2003 American Thoracic Society Behavioral Science Assembly **Junior Scholar Award**. *(Given to the individual who has made the most outstanding scientific contributions relevant to behavioral science and lung diseases early in his or her career.)*

C. Selected Peer-reviewed publications (selected from 55 peer reviewed publications)

Most relevant to the current application

1. **Gerald, LB**, Redden D, Turner-Henson A, Feinstein R, Hemstreet MP, Hains C, Brooks CM, Erwin S, & Bailey WC. (2002). "A multi-stage asthma screening procedure for elementary school children." Journal of Asthma 39(1):29-36. PMID: 11883737
2. **Gerald LB**, Turner-Henson A, Hains C, Tang S, Feinstein R, Wille K, Erwin S & Grad R. (2004). "Validation of a multi-stage asthma case detection procedure for elementary school children." Pediatrics,114(4):e459-e468. PMID: 15466072
3. Mangan J & **Gerald LB**. (2006). "Asthma Agents: monitoring asthma in school." Journal of School Health, 76(6): 300-302. PMID: 16918859
4. **Gerald LB**, Redden D, Wittich A, Hains C, Turner-Henson A, Hemstreet MP, Feinstein R, Erwin S & Bailey WC. (2006). "Outcomes for a comprehensive school based asthma management program." Journal of School Health, 76(6): 291-296. PMID: 16918857
5. Wheeler, Lani S., Sarah L. Merkle, **Lynn B. Gerald**, & Virginia S. Taggart. (2006). "Managing asthma in schools: lessons learned and recommendations." Journal of School Health. 76(6):340-344. PMID: 16918868
6. Merkle, Sarah L., Lani S. Wheeler, **Lynn B. Gerald,** Virginia S. Taggart. (2006). "Introduction: Learning From Each Other About Managing Asthma in Schools." Journal of School Health. 76(6):202-204. PMID: 16918838
7. **Lynn B. Gerald,** Marianna M. Sockrider, Roni Grad, Bruce G. Bender, Leslie P. Boss, Stanley P. Galant, Jorrit Gerritsen, Christine L. M. Joseph, Robert M. Kaplan, Julie A. Madden, Joan M. Mangan, Greg J. Redding, Diana K. Schmidt, Christina D. Schwindt, Virginia S. Taggart, Lani S. Wheeler, Kristin N. Van Hook, Paul V. Williams, Barbara P. Yawn, and Bulend Yuksel, on behalf of the ATS Ad Hoc Committee on Issues in Screening for Asthma in Children. (2007). "An Official ATS Workshop Report: Issues in Screening for Asthma in Children." Proceedings of the American Thoracic Society 4:133-141. PMID: 17494724
8. McClure, Leslie A., Kathy F. Harrington, Holli Graham, & **Lynn B. Gerald.** (2008). "Internet-based monitoring of asthma symptoms, peak flow meter readings, and absence data in a school-based clinical trial". Controlled Clinical Trials. 5:31-37. PMID: 18283077
9. **Gerald, Lynn B.,** Leslie McClure, Kathy Harrington, Joan M. Mangan, Linda Gibson, Jody Atchison, & Roni Grad. (2008) "Design of the supervised asthma therapy study: implementing an adherence intervention in urban elementary schools." Contemporary Clinical Trials. 29(2):304-310.
10. **Gerald, Lynn B.**, Joan M. Mangan, Leslie McClure, Linda Gibson, Jody Atchison, & Roni Grad. (2009). "Increasing adherence to inhaled steroid therapy among schoolchildren: randomized controlled trial of school based supervised asthma therapy." Pediatrics.*123:466-474.* PMID: 19171611
11. Grad, Roni, Leslie McClure, Sijian Zhang, Joan M. Mangan, Linda Gibson, & **Lynn B. Gerald.** (2009). "Peak flow measurements in children with asthma: what happens at school?" Journal of Asthma; 46:535-540.
12. Gerald, Joe K., Yanhui Sun, Roni Grad, & **Lynn B. Gerald.** (2009). "Asthma morbidity among children evaluated by asthma case detection." Pediatrics. 124(5):927-933. PMID: 19841121
13. Gerald, Joe K., Roni Grad, William C. Bailey, & **Lynn B. Gerald**. "Cost-Effectiveness of School-Based Asthma Screening in an Urban Setting". Journal of Asthma and Clinical Immunology. 125:643-650.

Accompanying Editorial by Sean McElligott and Daniel Polsky 651-652. PMID: 20226298

Additional recent publications of importance to the field (in chronological order)

1. Joan M. Mangan, Angelina Wittich, & **Lynn B**. **Gerald**. (2007). "The potential for reducing asthma disparities through improved family and social function and modified health behaviors." CHEST 132:789-801. PMID: 17998343
2. **Gerald, Lynn B.**, Joe K. Gerald, Linda Gibson, Karna Patel, Sijian Zhang, & Leslie A. McClure. (2009). "Changes in ETS exposure and asthma morbidity among urban school children." CHEST; 135:911-916. PMID: 19017893
3. Wheeler, L., Rebecca Buckley, **Lynn B. Gerald**, Sarah Merkle, & Teresa Morrison. (2010). "Working with Schools to Improve Pediatric Asthma Management." Pediatric Asthma, Allergy, and Immunology. 22(4):197-207.

D. Research Support

Ongoing Research Support

T76MC04925
HRSA/MCH Garcia/Gerald (PI) (6/01/10 – 5/31/15) Maternal and Child Health Public Health Training Program. The over arching goal for the training program is to increase the number and quality of culturally competent MCH professionals who will provide the next generation of MCH public health leadership for the development of evidence-based policies, programs, and program evaluation to address the health and wellness women, children and families throughout the Southwest and Rocky Mountain region, and nationally.

1R40MC08728
HRSA/MCH Gerald (PI) (9/01/07- 12/30/08) Harrington (PI) (1/01/09-Present) 09/01/07 – 08/31/2010
The Impact of Caregiver's (Parent) Health Literacy on Pediatric Asthma Outcomes. This project will examine the effect of a caregiver's health literacy on their child's asthma outcomes.

1R01HLHL086972
NHLBI Gerald (PI) (08/01/07 – 12/30/08) Bailey (PI) (1/01/09 – Present) 08/01/07 -- 05/31/12
Effect of a School Based Hand Sanitizer Program on Asthma. This project will test the effect of a school based hand sanitizer program on asthma exacerbations in elementary school children.

American Lung Association Gerald (PI) 01/01/10—06/30/10
Asthma Clinical Research Center. The American Lung Association's Asthma Clinical Research Centers consists of 19 clinical centers and a data and coordinating center who have the mission of improving asthma care through clinical research in diverse populations. The ALA-ACRC conducts various clinical studies related to asthma.

Completed Research Support (in past three years, selected)

American Lung Association Gerald (PI) 07/01/04 – 12/30/09
Asthma Clinical Research Center. The American Lung Association's Asthma Clinical Research Centers consists of 19 clinical centers and a data and coordinating center who have the mission of improving asthma care through clinical research in diverse populations. The ALA-ACRC conducts various clinical studies related to asthma.

1R01HL072817-01 NHLBI Gerald (PI) 04/15/04 – 04/15/09
Effectiveness of the TB Contact Priority Model. This project will use a behaviorally focused intervention to implement and test the effectiveness of the TB contact priority model in field implementation.

1R01HL075043-01 NHLBI Gerald (PI) 04/15/04 – 03/31/07
Effectiveness of School Based Supervised Asthma Therapy. This project tested the effectiveness of a school based supervised asthma therapy program in children from urban schools.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Joe K. Gerald, MD, PhD	Assistant Professor
eRA COMMONS USER NAME geraldj	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
University of Alabama at Birmingham	BS	1990	Biology
University of South Alabama	MD	1994	Medicine
University of Alabama at Birmingham	PhD	2007	Health Services Administration
University of Alabama at Birmingham	Post-Doc	2007	Outcomes Research (NRSA T32)

A. Personal Statement

As a health services researcher with expertise in cost-effectiveness analysis, I am well-suited to evaluate the economic impact of health interventions among children with asthma. I have previously conducted economic analyses of pulmonary interventions including tuberculosis contact investigation strategies, school-based asthma screening strategies and hand hygiene strategies in elementary schools. My particular expertise is using short-cycle (daily) Markov modeling to estimate the cost per quality-adjusted life-year (QALY) of various health interventions. This short-cycle approach is well-suited to model chronic conditions such as asthma that are associated with frequent, debilitating symptoms.

I successfully used community-based, standard-gamble derived daily preference weights to conduct a reference case cost-effectiveness analysis of school-based asthma screening. This work was recently published in the Journal of Asthma and Clinical Immunology (Gerald 2010). This work is one of the foundational elements for the envisioning of this current grant application.

The current application builds logically on my prior work and as a co-investigator I bring unique additional expertise to complement my fellow investigators. In summary, I have demonstrated a productive record of research and scholarship in the economic evaluation of pulmonary disease that has prepared me to meaningfully contribute to the proposed school-based research project evaluating the effectiveness and cost-effectiveness of supervised asthma care in elementary schools.

B. Positions and Honors

Positions and Employment

1994 - 1995	Internship, Internal Medicine/Pediatrics, University of Alabama at Birmingham
1995 - 2003	Assistant Professor, Surgical Physician Assistant Program, School of Health Professions, University of Alabama at Birmingham
1997 - 2002	Director, Surgical Physician Assistant Program, School of Health Professions, University of Alabama at Birmingham
2000 - 2001	Chair, Department of Critical Care, School of Health Professions, University of Alabama at Birmingham
2002 - 2003	Internship, Internal Medicine, University of Alabama at Birmingham
2004 - 2007	Post-Doctoral Fellow, Health Services and Outcomes Research Training Program (NRSA T32), Division of Preventive Medicine, University of Alabama at Birmingham
2008 - 2009	Analyst, Health System Information Services, University of Alabama at Birmingham
2009 -	Assistant Professor, Department of Community, Environment and Policy, Mel and Enid Zuckerman College of Public Health, University of Arizona
2009 -	Director, Undergraduate Program in Public Health, Mel and Enid Zuckerman College of Public Health, University of Arizona
2010 -	Chair, Public Health Policy and Management, Mel and Enid Zuckerman College of Public Health, University of Arizona

Honors

2000 Finalist, Ellen Gregg Ingalls/UAB National Alumni Award for excellence in classroom teaching
2001 Recipient, Ellen Gregg Ingalls/UAB National Alumni Award for excellence in classroom teaching

Other Experience and Professional Membership

2007 Reviewer, NASA Research Announcement Science Mission Directorate, Washington, D.C.
2009 Reviewer, 2009/10 ZRG1 RPHB-A (58) R, RFA OD-09-003: Challenge Grants Panel 4.
2009 Reviewer, 2009/10 ZRG1 RPHB-A (58) R, RFA OD-09-003: Challenge Grants Panel 27.

B. Peer-reviewed publications (in chronological order)

Peer-Reviewed Manuscripts

1. **Gerald JK**. Cost-Effectiveness of a Multi-Stage School-Based Asthma Case Detection Program in an Urban School System. Dissertation (2007)
2. Gerald LB, **Gerald JK**, Gibson L, Patel K, Zhang S, & McClure LA. Changes in ETS exposure and asthma morbidity among urban school children. Chest 2009:135:911-916. PMID: 19017893
3. Pisu M, **Gerald JK,** Schmiyah J, Bailey WC, Gerald LB. Targeted TB Investigation Saves Money without Sacrificing Control. J Public Health Manag Pract. 2009 Jul-Aug;15(4):319-27. PMID: 19525776
4. **Gerald JK**, Fineberg NS, Sun Y, Gerald LB. Respiratory Symptoms, Emergency Department Visits and Hospitalizations in a School-Based Asthma Case Detection Study. Pediatrics. 2009;124:e927–e933. PMID 19841121
5. **Gerald JK**, Grad R, Bailey WC, Gerald LB. Cost-Effectiveness of School-Based Asthma Screening in an Urban Setting. J Allergy Clin Immunol. 2010;125:643-50. A*ccompanying Editorial by Sean McElligott and Daniel Polsky 651-652.* PMID: 20226298

Published Abstracts

1. **Gerald JK**, Houston TK, Funkhouser E, Levine DA, Tipton EF, Kiefe CI. Geographic Variation in Performance Measures across Primary Care Clinics: The VA MI Plus Study. 2007 Academy Health Annual Research Meeting. Orlando, FL.
2. **Gerald JK**, Fineberg NS, Sun Y, Gerald LB. Cost-Effectiveness of School-Based Asthma Case Detection. 2008 American Thoracic Society International Conference. Toronto, Canada.
3. **Gerald JK**, Fineberg NS, Sun Y, Gerald LB. Health Care Use among Children Identified by Asthma Case Detection. 2008 American Thoracic Society International Conference. Toronto, Canada.
4. **Gerald JK**, Gordon G, Day T, Houston TK, Hicks J, Berner ES. Does Physician Use of a Referring Physician Portal Differ for Patients Referred for Hospitalization versus Out-Patient Consultation? 2009 Healthcare Information Management Systems Society International Meeting. Chicago, IL.
5. Gerald LB, **Gerald JK**, McClure LA, Grad R. Quick Relief Medication at School. Am J Respir Crit Care Med 2009;179:A2454. Presented at the American Thoracic Society International Meeting, San Diego, CA.
6. **Gerald JK,** McClure LA, Harrington KF, Lee TA, Gerald LB. The Pediatric Asthma Health Outcome Measure, Not Just Quality-of-Life? Am J Respir Crit Care Med 2009;179:A4312. Presented at the American Thoracic Society International Meeting, San Diego, CA.
7. **Gerald JK**, McClure LA, Harrington KF, Lee TA, Gerald LB. Parent and Child Agreement on the Pediatric Asthma Health Outcome Measure. Am J Respir Crit Care Med 2009;179:A2457. Presented at the American Thoracic Society International Meeting, San Diego, CA.
8. Gerald LB, McClure L, Harrington KF, **Gerald JK**, Bailey WC. Daily symptom and peak flow monitoring: do they predict respiratory-related school absences? Am J Respir Crit Care Med 2010: TBA. Presented at 2010 ATS International Conference in New Orleans, Louisiana.
9. **Gerald JK**, Harrington KF, McClure L, Bailey WC, Gerald LB. Daily Respiratory Symptom Reporting versus Two-Week Recall in Children with Asthma. Am J Respir Crit Care Med 2010: TBA. Presented at 2010 ATS International Conference in New Orleans, Louisiana.

Books and Book Chapters

1. Watson RS, **Gerald JK**, Preedy VR. Nutrients, Dietary Supplements, and Nutriceuticals: Cost Analysis Versus Clinical Benefits. New York: Humana Press, 2010**.**

C. Research Support in Past Three Years

Ongoing Research/Consulting Support
University of Alabama at Birmingham Gerald (PI) 7/01/08 – present
Consulting Contract
Development of Automated Surveillance System for Severe Sepsis
This consulting contract was awarded to develop and validate an automated surveillance system to detect severe sepsis in hospitalized patients using an existing electronic health record system.
Role: Principal-Investigator

Ongoing Research Support
R01HL86972 Bailey (PI) 7/01/07 – 6/30/11
NHLBI
Effect of a school based hand sanitizer program on asthma.
This study will examine the effectiveness of a school based hand sanitizer program on asthma exacerbations in elementary school children.
Role: Investigator

Completed Research Support
SDR-03-090-1 Kennedy (PI) 09/01/2003-06/30/2010
HSR&D
VA MI-Plus: Web Enhanced Guideline Implementation for Post-MI CBOC Patients.
This study was a randomized controlled trial of an internet-based educational intervention targeting primary care providers caring for post-MI patients with multiple co-morbidities in community-based outpatient-clinics sponsored by the Veterans Administration.
Role: Investigator

HSR&D Local Improvement Project #01144 Levine (PI) 05/01/04-09/30/2004
Birmingham VAMC
Improving Early Recognition of Acute Myocardial Infarction in VHA .
This study examined the effectiveness of nurse-based activation of cardiology consultation in the emergency department to improve outcomes in acute myocardial infarction.
Role: Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Roni Grad, M.D.	Associate Professor of Pediatrics
eRA COMMONS USER NAME (credential, e.g., agency login)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Boston University, Boston, MA	B.A.	1976 – 1982	Medical Science major/ History minor
Boston University, Boston, MA	M.D.	1978 – 1982	Medicine
St. Christopher's Hospital for Children Philadelphia, PA	Residency	1982 – 1985	Pediatrics
University of Arizona College of Medicine Tucson, AZ	Fellowship	1985 – 1988	Pediatric Pulmonary

A. Personal Statement. I am a Pediatric Pulmonologist with a busy academic practice. My major interests lie in diseases that are public health issues, and devising novel low-tech methods of preventing morbidity. I have worked with Dr. Gerald on school-based interventions in childhood asthma for the past seven years and served as the Investigator responsible for clinical supervision on these studies. I also have a history of strong clinical collaboration with Dr. Clemens in regards to caring for children with asthma. Therefore, I have the experience and expertise required for this role in the current project.

B. Positions and Honors

Positions and Employment

Summer 1979 Teaching Assistant, Department of Anatomy, Sargent College of Allied Health Professions, Boston University Boston, MA
1988 – 1990 Research Instructor, Department of Pediatrics, University of Arizona College of Medicine, Tucson, AZ
1990 – 1991 Assistant Professor, Department of Pediatrics, University of Arizona College of Medicine, Tucson, AZ
1991 – 1995 Assistant Professor, Department of Pediatrics, Director, Cystic Fibrosis Center University of New Mexico School of Medicine, Albuquerque, NM
1995 – 1997 Clinical Assistant Professor (non-paid appointment), Department of Pediatrics, University of Texas Health Science Center at San Antonio, San Antonio, TX
1998 – 2008 Associate Professor, Department of Pediatrics, University of Alabama at Birmingham, Birmingham, AL
2008 – Present Associate Professor, Department of Pediatrics, University of Arizona College of Medicine, Tucson, AZ

Other Experience and Professional Memberships

1989 American Thoracic Society
1989 Fellow, American Academy of Pediatrics
1991 – 1995 Member, Board of Directors New Mexico Chapter, Cystic Fibrosis Foundation
1992 – 1995 Member, Asthma Functional Outcome Committee American Academy of Pediatrics
1993 – 1994 Secretary-Treasurer, New Mexico Chapter American Thoracic Society
1994 – 1995 Secretary, Western Consortium of Cystic Fibrosis Caregivers
1994 – 1995 Vice President, New Mexico Chapter American Thoracic Society
1994 European Respiratory Society

1998	Jefferson County Medical Society
1998	Medical Association of the State of Alabama
1999 – 2001	Planning Committee of the Alabama Lung Association Statewide Asthma Summit
2004 – 2005	Planning Committee, Issues in Screening for Asthma in Children Workshop, American Thoracic Society
2005 - 2008	Chair, asthma education committee, Alabama Chapter, AAP
2007 – 2011	Program Committee, Behavioral Sciences Assembly, American Thoracic Society
2007 - 2008	Expert Panel, Alabama Medicaid
2010 - 2013	Nominating Committee, Behavioral Sciences Assembly, American Thoracic Society

Honors

1982	Boston University School of Medicine Alumni Association Award of Excellence
2005	Recipient of asthma education award, Alabama Chapter, American Academy of Pediatrics
2005	Nominee, Argus Society Teaching Award, UAB School of Medicine
2008	Special Achievement Award, American Academy of Pediatrics

C. Selected Peer-reviewed Publications

Most relevant to the current application:

1. **Grad R**, Sammut PH, Britton JR, Goodrich P, Hoyme HE, Dambro NN. Bronchoscopic evaluation of airway obstruction in campomelic dysplasia. Pediatri Pulmonol 1987; 3(5):364-67.
2. Witten ML, **Grad R**, Quan SF, Lantz RC, Sobonya RE, Lemen RJ. Effects of respiratory viruses on pulmonary alveolar macrophages. Pediatr Pulmonol 1992; 12(2):105-12.
3. Katz RW, Kelly HW, Crowley MR, **Grad R**, McWilliams BC, Murphy SJ. Safety of continuous nebulized albuterol for bronchospasm in infants and children. Pediatrics 1993; 92(5):666-69.
4. Coultas DB, Gong H, **Grad R**, Handler A, McCurdy SA, Player R, Rhoades ER, Samet JM, Thomas A, Westley M. State of the Art: Respiratory disease in minorities of the United States. Am J Respir Crit Care Med 1994; 149(3 Pt. 2):S93-131.
5. Grad R. Risk of asthma in children with exposure to mite and cat allergens. Lancet, 2000; 356(9239): 1555.
6. Gerald L, **Grad R**, Turner-Henson A, Hains C, Tang S, Feinstein R, Wille K, Erwin S, Bailey WC. Validation of a Multistage Asthma Case Detection Procedure for Elementary School Children. Pediatrics 2004; 114:e459-e468.
7. Gerald LB, Sockrider MM, **Grad R**, et al. An official ATS workshop report: Issues in Screening for Asthma in Children. Proc Am Thor Soc 2007; 4:133-41.
8. Wittich AR, Mangan J, **Grad R**, Wang W, Gerald LB. Pediatric Asthma: Caregiver Health Literacy and the Clinician's Perception. J Asthma 2007; 44:51-55
9. Gerald LB, McClure LA, Harrington KF, Mangan JM, Gibson L, Atchison J, **Grad R.** Design of the supervised asthma therapy study: Implementing an adherence intervention in urban elementary schools. Contemporary Clinical Trials 2008; 29:304-10.
10. Gerald LB, McClure LA, Mangan JM, Harrington, KF, Gibson L, Erwin S, Atchison J, **Grad R.** Increasing adherence to inhaled steroid therapy among schoolchildren: Randomized, controlled trial of school-based supervised asthma therapy. Pediatrics. 2009;123:466-74.
11. **Grad R.**, McClure LA, Zhang S, Mangan JM, Gibson L, Gerald LB. Peak flow measurements in children with asthma and what happens at school. J Asthma 2009;46:535-40.
13. Gerald LB, McClure LA, Mangan JM, Harrington, KF, Gibson L, Erwin S, Atchison J, **Grad R.** Increasing adherence to inhaled steroid therapy among schoolchildren: Randomized, controlled trial of school-based supervised asthma therapy. Pediatrics. 2009;123:466-74.
14. Gerald JK, Sun Y, **Grad R**, Gerald LB. Asthma morbidity among children evaluated by asthma case detection. Pediatrics 2009;124:e927-33.
15. Gerald JK, **Grad R**, Bailey WC, Gerald LB. Cost-effectiveness of school- based asthma screening in an urban setting. J Allergy Clin Immunol 2010;125:643-50.
16. Gerald J., Yanhui S., **Grad R.**, Gerald L. Asthma Morbidity Among Children Evaluated by Asthma Case Detection. Pediatrics. 2009; 124;5:e927-933.

D. Research Support

Ongoing Research Support

5U10HL0981112-02 Fernando Martinez (PI) 07/01/10– 06/30/2011
NIH/NHLBI
Arizona/Duke Clinical Center for AsthmaNet – Tucson Clinical Center
This application presents how the AsthmaNet network has established a successful infrastructure to conduct clinical research, reviews progress made with the currently conducted and/or completed trials, and presents three sample protocols that the network considers to be of sufficient scientific merit to warrant renewed funding for an additional five years.
Role: Investigator

American Lung Association Lynn Gerald (PI) 01/01/10—06/30/11
Asthma Clinical Research Center. The American Lung Association's Asthma Clinical Research Centers consists of 19 clinical centers and a data and coordinating center who have the mission of improving asthma care through clinical research in diverse populations. The ALA-ACRC conducts various clinical studies related to asthma.
Role: Investigator

National Heart, Lung, and Blood Institute Fernando Martinez (PI) 10/1/09 – 09/30/11
The Asthma BioRepository for Integrative Genomics Research. Subcontract from Harvard University. To establish the BioRepository for Integrative Genomic Exploration (BRIDGE), an open-access collection of immortalized cell lines, cDNA and DNA from more than 2,700 well-characterized asthma subjects participating in ongoing genetic studies of asthma.
Role: Investigator

GlaxoSmithKline Mark Brown (PI) 7/1/10 – 6/30/11
A randomized, double-blind, parallel group study of FSC 100/50 and FP 100, both twice daily, in a pediatric population during the Fall viral season (ADA113872). This study is to assess the safety of an investigational drug in children 4 to 11 years of age who have asthma. The subjects will attend 7 clinic visits, of which up to 3 will be in the morning, and have lung function tests performed.
Role: Sub-investigator

GlaxoSmithKline Mark Brown (PI) 2/1/10 – 1/31/13
A Long-Term, Randomized, Double-Blind, Parallel Group Study of Fluticasone Furoate/GW642444 Inhalation Powder Once-Daily and Fluticasone Furoate Inhalation Powder Once-Daily in Subjects with Asthma (GSK HZA 106837). This study will establish the safety as well as demonstrate benefit of the addition of a LABA to an ICS by utilizing an endpoint (time to first severe asthma exacerbation) that informs on both safety and efficacy.
Role: Sub-investigator

Completed Research Support (in past three years)

American Lung Association Lynn Gerald (PI) 07/01/04 – 12/30/09
Asthma Clinical Research Center. The American Lung Association's Asthma Clinical Research Centers consists of 19 clinical centers and a data and coordinating center who have the mission of improving asthma care through clinical research in diverse populations. The ALA-ACRC conducts various clinical studies related to asthma.
Role: Investigator

1R40MC08728
HRSA/MCH Lynn Gerald (PI) (9/01/07- 12/30/08) Kathy Harrington (current PI) 09/01/07 – 08/31/2010
The Impact of Caregiver's (Parent) Health Literacy on Pediatric Asthma Outcomes. This project will examine the effect of a caregiver's health literacy on their child's asthma outcomes.
Role: Investigator (9/1/07 – 06/01/08)

1R01HLHL086972
NHLBI Lynn Gerald (PI) (08/01/07 – 12/30/08) William Bailey (current PI) 08/01/07 -- 05/31/12
Effect of a School Based Hand Sanitizer Program on Asthma. This project will test the effect of a school based hand sanitizer program on asthma exacerbations in elementary school children.
Role: Investigator (9/1/07 – 06/01/08)

1R01HL075043-01 NHLBI Lynn Gerald (PI) 04/15/04 – 03/31/07
Effectiveness of School Based Supervised Asthma Therapy. This project tested the effectiveness of a school based supervised asthma therapy program in children from urban schools.
Role: Investigator

R01 HL64307 Fernando Martinez (PI) 09/30/99-12/31/09 (NC Extension)
NIH/NHLBI
CARE Network – Tucson Clinical Center
This application presents how the CARE network has established a successful infrastructure to conduct clinical research, reviews progress made with the currently conducted and/or completed trials, and presents three sample protocols that the network considers to be of sufficient scientific merit to warrant renewed funding for an additional five years.
Role: Investigator

1I-AI-25482 Wayne Morgan (PI) 09/30/06-09/29/09
NIH
Inner-City Asthma Consortium: Immunologic Approaches to Reduce Asthma
This application is in response to a request for proposals from the NIH to establish an inner-city asthma consortium to design and conduct clinical trials and mechanistic and biomarker studies in order to reduce severe asthma, to prevent asthma among children residing in the inner cities of the United States, and to expand the inner city asthma consortium to encompass studies of the immunopathogenesis of asthma.
Role: Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Scott C. Carvajal, PhD, MPH	Associate Professor of Health Promotion Sciences, Latin American Studies & Psychology
eRA COMMONS USER NAME (credential, e.g., agency login) Carvajal	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of Texas, Austin, TX	BA	1992	Psychology
University of Houston, Houston, TX	MA	1995	Psychology
University of Houston, Houston, TX	PhD	1996	Social Psy./Quant Mthds
University of Texas, Houston, TX	MPH	1997	Health Prom./Health Ed.
University of Texas, Houston, TX	Postdoctoral	1997	Beh. Science/Biometry

A. Personal Statement

I am a multi-discipline trained applied social and quantitative psychologist with expertise in health promotion theory, Latino/cultural behavioral research methods, intervention design and evaluation methods. My principal research (funded by NIDA, NIAAA & currently NICHD & CDC) has focused on understanding a range of health behaviors that convey cancer risk or protection (e.g., substance abuse, sexual risk taking, healthy food choice, physical activity), with a major emphasis on testing social ecological models within minority populations (Mexican-descent populations in particular). I was the Director of Substance Abuse Core for an NCMHD/NIH-funded (2003-2009) Center for Health Equality, a Center of Excellence focusing on eliminating health disparities in Arizona Latinos and American Indians. As part of that Center, I had an important role in review and oversight of pilot research activities including evaluation. I have also been an important collaborator as a lead analyst and/or behavioral science methodologist on six major, federally-funded (e.g., NCI, CDC, NIMH), health promotion interventions for multi-ethnic or minority populations. Within these projects I have contributed (as lead or co-author) on works focusing on theoretical models for behavioral change, testing psychosocial mediators of behavior change, and statistical models for evaluating program impact on such mediators and outcomes. I have expertise in both quantitative and qualitative evaluation methodology as these studies have used mixed methods. I am committed to an interdisciplinary science approach in addressing health problems and this is reflected in my participation in groups such as the Community Influences on Health Behaviors (NIH Chartered Study Section) and the Cancer Prevention and Control Division, Arizona Cancer Center. I have the expertise and experience required to lead the evaluation for the proposed project and to ensure that the interventions proposed are culturally appropriate.

B. Positions and Honors

Professional Experience and Employment

1998-2001 Senior Research Associate/Senior Analyst, ETR Associates, Scotts Valley, CA
2000-2002 Associate Research Professor, Mexican American Studies & Research Center, University of Arizona
2002-2006 Assistant Professor, Mexican American Studies & Research Center, University of Arizona
2006-2009 Associate Professor (with tenure) and Graduate Program Chair, Mexican American Studies & Research Center, University of Arizona
2002-2009. Assistant/Associate Professor (joint, non-FTE appointment), Health Promotion Sciences, Mel and Enid Zuckerman College of Public Health, University of Arizona
2006-pres. Assistant/Associate Professor (joint, non-FTE appointment), Latin American Studies, University of Arizona
2001-pres. Assistant/Associate Professor (joint, non-FTE appointment), Psychology Department, University of Arizona

2010-pres. Associate Professor (with tenure), Health Promotion Sciences, Mel and Enid Zuckerman College of Public Health, University of Arizona
2010-pres. Chair, Health Behavior Health Promotion Section, Health Promotion Sciences, Mel and Enid Zuckerman College of Public Health, University of Arizona

Honors and Invited Service

Permanent Member (invitation accepted 9/18/2007; term ends June 30, 2011), Community Influences on Health Behavior (CIHB) Study Section of Health of the Population (HOP) Integrated Review Group, Center for Scientific Review-National Institutes of Health.

Reviewer, Behavioral Science Track Award for Rapid Transition (B/START), National Institute on Drug Abuse, March, 25-April 12, 2007.

Ad-Hoc Member (June 8-9, 2006; February 8-9, 2007), Community Influences on Health Behavior (CIHB) Study Section of Health of the Population (HOP) Integrated Review Group, Center for Scientific Review-National Institutes of Health.

Member/Comprehensive Member/Full Investigator, 2002-present, Cancer Prevention and Control Division, Arizona Cancer Center.

1st Martin E.P. Seligman Award for Outstanding Dissertation Research on Optimism and Hope. American Psychological Association 1999 Convention, co-sponsored by the John Templeton Foundation.

C. Selected (15) Peer-reviewed Publications (Selected from 31 peer-reviewed publications)

Most relevant to the current application

1. Gritz, E.R., Tripp, M.K., James, A.S., Carvajal, S.C., Harrist, R.B., Mueller, N.H., Chamberlain, R.M., Parcel, G.S. (2005). An intervention for parents to promote preschool children's sun protection: Effects of Sun Protection is Fun! Preventive Medicine, 41, 357-366.
2. Tripp, M., Carvajal, S.C., McCormick, L., Hermann, N., Hu, S., Parcel, G.S., & Gritz, E. (2003). The validation of an instrument to assess the determinants of parents' sun protection behaviors toward their children. Health Education Research, 18, 58-73.
3. Carvajal, S.C., Baumler, E., Harrist, R.B., & Parcel, G.S. (2001). Multilevel models and unbiased tests for group based interventions: Examples from the Safer Choices Study. Multivariate Behavioral Research, 36, 185-205
4. Coyle, K., Basen-Engquist, K., Kirby, D., Parcel, G.S., Banspach, S., Collins, J.L., Baumler, E.R., Carvajal, S.C., & Harrist, R. (2001). Long-term impact of a multi-component school-based HIV, other STD and pregnancy prevention program. Public Health Reports, 116, 82-93.
5. Basen-Engquist, K.B., Coyle, K., Parcel, G.S., Kirby, D., Banspach, S., Carvajal, S.C., & Baumler, E. (2001). Schoolwide effects of a multicomponent HIV, STD, and pregnancy prevention program for high school students. Health Education and Behavior, 28, 166-185.

Additional recent publications of importance to the field (in chronological order)

1. Carvajal, S.C., & Young, R.S. (2009). Culturally Based Substance Abuse Treatment for American Indians/Alaska Natives and Latinos. Journal of Ethnicity and Substance Abuse, 8, 207-222.
2. Romero, A.J., Carvajal, S.C., Valle, F., & Orduno, M. (2007). Adolescent bicultural stress and its impact on mental well-being among Latinos, Asian Americans and European Americans. Journal of Community Psychology, 35, 519-534.
3. Romero, A.J., Martinez, D., & Carvajal, S.C. (2007). Socio-cultural stress as a source of adolescent health disparities in Latinos and non-Latino Whites. Ethnicity and Health, 21, 443-463.
4. Carvajal, S.C. & Granillo, T. (2006). A prospective test of distal and proximal determinants of smoking initiation in early adolescents. Addictive Behavior, 31, 649-660.
5. Carvajal, S.C., Estrada, A.L., & Estrada, B.D. (2005). Longitudinal prediction of unprotected sex in predominantly Latino male IDUs. Journal of Applied Biobehavioral Research, 10, 133-148.

6. Carvajal, S.C., Hanson, C.E., Downing, R.A., Coyle, K.C., & Pederson, L.L. (2004). Theory-based determinants of youth smoking: A multiple influence approach. Journal of Applied Social Psychology, 34, 59-84.
7. Carvajal, S.C., Evans, R.I., Nash, S.G. & Getz, J.G. (2002). Global positive expectancies of the self and adolescents' substance use avoidance: Testing a social influence mediational model. Journal of Personality, 70, 421-442.
8. Carvajal, S.C., Hanson, C.E., Romero, A.J., & Coyle, K.C. (2002). Behavioral risk factors and protective factors in adolescents: A comparison of Latinos and non-Latino Whites. Ethnicity and Health, 7, 181-193.
9. Carvajal, S.C., Parcel, G.S., Basen-Engquist, K.B., Banspach, S., Coyle, K., Kirby, D., & Chan, W. (1999). Psychosocial predictors of the delay of first intercourse in adolescents. Health Psychology, 18, 443-452.
10. Carvajal, S.C., Photiades, J.R., Evans, R.I., & Nash, S.G. (1997). Relating a social influence model to the role of acculturation in substance use among Latino adolescents. Journal of Applied Social Psychology, 17, 1616-1628.

D. Research Support

Ongoing Research Support

U48/CCU915770 (Carvajal) 09/30/09-09/29/14
CDC
Arizona Prevention Research Center
This project, within the Canyon Ranch Center for Health Promotion will be involved in developing a model for community health worker community advocacy and increasing partnerships and collaborations along the US-Mexico Border, including the continuation of the Arizona Prevention Research Center.
Role: Principal Investigator/Director

R03HD053590 (Carvajal, S. PI) 2008-2011
NIH/NICHD
Determinants and disparities in high-risk sexual behavior in US adolescents
This study will identify factors contributing to youths' high-risk sexual behaviors and their disparities using data from the National Longitudinal Study of Adolescent Health (Add Health).
Role: Principal Investigator

Completed Research Support

P60MD000155 Rosales, C. (PI) 2003-2010
NIH/NCMHD
Towards the Eradication of Health Disparities in Arizona Hispanic and American Indian Populations
This project is developing a Center of Excellence aiming to eliminate health disparities in Arizona Hispanics and Native Americans, with a particular focus on those due to substance abuse and diabetes.
Role: Co-Investigator and Director of the Substance Abuse Research Component Core

R21OH008747 Rosales, C. (PI) 2006-2008
CDC/NIOSH
Challenges to Farmworker Health at the U.S.-Mexico Border: The Relationship Between Health Risks and Public Policy. This is a community based participatory research study addressing factors related to farmworker health in the Yuma area, Arizona.
Role: Co-PI

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Conrad J. Clemens	Associate Professor of Pediatrics Director, Pediatric Residency Program Healthcare Consultant, Tucson Unified School District
eRA COMMONS USER NAME (credential, e.g., agency login)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
Goshen College	BA	1985	Biology/History
Johns Hopkins University	MD	1990	Medicine
Johns Hopkins University	Residency	1993	Pediatrics
University of Washington	Fellow	1996	Academic Pediatrics
University of Washington	MPH	1996	Health Services

A. Personal Statement

As a general academic pediatrician, I have been committed to improving the health of our pediatric population for the entirety of my career. As a clinician, I have cared for hundreds of children with asthma. As an advocate, I have worked as healthcare consultant at TUSD to improve the overall health of the children and specifically those with poorly controlled asthma. As a member of the Board of Directors for the Arizona Chapter of the American Academy of Pediatrics, I advocate for children state-wide. In my position and program director of the Pediatric Residency Program I am charged with the training of our future pediatricians – training that must be evidence-based, as well as both child and community centered. In this vein, our training program works closely with our world-renowned pediatric pulmonary colleagues to ensure that our trainees understand the clinical and community complexities of asthma and the best treatment evidence to date. I am also active at 'transporting' this evidence to the network of primary care physicians in Southern Arizona. Finally, as a clinical researcher, my focus has always been on common clinical problems and public health issues. This proposed research beautifully weaves together both my overall 'vision' of child health as well as individual threads of my professional life. I am excited for the possibilities of this project and committed to its successful completion.

B. Positions and Honors

Faculty Appointments

1994-1996 Acting Instructor in Pediatrics, University of Washington
1996-2002 Assistant Professor of Pediatrics, University of North Carolina
2002- Associate Professor of Pediatrics, University of Arizona

Administrative Appointments

1997-2001 Medical student clerkship Director, The University of North Carolina School of Medicine
2002-2007 Director, University Physician's Children's Center at Kino
2002-2007 Medical Executive Committee, University Physician Hospital at Kino
2003- Clinical Steering Committee, Department of Pediatrics, University of Arizona
2004-2005 Associate Head, Section of General Pediatrics, Department of Pediatrics, University of Arizona.
2005-2009 Head, Section of General Pediatrics, Department of Pediatrics, University of Arizona
2005-2007 Co-medical Director, Children's Clinics for Rehabilitative Services
2005- Healthcare consultant, Tucson Unified School District
2006 - Co-chair, Dean's Council for Faculty Affairs, University of Arizona College of Medicine
2007 - Director, Pediatric Residency Program, University of Arizona
2007 - Co-director, Pediatric/Emergency Medicine Residency Program, University of Arizona
2009 - Chair, Graduate Medical Education Committee, University of Arizona College of Medicine
2010 - Associate Head, Department of Pediatrics, University of Arizona

Board Certification
1993 Pediatrics, (re-certification 2000, 2007)

Honors and Awards
1985 Rotary Foundation International Scholarship, University of Sussex, England
1996 Research Award, Western Ambulatory Pediatric Association, University of Washington
2001 AOA Medical Honor Society, University of North Carolina
2003 Resident Teaching Award in Pediatrics, University of Arizona
2003 Vernon & Virginia Award: Excellence in Graduate Medical Education Teaching, University of Arizona
2005 Resident Teaching Award in Pediatrics, University of Arizona
2005 Vernon & Virginia Award: Excellence in Graduate Medical Education Teaching, University of Arizona
2007 Excellence in Resident Advocacy, Department of Pediatrics, University of Arizona
2008-10 *Best Doctors in America*
2008-10 *Tucson Lifestyle Magazine,* Best Doctors

C. Peer-reviewed publications

1. Liu LL, **Clemens CJ**, Shay DK, Davis RL, Novack AH, "The Safety of Early Newborn Discharge: The Washington State Experience. JAMA, 1997;278:293-29.
2. **Clemens CJ**, Davis RL, Novack AH, Connell FA, "Pediatric Home Health Care in King County, Washington." Pediatrics, 1997;99:581-584.
3. **Clemens CJ**, Taylor JA, Almquist JR, Quinn HA, Mehta A, Naylor GS. "Is an antihistamine-decongestant combination effective in temporarily relieving symptoms of the common cold in preschool children?" The Journal of Pediatrics, 1997;130:463-466.
4. Piehl MD, **Clemens CJ**, Joines JD. "'Narrowing the Gap': Decreasing Emergency Department Utilization by Medicaid Children by Improving Access to Primary Care." Archives of Pediatric & Adolescent Medicine. 2000;154:791-795
5. **Clemens CJ**, Davis SA and Bailey AR. "The False Positive in Universal Newborn Hearing Screening." Pediatrics 2000:106(1). URL: http//www.pediatrics.org/cgi/content/full/106/1/e7.
6. **Clemens CJ**, Davis SA. "Minimizing False Positives in Universal Newborn Hearing Screening: A Simple Solution." Pediatrics. 2001:107(3) URL: http//www.pediatrics.org/cgi/content/full/107/3/e37.
7. **Clemens CJ**, Doolittle RP, Hoyle MA. "Kindergarten Health Assessment Reports: What do schools really learn from them? Clinical Pediatrics, 2002;41(2):93-98.
8. **Clemens CJ**, Nunnally T. "Using the Kindergarten Health Assessment Report as a Health Report Card." Journal of School Health, 2002;72(5):220-223.
9. **Clemens CJ**, Gable EK. "The development of a Group B Streptococcus prevention policy at a community hospital." Journal of Perinatology. 2002;22:523-525.
10. Carbone P, **Clemens CJ**, Ball T. "The efficacy of a gunlock distribution program in a Hispanic Community." Archives of Pediatric and Adolescent Medicine, 2005;159:1049-54.

D. Research Support
<u>Ongoing Research Support</u>

American Academy of Pediatrics CATCH Grant. Clemens (PI) 7/1/09 – 6/30/11. "*Ready Set Start Smart*: A program for preventing childhood obesity."

Developed by pediatric residents, this is an intervention study that enrolls infants at birth and provides an educational message at each well child visit during the first two years of life. Changes in BMI, knowledge and behavior are measured.

Nestle Formula Company. Clemens (PI) 11/24/09 – 11/23/10. *"Effects of an Infant Formula with Probiotics on signs and symptoms of colic."*

This is a multisite clinical trial that enrolls infants with colic who are then randomized to a formula containing probiotics vs. "usual formula." Resolution of colic symptoms are measured.

Completed Research Support (in past three years)

Department of Health and Human Services Bassford (PI). 7/1/2007 – 6/30/09 . *"Sonoran UCEDD (University Center of Excellence for Developmental Disabilities)."*

Served as facilitator and content expert for a project involving transitioning youth with special health care needs from their pediatrician to a health care provider for adults

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Dean Billheimer	Associate Professor of Biometry Director, Arizona Statistics Consulting Laboratory
eRA COMMONS USER NAME (credential, e.g., agency login) dbillheimer	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Rose-Hulman Inst of Technology, TerreHaute, IN	BS	1982	Chemical Engineering
New Mexico State University, Las Cruces, NM	MS	1990	Experimental Statistics
University of Washington, Seattle, WA	PhD	1995	Statistics

A. Personal Statement

The proposed research evaluates effectiveness and cost-effectiveness of a comprehensive school-based asthma program. As Associate Professor of Biometry, and Director of The University of Arizona Statistics Consulting Laboratory I have a broad background and expertise in biological and medical study design, conduct, and data analysis. My collaborative experience spans the range from basic science laboratory studies to translational studies to clinical trials. I have participated as co-author/co-investigator on manuscripts and NIH grants in multiple areas of biomedical research including proteomics, oncology, pulmonology, endocrinology, and medical imaging. In addition, I have been principal investigator in projects developing new statistical methods to address emergent problems in compositional data analysis and in high-dimensional "omics" data. I believe that my training and experience make me well-suited to contribute to the successful completion of the proposed work.

B. Positions and Honors

Positions and Employment

1982-1985 Process Engineer, Pfizer Inc., Terre Haute, IN
1988-1989 Database Programmer, New Mexico State University, Las Cruces, NM
1989-1990 Consulting Statistician, USDA, Jornada Experimental Range, Las Cruces, NM
1990-1991 Consulting Statistician, University of Kansas Medical Center, Kansas City, KS
1992-1994 Research Assistant, Statistics Department, University of Washington, Seattle, WA
1994-1995 Consulting Statistician, Statistics Consulting Center, University of Washington, Seattle, WA
1995-1996 Assistant Professor, University of Alaska, Fairbanks, AK
1996-1999 Statistician, The Boeing Company, Seattle, WA
1996-1999 Affiliate Assistant Professor, Department of Statistics, University of Washington, Seattle, WA
1996-2001 Research Scientist, National Research Center for Statistics and the Environment, University of Washington, Seattle, WA
1999-2001 Director of Statistical Consulting, Center for Statistics and the Social Sciences, University of Washington, Seattle, WA
2001-2007 Assistant Professor, VICC Biostatistics Shared Resource, Vanderbilt University, Nashville, TN
2001-2007 Assistant Professor, Department of Biostatistics, Vanderbilt University, Nashville, TN
2005-2007 Director, High-Dimensional Data Analysis Center, Vanderbilt University, Nashville, TN
2007-2008 Director, Biostatistics Shared Resource, Huntsman Cancer Institute, Salt Lake City, UT
2007-2008 Associate Professor, Dept of Oncological Sciences, University of Utah, Salt Lake City, UT
2008-Present Associate Professor of Biometry, University of Arizona, Tucson, AZ
2008-Present Director, Arizona Statistics Consulting Laboratory, University of Arizona, Tucson, AZ

C. Selected peer-reviewed publications (from > 50 total).

1. **Billheimer D**: “Compositional Receptor Modeling,” 2001, Environmetrics; 12, 451-467.

2. **Billheimer D**, Guttorp P, and Fagan WF: “Statistical Interpretation of Species Composition,” 2001, Journal of the American Statistical Association, 96, 1205-1214.
3. Goldstein RE, **Billheimer D**, Martin WH, and Richards K: “Sestamibi Scanning and Minimally Invasive Radioguided Parathyroidectomy without Intraoperative Parathyroid Hormone Measurement,” Ann Surg. 2003 May;237(5):722-30; discussion 730-1. PMID: 12724639
4. Chaurand P, Schwartz SA, **Billheimer D**, Xu BJ, Crecelius A, and Caprioli RM: ``Integrating Histology and Mass Spectrometry,'' Anal Chem. 2004 Feb 15;76(4):1145-55. PMID: 14961749
5. Tsiatis AC, Manes B, Calder C, **Billheimer D**, Wilkerson KS, and Frangoul H: “Incidence and Clinical complications of Vancomycin-Resistant Enterococcus in Pediatric Stem Cell Transplant Patients,” Bone Marrow Transplant. 2004 May;33(9):937-41. PMID: 15034540
6. Scarfone C, Lavely WC, Cmelak AJ, Delbeke D, Martin WH, **Billheimer D**, and Hallahan DE: “Prospective Feasibility Trial of Radiotherapy Target Denition for Head and Neck Cancer Using 3-dimensional PET and CT Imaging,'' J. Nucl. Med., 2004; Apr;45 (4): 543-552. PMID: 15073248
7. Etzioni R, Hawley S, **Billheimer D**, True L, and Knudsen B: “Analyzing Patterns of Staining in Immunohistochemical Studies: Application to a Study of Prostate Cancer Recurrence,” 2005, Cancer Epidemiol Biomarkers & Prev; 2005 May;14(5): 1040-6. PMID: 15894650
8. Chakravarthy AB, Kelley MC, McLaren B, Truica CI, **Billheimer D**, Mayer IA, Grau AM, Johnson DH, Simpson JF, Beauchamp RD, Jones C, and Pietenpol JA: “Neoadjuvant Concurrent Paclitaxel and Radiation in Stage II/III Breast Cancer.” Clin Cancer Res. 2006 Mar 1;12(5):1570-6. PMID: 16533783
9. Yankeelov T, DeBusk L, **Billheimer D**, Luci J, Lin C, Price R, and Gore J: “Repeatability of a Reference Region Model for the Analysis of DCE-MRI Data,'' J. Mag. Res. Imag;. 2006; Nov;24(5): 1140-7. PMID: 17024660
10. Li JQ, Xu BJ, Shakhtour B, Deane N, Merchant N, Heslin MJ, Washington K, Coffey R, Beauchamp D, Shyr Y, and **Billheimer D**: “Variability of In Situ Proteomic Profiling and Implications for Study Design in Colorectal Tumors,'' Int J Oncol, 2007; Jul;31(1): 103-11. PMID: 17549410
11. Frangoul H, Nemecek ER, **Billheimer D**, Pulsipher MA, Khan S, Woolfrey A, Manes B, Cole C, Walters MC, Ayas M, Ravindranath Y, Levine JE, Grupp SA. A prospective study of G-CSF primed bone marrow as a stem-cell source for allogeneic bone marrow transplantation in children: a Pediatric Blood and Marrow Transplant Consortium (PBMTC) study. Blood. 2007 Dec 15;110(13):4584-7. Epub 2007 Sep 7. PMID: 17827386
12. Sanders ME, Dias EC, Xu BJ, Mobley JA, **Billheimer D**, Roder H, Grigorieva J, Dowsett M, Arteaga CL, Caprioli RM. Differentiating Proteomic Biomarkers in Breast Cancer by Laser Capture Microdissection and MALDI MS. J Proteome Res. 2008 Apr 4;7(4):1500-1507. Epub 2008 Apr 4. PMID: 18386930
13. Ware LB, Koyama T, **Billheimer DD**, Wu W, Bernard GR, Thompson BT, Brower RG, Standiford TJ, Martin TR, Matthay MA; the NHLBI ARDS Clinical Trials Network. Prognostic and Pathogenetic Value of Combining Clinical and Biochemical Indices in Patients With Acute Lung Injury. Chest. 2010 Feb;137(2):288-296. Epub 2009 Oct 26. PMID: 19858233
14. Paulovich AG, **Billheimer D**, Ham AJ, Vega-Montoto L, Rudnick PA, Tabb DL, Wang P, Blackman RK, Bunk DM, Cardasis HL, Clauser KR, Kinsinger CR, Schilling B, Tegeler TJ, Variyath AM, Wang M, Whiteaker JR, Zimmerman LJ, Fenyo D, Carr SA, Fisher SJ, Gibson BW, Mesri M, Neubert TA, Regnier FE, Rodriguez H, Spiegelman C, Stein SE, Tempst P, Liebler DC. Interlaboratory study characterizing a yeast performance standard for benchmarking LC-MS platform performance. Mol Cell Proteomics. 2010 Feb;9(2):242-54. Epub 2009 Oct 26. PMID: 19858499
15. Li M, Gray W, Zhang H, Chung CH, **Billheimer D**, Yarbrough WG, Liebler DC, Shyr Y, Slebos RJ. Comparative shotgun proteomics using spectral count data and quasi-likelihood modeling. J Proteome Res. 2010 Jun 29. PMID: 20586475

D. Research Support

Ongoing Research Support

RC1 ES018328 Lau (PI) 10/01/09 – 09/30/11
NIH Recovery Fund
Proteomic Signatures of an Early Life Asthma-Protective Exposure
The goal of this project is to identify and characterize proteomic signatures of early life dog exposures in the plasma or serum of children, and their association with childhood asthma.
Role: Co-Investigator

P30 ES006694 Lau (PI) 04/01/06 – 03/31/11
NIH/NIEHS
Southwest Environmental Health Sciences Center
The goal of this program is to understand the mechanisms by which exposure to environmental agents contribute to human disease.
Role: Co-Investigator

R01DK082542-01A2 Nelson (PI) 03/01/10 – 02/28/15
Arizona State University (NIH)
Population-Based Proteomic Investigation of Type 2 Diabetes Melitus
This project is a clinical study using proteomics and metabolomics to investigate potential biomarkers in blood and urine samples which might identify type 2 diabetes and pre-diabetic conditions.
Role: Co-Investigator

RC1HL100800-01 Vercelli (PI)
NIH/NHBLI
Epigenetic Predictors of Asthma in Neonates 10/01/09 – 09/30/11
The goal of this program is to understand the use of epigenetic signatures in blood cells to predict disease. Because asthma typically begins in early life, and the asthma status of the child is strongly related to that of the mother, the overall hypothesis driving this application is that signatures detectable in epigenome, and more specifically, in the methylome, at birth can serve as predictors of asthma status later in life.
Role: Co-Investigator

Completed Research Support

Billheimer (PI) 09/01/09 – 08/31/10
Jim Ayers Institute for Precancer Detection and Diagnosis
Statistical Methods for Protein Analysis
The focus of this project is the development and evaluation of targeted mass spectral methods for protein quantification of cancer biomarkers, as well as the evaluation of shotgun proteome analysis methods and applications in cancer research.

1U24 CA126479-01 Billheimer (PI) 09/28/06-08/31/11
NCI
Clinical Proteomic Technology Assessment for Cancer
This project will improve and standardize proteomics technology platforms for application to clinical studies in cancer research.
Role: Co-Investigator

5P01 CA073992-10 Burt (PI) 08/10/98–08/31/08
NIH/NCI
Molecular, Clinical Approaches to Colon Cancer Precursors
The major goal of this project is the investigation of the genetics and molecular and cell biology of the adenomatous polyp, and clinical investigation of its prevention and natural history.
Role: Co-Investigator

5P50 CA90949-05 Carbone (PI) 06/01/01-12/31/05
NCI
Lung SPORE Pilot Project
This study will investigate the molecular features of tumors or tumor host interactions that determine their clinical behavior and represent potential molecular targets for interventions that will prevent the occurrence or improve the outcome of lung cancer patients.

Role: Co-Investigator

5P50 CA95103-05 Coffey (PI) 09/24/02-04/30/07
NCI
SPORE in GI Cancer
The goal of this project is to investigate the molecular features of gastrointestinal tumors.
Role: Co-Investigator

1R01 CA114471-01A1 Mahadevan-Jansen (PI) 07/20/06-05/31/11
NIH
Development of a Handheld Probe for Confocal Microscopy and Raman Spectroscopy of Skin
The specific aims of the proposed project are to develop and test a compact handheld Raman probe with video imaging capability and to develop and test a handheld confocal imaging device at video rate.
Role: Co-Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME James L. Goodwin III	POSITION TITLE Research Assistant Professor of Medicine Associate Scientific Investigator
eRA COMMONS USER NAME jamiegoodwin	

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
State University of New York, Albany, NY	BS	05/89	Business
University of Southern California, Los Angeles, CA	MS	05/93	Systems Management
University of Arizona, Tucson, Tucson, AZ	PhD	12/02	Epidemiology

A. Personal Statement

The goal of the proposed research is to prospectively evaluate the cost-effectiveness of a comprehensive school-based asthma screening and management program. This will be done by conducting a prospective randomized controlled trial in 500 children with asthma to evaluate the cost-effectiveness of a comprehensive school-based asthma screening and management program in a large, urban elementary school system in the Southwestern United States. I have the experience and demonstrated success to execute the requirements of this project. As a co-investigator on the Tucson Children's Assessment of Sleep Apnea (TuCASA) study, I personally enrolled 18 elementary schools in the Tucson Unified School District to recruit children of a similar demographic to this study. I have been project manager or investigator on a variety of large, NIH funded, multi-center asthma projects to include the Childhood Asthma Research and Education Network (CARE), the NIAID Inner-City Asthma Study (ICAS), the Inner-City Asthma Consortium (ICAC), and now the AsthmaNet series of studies newly funded by the NHLBI. I have managed the successful recruitment for and execution of 13 asthma clinical research, epidemiological, and industry funded studies. I have directly supervised and trained dozens of research coordinators and technicians to successfully execute study procedures in asthma and sleep research; maintaining high standards for certification, training, and performance. Based on my performance in these previous projects, I am confident that I can achieve results in training research personnel to a high standard and then supervising them in the successful execution of this study.

B. Positions and Honors

Positions and Employment

2009 - present Managing Director, Clinical and Translational Science Center, BIO5 Institute, University of Arizona, Tucson, Arizona
2004 - present Assistant Professor, Mel and Enid Zuckerman College of Public Health, University of Arizona, Tucson, Arizona
2003 - present Research Assistant Professor of Medicine, College of Medicine, University of Arizona, Tucson, Arizona
1999 - present Associate Scientific Investigator, Arizona, Arizona Respiratory Center, University of Arizona, Tucson, Arizona

Other Experience and Professional Memberships

2009 - present Co-Chair, Institutional Review Board (IRB), University of Arizona, Tucson, Arizona
2003 - 2009 Primary and Voting Member, Institutional Review Board, University of Arizona, Tucson, Arizona
1999 - 2002 Society for Epidemiological Research
2000 - 2002 Society for Clinical Trials

2001 - present American Academy of Sleep Medicine
2007 - 2008 Society for Academic Emergency Medicine

C. Selected Peer-reviewed Publications (Selected from 30 peer-reviewed publications)

Most relevant to the current application

1. **Goodwin JL**, Kaemingk KL, Mulvaney SA, Morgan WJ, Quan SF. Clinical Screening of School Children for Polysomnography to Detect Sleep Disordered Breathing--the Tucson Children's Assessment of Sleep Apnea Study (TuCASA). J Clin Sleep Med 2005;1(3):247-54.
2. Lind BK, **Goodwin JL**, Hill JG, Ali T, Redline S, Quan SF. Recruitment of Healthy Adults Into a Study of Overnight Sleep Monitoring in the Home: Experience of the Sleep Heart Health Study. Sleep Breath, 2003; 7:13-24.
3. Lundy SM, Silva GE, Kaemingk KL, **Goodwin JL**, Quan SF. Cognitive Functioning and Academic Performance in Elementary School Children with Depressive Symptoms. The Open Pediatric Medicine Journal, 2010;4:1-9.
4. **Goodwin JL**, Enright PL, Kaemingk KL, Rosen GM, Morgan WJ, Fregosi RF, Quan SF. Feasibility of Using Unattended Polysomnography in Children - Report of the Tucson Children Assessment of Sleep Apnea Study (TuCASA). Sleep, 2001; 24:937-44.
5. Zhao Q, Sherrill DL, **Goodwin JL**, Quan SF. Association Between Sleep Disordered Breathing and Behavior in School-aged Children. The Open Epidemiology Journal, 2008 (1) 1-9.
6. Kushida CA, Nichols DA, Quan SF, **Goodwin JL**, White DP, Gottlieb DJ, Walsh JK, Schweitzer PK, Guilleminault C, Simon RD, Leary EB, Hyde PR, Holmes TH, Bloch DA, Green S, McEvoy LK, Gevins A, Dement WC. The Apnea Positive Pressure Long-term Efficacy Study (APPLES): Rationale, Design, Methods, and Procedures. J Clin Sleep Med 2006; 2(3):288-300.

Additional recent publications of importance to the field (in chronological order)

1. **Goodwin JL**, Babar SI, Kaemingk KL, Rosen GM, Morgan WJ, Sherrill DL, Quan SF. Symptoms Related to Sleep Disordered Breathing in Caucasian and Hispanic Children – the Tucson Children's Assessment of Sleep Apnea Study (TuCASA). Chest, 2003; 124:196-203.
2. **Goodwin JL**, Kaemingk KL, Fregosi RF, Rosen GM, Morgan WJ, Sherrill DL, Quan SF. Clinical Outcomes Associated with Sleep Disordered Breathing in Caucasian and Hispanic Children – The Tucson Children's Assessment of Sleep Apnea Study (TuCASA). Sleep, 2003; 26(5):587-91.
3. Kaemingk KL, Pasvogel AE, **Goodwin JL**, Mulvaney SA, Martinez F, Enright PL, Rosen GM, Morgan WJ, Fregosi RF, Quan SF. Learning and Memory in Children With Sleep Disordered Breathing: Findings of the Tucson Children's Assessment of Sleep Apnea (TuCASA) Prospective Cohort Study. J Int Neuro Soc, 2003;9:1016-26.
4. **Goodwin JL**, Kaemingk KL, Fregosi RF, Smith T, Rosen GM, Morgan WM, Smith T, Quan SF. Parasomnias and Sleep Disordered Breathing in Caucasian and Hispanic Children--the Tucson Children's Assessment of Sleep Apnea Study (TuCASA). BMC Med 2004, 2:4
5. Mulvaney SA, **Goodwin JL**, Morgan WJ, Rosen GR, Quan SF, Kaemingk KL. Behavior Problems Associated with Sleep Disordered Breathing in School-Aged Children--the Tucson Children's Assessment of Sleep Apnea Study. J Pediatr Psychol 2006, Apr;31(3):322-30.
6. **Goodwin JL**, Silva GE, Kaemingk KL, Sherrill DL, Morgan WJ, Quan SF. Comparison between reported and recorded total sleep time and sleep latency in 6 – 11 year-old children: the Tucson Children's Assessment of Sleep Apnea Study (TuCASA). Sleep Breath 2007;11(2):85-92.
7. Mulvaney SA, Kaemingk KL, **Goodwin JL**, Quan SF. Parent-rated behavior problems associated with overweight before and after controlling for sleep disordered breathing. BMC Pediatr 2006 Dec 14;6:34
8. Venker CC, **Goodwin JL**, Roe DJ, Kaemingk KL, Mulvaney SA, Quan SF. Normative psychomotor vigilance task performance in children ages 6 to 11: The Tucson Children's Assessment of Sleep Apnea (TuCASA). Sleep Breath. 2007 Dec;11(4):217-24.
9. **Goodwin JL**, Vasquez MM, Silva GE, Quan SF. Incidence and Remission of Sleep Disordered Breathing and Related Symptoms in 6-17 Year Old Children-the Tucson Children's Assessment of Sleep Apnea Study (TuCASA). J Pediatr. 2010 Jul;157(1):57-61.

D. Research Support

Ongoing Research Support

U10HL098115 Martinez (PI) 9/30/09 - 9/29/16
Clinical Centers for the NHLBI Asthma Network (AsthmaNet)
The goal of this project is to develop and conduct multiple clinical trials to address the most important asthma management questions and new treatment approaches in pediatric and adult populations.
Role: Participating Investigator

1RC2HL101543 Martinez (PI) 10/1/09 - 9/30/11
The Asthma BioRepository for Integrative Genomics Research (ABRIDGE)
The goal of this project is to establish an open-access collection of immortalized cell lines, cDNA and DNA from more than 2,700 well-characterized subjects participating in ongoing genetic studies of asthma.
Role: Participating Investigator

American Lung Association Gerald (PI) 01/01/10—06/30/11
Asthma Clinical Research Center. The American Lung Association's Asthma Clinical Research Centers consists of 19 clinical centers and a data and coordinating center who have the mission of improving asthma care through clinical research in diverse populations. The ALA-ACRC conducts various clinical studies related to asthma.
Role: Participating Investigator

Completed Research Support

1 U01 HL68060 Quan (PI) 9/1/02 - 8/31/08.
Apnea Positive Pressure Long-term Efficacy Study (APPLES)
The goal of this study is to assess the long-term effectiveness of CPAP therapy on neurocognitive function, mood, sleepiness, and quality of life.
Role: Participating Investigator

Respironics, Inc. Quan (PI) 12/01/05 – 3/31/07
The Effect of Vestibular Stimulation on Transient Insomnia Induced by a 4-Hour Phase Advance of Sleep Time
The goal of this study is to investigate the effects of non-invasive electrical stimulation of the vestibular nerve in healthy adult subjects whose sleep pattern is intentionally phase advanced to create a model of transient insomnia.
Role: Participating Investigator

Respironics, Inc. Goodwin (PI) 8/21/08 – 7/31/09
Evaluation of Software Enhancements to the Respironics BiPAP auto SV Device
The goal of this study is to evaluate the performance of two auto-titatrating CPAP devices in treating complex sleep apnea.
Role: Primary Investigator

2 R01 HL062373-05A2 Quan (PI) 7/1/2001 - 8/31/10
Prevalence and Correlates of Childhood Sleep Apnea (TuCASA)
The goal of this study is to examine the natural history and epidemiology of sleep disordered breathing in children from 6-18 years of age.
Role: Co-Investigator

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Todd A. Lee, PharmD, PhD	Associate Professor
eRA COMMONS USER NAME toddlee	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Drake University, Des Moines, IA	PharmD	1997	Pharmacy
University of Washington, Seattle, WA	PhD	2001	Outcomes Research/ Pharmacoeconomics

A. Personal Statement

The specific aim of the proposed project is to evaluate the cost-effectiveness of a comprehensive school-based asthma screening and management program. I will serve as a co-investigator on this project and provide expertise in the conduct of the cost-effectiveness analysis alongside the clinical trial. I have expertise in economic evaluations of medical interventions aimed at better understand the value of these new interventions. I have extensive experience with economic evaluations conducted alongside clinical trials as well as developing economic models, including decision-tree and Markov health state models. Importantly, I was involved in the cost-effectiveness analysis of the Pediatric Asthma Care PORT which will provide valuable experience for conducting the economic evaluation proposed as part of this study. In addition, I also have experience in evaluating patient preferences utilizing several different elicitation techniques and was part of the team that developed the Pediatric Asthma Health Outcome Measure which will be used as the primary outcome measure for this cost-effectiveness analysis. Given this experience, I am well-suited to collaborate with the study team on the evaluation of the cost-effectiveness of the school-based asthma program.

B. Positions and Honors

Positions and Employment

2001-present Research Scientist, Center for Management of Complex Chronic Care (CMC3), Hines VA Hospital, Hines, IL
2002-2008 Research Assistant Professor, Institute for Healthcare Studies and Division of General Internal Medicine, Northwestern University Feinberg School of Medicine, Chicago, IL
2007-present Director, CMC3 HSR&D Post-Doctoral Fellowship, Hines VA Hospital, Hines, IL
2009-present Associate Professor, Departments of Pharmacy Practice and Pharmacy Administration, University of Illinois at Chicago, Chicago, IL
2009-present Assistant Director, Center for Pharmacoeconomic Research, University of Illinois at Chicago, Chicago, IL

Other Experience and Professional Membership

2005 VA HSR&D Scientific Merit Review Board (SMRB), Chronic Disease Management and Behavioral Processes Review Group, Ad hoc reviewer
2005 VA HSR&D Scientific Merit Review Board (SMRB), Quality Measurement and Effectiveness Review Group, Ad hoc reviewer
2005 Michael Smith Foundation for Health Research, Career Awards, External reviewer
2005 – 2009 VA HSR&D Scientific Merit Review Board (SMRB), Chronic Diseases and Quality Measurement & Effectiveness, Member
2007 AHRQ, Centers for Education and Research in Therapeutics Special Emphasis Panel (CERTs SEP), Reviewer

Honors and Awards

1991 – 1996 Drake University Trustee Scholarship

1997 – 1999	Achievement Rewards for College Scientists (ARCS) Fellowship
1999	Best Contributed Poster Presentation – Student ISPOR 4th Annual International Meeting
1999 – 2001	AFPE – Pre-Doctoral Fellowship
2003	American Foundation for Pharmaceutical Education (AFPE) Scholar and Fellow
2005	Center Director's Award, Midwest Center for Health Services and Policy Research
	ISPOR Bernie J. O'Brien New Investigator Award

C. Selected peer-reviewed publications (From a total of 66 publications)

Publications relevant to current application

1. **Lee TA**, Hollingworth W, Sullivan SD. Comparison of directly elicited preferences to preferences derived from the SF-36 in adult asthmatics. *Med Decis Making*. 2003; 23(4): 323-334.
2. Chiou CF, Weaver MR, Bell MA, **Lee TA**, Krieger JW. Development of a multi-attribute pediatric asthma health outcome measure (PAHOM). *Int J Qual Health Care*. 2005; 17(1): 23-30.
3. Pickard AS, Wang Z, Walton SM, **Lee TA**. Are decisions using cost-utility analyses robust to choice of SF-36/SF-12 preference-based algorithm? *Health Qual Life Outcomes*. 2005; 3(11).
4. Sullivan SD, **Lee TA**, Blough DK, Finkelstein JA, Lozano P, Inui TC, Fuhlbrigge AL, Carey VJ, Wagner E, Weiss KB. A multi-site randomized trial of the effects of physician education and organizational change in chronic asthma care: Cost-effectiveness analysis of the Pediatric Asthma Care PORT. *Arch Pediatr Adolesc Med*. 2005; 159(5): 428-434.
5. **Lee TA**, Hacek DM, Stroupe KT, Collins SM, Peterson LR. Three surveillance strategies for vancomycin-resistant enterococci in hospitalized patients: detection of colonization and a cost-effectiveness model. *Infect Control Hosp Epidemiol*. 2005; 26(1): 39-46.
6. **Lee TA**, Fuhlbrigge AL, Sullivan SD, Finkelstein JA, Inui TS, Lozano P, Weiss KB. Agreement between caregiver reported healthcare utilization and administrative data for children with asthma. *J Asthma*. 2007; 44(3): 189-194.
7. Khare RK, Courtney DM, Powell ES, **Lee TA**. Sixty-four slice computed tomography of the coronary arteries: cost-effectiveness analysis of patients presenting to the ED with low risk chest pain. *Ann Emerg Med*. 2008; 15: 623-632.
8. Scheetz MH, Bolon MK, Postelnick M, Noskin GA, **Lee TA**. Cost effectiveness analysis of an antimicrobial stewardship team on blood stream infections: a probabilistic analysis. *J Antimicrob Chemother*. 2009; 63(4): 816-825.

Other recent publications

9. **Lee TA**, Pickard AS, Au DH, Bartle B, Weiss KB. Risk of deaths associated with medications for recently diagnosed chronic obstructive pulmonary disease. *Ann Intern Med*. 2008; 149(6): 380-390.
10. **Lee TA**, Wilke CT, Joo M, Stroupe KT, Krishnan J, Schumock GT, Pickard AS. Outcomes associated with tiotropium use in COPD patients. *Arch Intern Med*. 2009; 169(15): 1403-1410.
11. **Lee TA**, Pickard AS, Bartle B, Schumock GT. Mortality risk in patients receiving drug regimens with theophylline for chronic obstructive pulmonary disease. *Pharmacotherapy*. 2009; 29(9): 1039-1053.
12. Joo MJ, Au DH, Fitzgibbon ML, **Lee TA**. Inhaled corticosteroids and risk of pneumonia in newly diagnosed COPD. *Respir Med*. 2010; 104(2): 246-252.
13. Nielsen R, Johannessen A, Benediktsdottir B, Gislason T, Buist AS, Gulsvik A, Sullivan SD, **Lee TA**. Present and future costs of COPD in Iceland and Norway: Results from the BOLD study. *Eur Respir J*. 2009; 34(4): 850-857.
14. Joo MJ, Au DH, **Lee TA**. Use of spirometry in the diagnosis of COPD and efforts to improve quality of care. *Transl Res*. 2009; 154(3): 103-110.
15. Ogale SS, **Lee TA**, Au DH, Boudreau DM, Sullivan SD. Cardiovascular events associated with ipratropium bromide in COPD. *Chest*. 2010; 137(1): 13-19.

D. Research Support

Ongoing

1RC2HL101618-01 Lee (Co-PI) 9/09 - 8/11
NHLBI
CONCERT-Clinical Effectiveness Research (CONCERT-CER)
The goal of this project is to develop infrastructure for comparative effectiveness studies in patients with chronic obstructive pulmonary disease.
Role: Co-PI

IIR 08-354 Hynes (PI) 5/09 – 4/12
VA HSR&D
Clinical guidelines for ESA use in cancer: impacts on clinical practice
The objective of this study is to evaluate the impact of clinical practice guidelines on the use of ESA in patients with cancer and to examine the association between ESA use and adverse effects.
Role: Co-Investigator

VA HSR&D Jordan (PI) 11/09 – 10/11
Depression care facility-level variation for persons with multimorbidity
The goal of this study is to examine facility and system characteristics associated with provision of evidence-based depression care.
Role: Co-I

IIR 07-178 Lee (PI) 07/10 – 06/12
VA HSR&D
Management and control of co-existing chronic disease in COPD patients
The objective of this study is to evaluate the management and control of key co-existing conditions in patients with COPD and compare the outcomes of patients based on management strategies for the co-existing conditions.
Role: PI

Completed

HHSP23320045013XI Hidalgo (PI) 10/08 – 9/10
Department of Defense
Complex chronic care among Tricare beneficiaries: cost effective treatment strategies
The objective of this study is to compare the prevalence and healthcare use of patients with multiple chronic conditions among VA and DOD beneficiaries.
Role: Project Lead Investigator

R21HS017635-01 Jordan (PI) 9/08 – 8/10
AHRQ
Effect of chronic illness complexity on evidence-based depression treatment
The goal of this project is to evaluate the association between multiple chronic conditions and the receipt of evidence-based depression treatment among those with new onset major depressive disorder.
Role: Co-Investigator

RWJ Weiss (PI) 12/07 – 8/10
Characterizing costs and episodes of care
The objective of this project is to create a process for defining episodes of care for chronic illnesses and to estimate costs associated with 20 chronic conditions as test cases for the process.
Role: Co-Investigator

IIR 05-293 Lee (PI) 07/06 – 12/10
VA HSR&D

NSAID related adverse events: evaluating risk using clinical information
The objective of this study is to evaluate the impact of clinical enriched datasets when examining the association between NSAID use and adverse events.
Role: PI

HHSA290-2005-0038-I-TO4-WA2 Pickard (PI) 11/08 – 12/09
AHRQ
Development of a multicenter prospective study to assess the effectiveness of treatment for COPD
The objective of this project was to develop a prioritized list of comparative effectiveness research topics through stakeholder input and design a prospective study to address the highest ranking priority area.
Role: Project Lead Investigator

IIR 03-307 Lee (PI) 10/04 – 09/07
VA HSR&D
Outcomes assessment associated with salmeterol use in obstructive lung disease
The objective of this study was to evaluate the outcomes associated with salmeterol use in VA patients with asthma and COPD, specifically looking at the risk of mortality in users versus non-users.
Role: PI

HHSA29020050038I-TO4-WA1 Pickard (PI) 8/07 – 12/08
AHRQ
Comparative effectiveness of anticholinergic medications in patients with chronic obstructive pulmonary disease
The goal of this project was to examine the comparative benefits and harms of ipratropium and tiotropium in the management of patients with COPD
Role: Project Lead Investigator

IIR 01-074 Valenstein (PI) 3/04 – 10/06
VA HSR&D
Improving antipsychotic adherence among patients with serious mental illness
This was a multi-site randomized controlled trial of a pharmacy based intervention aimed at improving the overall medication adherence of patients with schizophrenia and bipolar disorder that were previously non-adherent to medication therapy.
Role: Co-I (site PI)

2R01HS008368-07A1
AHRQ Weiss (PI) 9/02 – 3/05
Outcomes assessment in pediatric asthma
The Pediatric Asthma Care Port II study was conducted to test the cost-effectiveness of national asthma care guidelines as implemented via two alternative methods, a peer leader implemented model and a practice redesign implemented model. The project evaluated the effectiveness and cost-effectiveness of the methods tested in a multi-site randomized controlled trial.
Role: Co-Investigator

OMB Number: 4040-0001
Expiration Date: 06/30/2011

Previous Period

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 8063456170000

*** Budget Type:** ☒ Project ☐ Subaward/Consortium

Enter name of Organization: Arizona Board of Regents, Unive

Delete Entry *** Start Date:** 12/01/2011 *** End Date:** 11/30/2012 **Budget Period** 1

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.		Lynn	B	Gerald	Ph.D.	PD/PI	[redacted]	3.60			[redacted]	[redacted]	[redacted]
2.		Joe	K	Gerald	PhD	CO-Investigator	[redacted]	4.80			[redacted]	[redacted]	[redacted]
3.		Roni		Grad	MD	Co-Investigator	[redacted]	2.40			[redacted]	[redacted]	[redacted]
4.		Scott		Carvajal	PhD	CO-Investigator	[redacted]	1.80			[redacted]	[redacted]	[redacted]
5.		Conrad		Clemens	MD	CO-Investigator	[redacted]	1.20			[redacted]	[redacted]	[redacted]
6.		David	D	Billheimer	PhD	CO-Investigator	[redacted]	1.20			[redacted]	[redacted]	[redacted]
7.		James	L	Goodwin	PhD	CO-Investigator	[redacted]	2.40			[redacted]	[redacted]	[redacted]
8.													
9.	**Total Funds requested for all Senior Key Persons in the attached file**												
												Total Senior/Key Person	[redacted]

Additional Senior Key Persons: Add Attachment Delete Attachment View Attachment

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
	Post Doctoral Associates						
1	Graduate Students		6.00		17,500.00	7,455.00	24,955.00
	Undergraduate Students						
	Secretarial/Clerical						
3	Research Specialists	6.00			52,500.00	23,574.00	76,074.00
1	Project Coordinator	12.00			75,000.00	21,300.00	96,300.00
1	Research Associate	12.00			55,000.00	15,620.00	70,620.00
1	Statistical Analyst	3.60			21,600.00	6,134.00	27,734.00
1	Database Administrator	3.60			29,793.00	8,461.00	38,254.00
8	**Total Number Other Personnel**					**Total Other Personnel**	333,937.00

Total Salary, Wages and Fringe Benefits (A+B) 563,018.00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 8063456170000

*** Budget Type:** ☒ Project ☐ Subaward/Consortium

Enter name of Organization: Arizona Board of Regents, Unive

Delete Entry *** Start Date:** 12/01/2011 *** End Date:** 11/30/2012 **Budget Period 1**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

	Equipment item	* Funds Requested ($)
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.	**Total funds requested for all equipment listed in the attached file**	
	Total Equipment	

Additional Equipment: Add Attachment Delete Attachment View Attachment

D. Travel **Funds Requested ($)**

1.	Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	6,402.00
2.	Foreign Travel Costs	
	Total Travel Cost	6,402.00

E. Participant/Trainee Support Costs **Funds Requested ($)**

1.	Tuition/Fees/Health Insurance	
2.	Stipends	
3.	Travel	
4.	Subsistence	
5.	Other	
	Number of Participants/Trainees **Total Participant/Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION F-K, BUDGET PERIOD 1

Next Period

*** ORGANIZATIONAL DUNS:** 8063456170000

*** Budget Type:** ☒ Project ☐ Subaward/Consortium

Enter name of Organization: Arizona Board of Regents, Unive

Delete Entry *** Start Date:** 12/01/2011 *** End Date:** 11/30/2012 **Budget Period 1**

F. Other Direct Costs		Funds Requested ($)
1.	Materials and Supplies	107,000.00
2.	Publication Costs	
3.	Consultant Services	3,520.00
4.	ADP/Computer Services	
5.	Subawards/Consortium/Contractual Costs	48,345.00
6.	Equipment or Facility Rental/User Fees	
7.	Alterations and Renovations	
8.	Other Direct Cost/Expenses	25,304.00
9.		
10.		
	Total Other Direct Costs	184,169.00

G. Direct Costs	Funds Requested ($)
Total Direct Costs (A thru F)	753,589.00

H. Indirect Costs

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1.	MDTC	51.50	745,392.00	383,877.00
2.				
3.				
4.				
	Total Indirect Costs			383,877.00

Cognizant Federal Agency DHHS Audit Agency,Regional Inspector General for Audit, (415)4

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	1,137,466.00

J. Fee	Funds Requested ($)

K. * Budget Justification 1258-NIH R18 Budget Justification Jan Add Attachment Delete Attachment View Attachment

(Only attach one file.)

OMB Number: 4040-0001
Expiration Date: 06/30/2011

Previous Period

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

*** ORGANIZATIONAL DUNS:** 8063456170000

*** Budget Type:** ☒ Project ☐ Subaward/Consortium

Enter name of Organization: Arizona Board of Regents, Unive

Delete Entry *** Start Date:** 12/01/2012 *** End Date:** 11/30/2013 **Budget Period** 2

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.		Lynn	B	Gerald	Ph.D.	PD/PI	[redacted]	3.60			[redacted]	[redacted]	[redacted]
2.		Joe	K	Gerald	PhD	CO-Investigator	[redacted]	4.80			[redacted]	[redacted]	[redacted]
3.		Roni		Grad	MD	CO-Investigator	[redacted]	2.40			[redacted]	[redacted]	[redacted]
4.		Scott		Carvajal	PhD	CO-Investigator	[redacted]	1.80			[redacted]	[redacted]	[redacted]
5.		Conrad		Clemens	MD	CO-Investigator	[redacted]	1.20			[redacted]	[redacted]	[redacted]
6.		David	D	Billheimer	PhD	CO-Investigator	[redacted]	1.20			[redacted]	[redacted]	[redacted]
7.		James	L	Goodwin	PhD	CO-Investigator	[redacted]	2.40			[redacted]	[redacted]	[redacted]
8.													
9.	**Total Funds requested for all Senior Key Persons in the attached file**												
												Total Senior/Key Person	[redacted]

Additional Senior Key Persons: Add Attachment | Delete Attachment | View Attachment

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
	Post Doctoral Associates						
1	Graduate Students		6.00		18,025.00	7,679.00	25,704.00
	Undergraduate Students						
	Secretarial/Clerical						
3	Research Specialists	6.00			54,075.00	24,282.00	78,357.00
1	Project Coordinator	12.00			77,250.00	21,939.00	99,189.00
1	Research Associate	12.00			56,650.00	16,089.00	72,739.00
1	Statistical Analyst	3.60			22,248.00	6,318.00	28,566.00
1	Database Administrator	0.60			4,966.00	1,602.00	6,568.00
8	**Total Number Other Personnel**					**Total Other Personnel**	311,123.00

Total Salary, Wages and Fringe Benefits (A+B) 547,077.00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

*** ORGANIZATIONAL DUNS:** 8063456170000

*** Budget Type:** ☒ Project ☐ Subaward/Consortium

Enter name of Organization: Arizona Board of Regents, Unive

Delete Entry *** Start Date:** 12/01/2012 *** End Date:** 11/30/2013 **Budget Period 2**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

	Equipment item	* Funds Requested ($)
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.	**Total funds requested for all equipment listed in the attached file**	
	Total Equipment	

Additional Equipment: Add Attachment Delete Attachment View Attachment

D. Travel **Funds Requested ($)**

1.	Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	8,806.00
2.	Foreign Travel Costs	
	Total Travel Cost	8,806.00

E. Participant/Trainee Support Costs **Funds Requested ($)**

1.	Tuition/Fees/Health Insurance	
2.	Stipends	
3.	Travel	
4.	Subsistence	
5.	Other	
	Number of Participants/Trainees **Total Participant/Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION F-K, BUDGET PERIOD 2

Next Period

*** ORGANIZATIONAL DUNS:** 8063456170000

*** Budget Type:** ☒ Project ☐ Subaward/Consortium

Enter name of Organization: Arizona Board of Regents, Unive

Delete Entry *** Start Date:** *** End Date:** 11/30/2013 **Budget Period 2**

F. Other Direct Costs		Funds Requested ($)
1.	Materials and Supplies	88,700.00
2.	Publication Costs	
3.	Consultant Services	3,520.00
4.	ADP/Computer Services	
5.	Subawards/Consortium/Contractual Costs	113,892.00
6.	Equipment or Facility Rental/User Fees	
7.	Alterations and Renovations	
8.	Other Direct Costs/Expenses	79,304.00
9.		
10.		
	Total Other Direct Costs	285,416.00

G. Direct Costs		Funds Requested ($)
	Total Direct Costs (A thru F)	841,299.00

H. Indirect Costs

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1.	MDTC	51.50	726,352.00	374,071.00
2.				
3.				
4.				
	Total Indirect Costs			374,071.00

Cognizant Federal Agency DHHS Audit Agency, (415) 437-8360

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	1,215,370.00

J. Fee	Funds Requested ($)

K. * Budget Justification 1258-NIH R18 Budget Justification Jan Add Attachment Delete Attachment View Attachment

(Only attach one file.)

OMB Number: 4040-0001
Expiration Date: 06/30/2011

Previous Period

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

*** ORGANIZATIONAL DUNS:** 8063456170000

*** Budget Type:** ☒ Project ☐ Subaward/Consortium

Enter name of Organization: Arizona Board of Regents, Unive

Delete Entry *** Start Date:** 12/01/2013 *** End Date:** 11/30/2014 **Budget Period** 3

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.		Lynn	B	Gerald	Ph.D.	PD/PI	[redacted]	3.60			[redacted]	[redacted]	[redacted]
2.		Joe	K	Gerald	PhD	CO-Investigator	[redacted]	4.80			[redacted]	[redacted]	[redacted]
3.		Roni		Grad	MD	CO-Investigator	[redacted]	2.40			[redacted]	[redacted]	[redacted]
4.		Scott		Carvajal	PhD	CO-Investigator	[redacted]	1.80			[redacted]	[redacted]	[redacted]
5.		Conrad		Clemens	MD	CO-Investigator	[redacted]	1.20			[redacted]	[redacted]	[redacted]
6.		David	D	Billheimer	PhD	CO-Investigator	[redacted]	1.20			[redacted]	[redacted]	[redacted]
7.		James	L	Goodwin	PhD	CO-Investigator	[redacted]	2.40			[redacted]	[redacted]	[redacted]
8.													

9. **Total Funds requested for all Senior Key Persons in the attached file**

Total Senior/Key Person 243,034.00

Additional Senior Key Persons: Add Attachment | Delete Attachment | View Attachment

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
	Post Doctoral Associates						
1	Graduate Students		6.00		18,025.00	8,450.00	26,475.00
	Undergraduate Students						
	Secretarial/Clerical						
3	Research Specialists	6.00			54,075.00	26,634.00	80,709.00
1	Project Coordinator	12.00			77,250.00	24,915.00	102,165.00
1	Research Associate	12.00			56,650.00	18,271.00	74,921.00
1	Statiscal Analyst	3.60			22,248.00	7,175.00	29,423.00
1	Database Administrator	0.60			4,966.00	1,799.00	6,765.00
8	**Total Number Other Personnel**					**Total Other Personnel**	320,458.00

Total Salary, Wages and Fringe Benefits (A+B) 563,492.00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

*** ORGANIZATIONAL DUNS:** 8063456170000

*** Budget Type:** ☒ Project ☐ Subaward/Consortium

Enter name of Organization: Arizona Board of Regents, Unive

Delete Entry *** Start Date:** 12/01/2013 *** End Date:** 11/30/2014 **Budget Period 3**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

	Equipment item	* Funds Requested ($)
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.	**Total funds requested for all equipment listed in the attached file**	
	Total Equipment	

Additional Equipment: Add Attachment Delete Attachment View Attachment

D. Travel **Funds Requested ($)**

1.	Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	8,806.00
2.	Foreign Travel Costs	
	Total Travel Cost	8,806.00

E. Participant/Trainee Support Costs **Funds Requested ($)**

1.	Tuition/Fees/Health Insurance	
2.	Stipends	
3.	Travel	
4.	Subsistence	
5.	Other	

Number of Participants/Trainees **Total Participant/Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION F-K, BUDGET PERIOD 3

Next Period

*** ORGANIZATIONAL DUNS:** 8063456170000

*** Budget Type:** ☒ Project ☐ Subaward/Consortium

Enter name of Organization: Arizona Board of Regents, Unive

Delete Entry *** Start Date:** 12/01/2013 *** End Date:** 11/30/2014 **Budget Period 3**

F. Other Direct Costs		Funds Requested ($)
1.	Materials and Supplies	63,700.00
2.	Publication Costs	
3.	Consultant Services	3,520.00
4.	ADP/Computer Services	
5.	Subawards/Consortium/Contractual Costs	116,462.00
6.	Equipment or Facility Rental/User Fees	
7.	Alterations and Renovations	
8.	Other Direct Costs/Expenses	22,304.00
9.		
10.		
	Total Other Direct Costs	205,986.00

G. Direct Costs	Funds Requested ($)
Total Direct Costs (A thru F)	778,284.00

H. Indirect Costs

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1.	MDTC	51.50	656,288.00	337,988.00
2.				
3.				
4.				
	Total Indirect Costs			337,988.00

Cognizant Federal Agency DHHS Audit Agency, (415)437-8360

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	1,116,272.00

J. Fee	Funds Requested ($)

K. * Budget Justification 1258-NIH R18 Budget Justification Jan Add Attachment Delete Attachment View Attachment

(Only attach one file.)

OMB Number: 4040-0001
Expiration Date: 06/30/2011

Previous Period

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

*** ORGANIZATIONAL DUNS:** 8063456170000

*** Budget Type:** ☒ Project ☐ Subaward/Consortium

Enter name of Organization: Arizona Board of Regents, Unive

Delete Entry *** Start Date:** 12/01/2014 *** End Date:** 05/31/2015 **Budget Period** 4

A. Senior/Key Person

	Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.		Lynn	B	Gerald	Ph.D.	PD/PI	[redacted]	1.20			[redacted]	[redacted]	[redacted]
2.		Joe	K	Gerald	PhD	CO-Investigator	[redacted]	2.40			[redacted]	[redacted]	[redacted]
3.		Roni		Grad	MD	CO-Investigator	[redacted]	0.60			[redacted]	[redacted]	[redacted]
4.		Scott		Carvajal	PhD	CO-Investigator	[redacted]	0.60			[redacted]	[redacted]	[redacted]
5.		Conrad		Clemens	MD	CO-Investigator	[redacted]	0.60			[redacted]	[redacted]	[redacted]
6.		David	D	Billheimer	PhD	CO-Investigator	[redacted]	1.20			[redacted]	[redacted]	[redacted]
7.		James	L	Goodwin	PhD	CO-Investigator	[redacted]	2.40			[redacted]	[redacted]	[redacted]
8.													

9. **Total Funds requested for all Senior Key Persons in the attached file**

Total Senior/Key Person [redacted]

Additional Senior Key Persons: Add Attachment | Delete Attachment | View Attachment

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Project Coordinator	2.40			15,450.00	5,596.00	21,046.00
1	Research Associate	2.40			11,330.00	4,104.00	15,434.00
1	Statistical Analyst	3.60			22,915.00	7,391.00	30,306.00
1	Database Administrator	0.60			5,115.00	1,853.00	6,968.00
4	**Total Number Other Personnel**					**Total Other Personnel**	73,754.00

Total Salary, Wages and Fringe Benefits (A+B) 205,798.00

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

*** ORGANIZATIONAL DUNS:** 8063456170000

*** Budget Type:** ☒ Project ☐ Subaward/Consortium

Enter name of Organization: Arizona Board of Regents, Unive

Delete Entry *** Start Date:** 12/01/2014 *** End Date:** 05/31/2015 **Budget Period 4**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

	Equipment item	* Funds Requested ($)
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.	**Total funds requested for all equipment listed in the attached file**	
	Total Equipment	

Additional Equipment: Add Attachment Delete Attachment View Attachment

D. Travel **Funds Requested ($)**

1.	Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	10,403.00
2.	Foreign Travel Costs	
	Total Travel Cost	10,403.00

E. Participant/Trainee Support Costs **Funds Requested ($)**

1.	Tuition/Fees/Health Insurance	
2.	Stipends	
3.	Travel	
4.	Subsistence	
5.	Other	
	Number of Participants/Trainees **Total Participant/Trainee Support Costs**	

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION F-K, BUDGET PERIOD 4

Next Period

*** ORGANIZATIONAL DUNS:** 8063456170000

*** Budget Type:** ☒ Project ☐ Subaward/Consortium

Enter name of Organization: Arizona Board of Regents, Unive

Delete Entry *** Start Date:** 12/01/2014 *** End Date:** 05/31/2015 **Budget Period 4**

F. Other Direct Costs		Funds Requested ($)
1.	Materials and Supplies	2,250.00
2.	Publication Costs	
3.	Consultant Services	
4.	ADP/Computer Services	
5.	Subawards/Consortium/Contractual Costs	50,392.00
6.	Equipment or Facility Rental/User Fees	
7.	Alterations and Renovations	
8.	Other Direct Costs/Expenses	51,996.00
9.		
10.		
	Total Other Direct Costs	104,638.00

G. Direct Costs		Funds Requested ($)
	Total Direct Costs (A thru F)	320,839.00

H. Indirect Costs

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1.	MDTC	51.50	270,446.00	139,280.00
2.				
3.				
4.				
	Total Indirect Costs			139,280.00

Cognizant Federal Agency DHHS Audit Agency, (415)437-8360

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	460,119.00

J. Fee	Funds Requested ($)

K. * Budget Justification 1258-NIH R18 Budget Justification Jan Add Attachment Delete Attachment View Attachment

(Only attach one file.)

Budget Justification

Personnel

Lynn B. Gerald, PhD, MSPH. Principal Investigator. Dr. Gerald is the Canyon Ranch Endowed Chair and a Professor in the Mel and Enid Zuckerman College of Public Health at the University of Arizona. She is also a scientist in the Arizona Respiratory Center. Dr. Gerald has extensive experience in school based asthma research including implementation of asthma management programs, school based asthma screening, internet based asthma monitoring, and supervised asthma therapy. Dr. Gerald's expertise in large school based randomized trials will allow her to lead the team in the conduct of this research study. Dr. Gerald will have overall scientific and administrative responsibility for the proposed project. She will work with the investigative team and staff to ensure that the highest standards of scientific integrity are maintained. These tasks will require 3.6 calendar months effort in Years 1-3 and 1.2 calendar months effort in Year 4.

Joe K. Gerald, MD, PhD. Investigator. Dr. Gerald is an Assistant Professor of Public Health Policy and Management in the Mel and Enid Zuckerman College of Public Health at the University of Arizona. He is a health services researcher with expertise in cost-effectiveness analysis and has previously conducted economic analyses of pulmonary interventions including targeted tuberculosis contact investigation strategies, school-based asthma screening strategies and hand hygiene strategies in elementary schools. His specialty is using short-cycle (daily) Markov modeling to estimate the cost per quality-adjusted life-year (QALY) of various health interventions. This short-cycle approach is well-suited to model chronic conditions such as asthma that are associated with frequent, debilitating symptoms. He is also one of the few health economists to successfully use community-based, standard-gamble derived daily preference weights to conduct a reference case cost-effectiveness analysis of childhood asthma interventions. Dr. Gerald will assist the PI in scientific and administrative responsibility associated with the proposed research and will be closely involved in data collection. Specifically, Dr. Gerald will work with the PI, Investigators, and study staff on protocol development, data management and data collection protocols. He will also directly supervise Dr. Goodwin, the Project Manager, to coordinate and train of all research staff; supervise data collection; and coordinate preparation of all reports and manuscripts. These tasks will require 4.8 calendar months effort in Years 1-3 and 2.4 calendar months effort in Year 4.

Roni Grad, MD. Investigator. Roni Grad, MD. Investigator. Dr. Grad is a board certified pediatric pulmonologist and currently serves as an Associate Professor of Clinical Pediatrics at the University of Arizona. He is also a member of the Arizona Respiratory Center. He has an active clinical practice at The University Medical Center and has collaborated with Dr. Gerald on many school based asthma programs over the past 10 years. Dr. Grad will be responsible for the medical supervision of participants and serve as the lead clinician for the intervention activities. He and Dr. Clemens will help liaison with the children's primary care practitioner. These tasks will require 2.4 months effort in Years 1-3 and 0.6 calendar months effort in Year 4.

Scott Carvajal, PhD, MPH. Dr. Carvajal has expertise in the health of Latino populations. He had led or collaborated on many project that foster health behaviors in diverse youth populations. Dr. Carvajal will lead the evaluation for the proposed project. He will also work with the proposed research team to ensure that the interventions proposed are culturally appropriate and will facilitate interaction with the families of children with asthma. These tasks will require 1.8 calendar months effort In Years 1-3 and 0.6 calendar months effort in Year 4.

Conrad Clemens, MD, MPH. Investigator. Dr. Clemens is an Associate Professor of Pediatrics at the University of Arizona and serves as Medical Director for the Tucson Unified School

District. Dr. Clemens will assist Dr. Grad with medical supervision of participants will serve as the team's primary liaison with the school district and school nurses. In addition, Dr. Clemens has strong ties to the community pediatricians who serve as the primary care practitioner for many of these children and will communicate with them regarding asthma treatment issues. These tasks will require 1.2 calendar months effort in Years 1-3 and 0.6 calendar months effort in Year 4.

Dean Billheimer, PhD. Investigator/Statistician. Dr. Billheimer is a Director of Statistical Consulting at the BIO5 Institute and Associate Professor of Biometry at the University of Arizona. Dr. Billheimer will work with Drs. L. Gerald and J. Gerald to oversee the conduct of the study and will be responsible for overseeing all data analysis, data management, and data storage. He will also prepare the data for sharing at the end of the study. He will supervise Junmei Lui, the statistical analyst, who will serve as the primary programmer for the data management and analyses tasks. Dr. Billheimer's tasks will require 1.2 months effort in each year.

Jamie Goodwin, PhD. Project Manager/Director of Recruitment and Retention. Dr. Goodwin is the manager of the clinical research unit for the Arizona Respiratory Center and managing director of the Clinical and Translational Science Center. Dr. Goodwin has successfully managed many NIH funded trials, including trials of the Childhood Asthma Research and Education (CARE) network and for the Inner City Asthma Consortium (ICAC). He has also had primary managerial responsibility for several large local NIH funded studies such as the Tucson Children's Assessment of Sleep Apnea (TuCASA) study for which he successfully recruited 18 schools within the Tucson Unified School District. Dr. Goodwin brings a solid history of successful study management by his practical approach to administration and problem solving. These tasks will require 2.4 calendar months effort each year.

TBA Project Coordinator. The project coordinator will be an individual with expertise in conducting community based trials. He/she will have experience in training community organizations to conduct health interventions. He/she will be responsible for the day to day function of our research group including the evaluation and management of our team and oversight of data collection activities. These tasks will require 12 calendar months effort in Years 1-3 and 2.4 calendar months effort in Year 4.

Nancy Stroupe, MA, MPH. Research Associate. Ms. Stroupe has extensive experience and training in evaluation planning, design, and implementation. She has evaluated programs and interventions for tribal, state, and federal agencies in the areas of mental health, substance abuse, violence, infectious disease, and education. She has been an evaluation consultant for local communities and frequently conducts trainings for community members on collecting, utilizing, and disseminating evaluation data. She has been an invited member of evaluation committees for SAMHSA and CDC and recently served as the lead evaluator for a comprehensive mental health service delivery program for tribes in Arizona. Ms. Stroupe currently works as the Associate Director of Research and Evaluation in Health Promotion Sciences within the Mel and Enid Zuckerman College of Public Health. She will be responsible for assisting Dr. Gerald with developing the intervention manual as well as for the data collection for the process evaluation as well as monitoring implementation of the intervention. She will also assist with developing the evaluation reports and manuscripts. These tasks will require 12 calendar months effort in Years 1-3 and 2.4 calendar months effort in Year 4.

Junmei Liu, PhD. Statistical Analyst. Dr. Liu is a Statistical Analyst in the Statistical Consulting Unit at BIO5. She will be supervised by Dr. Billheimer to oversee data management and

perform the statistical analyses. She will work closely with Dr. Billheimer to prepare the study data for data sharing. These tasks will require 3.6 months effort in each year.

Sean Davey, MS. Database Administrator. Mr. Davey a Database Applications Developer at the Center for Toxicology and also the programmer for the GEISHA (http://geisha.arizona.edu) project run by Dr. Parker Antin (Dept. of Cell Biology and Anatomy). Mr. Davey has extensive experience in database theory and practice and in web database design and implementation. He will design the study database and create the web database application for data entry, data management and data analysis. He will work with Dr. Billheimer to oversee data security and integration of data from the child and parent interviews, medical records, and pharmaceutical claims databases. These tasks will require 3.6 months effort in Year 1 and 0.60 months effort in Years 2-4.

TBA. Graduate Assistant. One public health graduate assistant will be hired for this project. The graduate assistant will be supervised by J. Gerald and the Project Manager and will assist them with the day to day tasks of the proposed project. These tasks will require 6 academic months effort in Years 1-3.

TBA. Research Specialists. Three research specialists will be required for this school based project. They will be responsible for collecting and entering survey data from the parents and children as well as collecting and abstracting medical record data, under the supervision of the Project Manager. These tasks will require 6 calendar months effort in Years 1-3.

Consultant *Sue Erwin, RRT.* Ms. Erwin is a Clinical Trials Specialist at the University of Alabama at Birmingham's Lung Health Center and will serve as a consultant for the proposed study. She has over 25 years experience as a clinical research coordinator and has served as project coordinator for all of Dr. Gerald's previous school based asthma studies. She has extensive experience in working with school personnel and will work with Dr. Gerald, Dr. Goodwin, and Ms. Stroupe in training staff and developing study protocols as well as developing the intervention manual. Specifically, she will provide advice and expertise on integrating research data collection and protocols into the school system. She will travel to the University of Arizona once per year to meet with project staff and will be available by phone and email to help strategize and solve problems. We have budgeted for Ms. Erwin to travel to the University of Arizona once per year. These trips will be for 2 full days at a rate of $200 per day. We estimate her tasks to require 1 hour per week. Therefore, we have budgeted $1200 for travel for each trip, $400 for consulting fees in Arizona, and $40 per hour (4 hours each of month = $1920) in fees for phone calls and emails each week for a total of $3520 in each of Years 1-3.

Supplies

We will require 4 study specific computers for the Research Assistants and Project Coordinator. These computers will be used in the field to do direct data entry from participant interviews. We request $4000 for these costs in Year 1.

We have budgeted for medication costs for the supervised therapy component of the intervention. Because we want to supervise the medication that the child is on and not standardize medication, we will need to cover the costs of the extra inhalers required for use at school. We have estimated these costs to be $200,000 over the grant period ($75,000 in Years 1 and 2 and $50,000 in Year 3).

We will also need to ensure that quick relief medication is available at school for each child. We expect that we will be able to obtain a 2nd inhaler for use at school for approximately 50% of

children through their insurer; however, many children have difficulty obtaining a second inhaler from their insurer for use at school. Therefore, we request a total of $20,000 over Years 1-3 for the purchase on quick relief medication for those children who do not have it available. We will provide a spacer for each child's medication at school and estimate these costs to be $9000. These will be purchased in bulk in Year 1.

We have budgeted for study specific supplies at the amount of $1500 per FTE per year based on previous experience.

Travel

This project will require travel by the research staff to the schools involved for the purposes of recruitment, retention, data collection, and process evaluation and intervention implementation monitoring. The average round trip distance to these schools from the University is 20 miles. We estimate that Dr. Joe Gerald, Dr. Goodwin and Ms. Stroupe will drive approximately 70 miles per week while Drs. Lynn Gerald, Carvahal, and Grad will drive approximately 20 miles per week. Therefore, we are requesting $2403 in Years 1 and 4 [Years 1 and 4 = (70 miles per week * 3 staff)] + (20 miles per week * 3 staff) * 20 weeks @ $0.445 per mile = $2403]; and $4806 in Years 2 and 3 [Years 2 and 3 = (70 miles per week * 3 staff)] + (20 miles per week * 3 staff) * 40 weeks @ $0.445 per mile = $4806].

We request travel for two investigators to attend national meetings in Years 1-3 to interact with other professionals conducting similar research and to disseminate findings. ($2000 * 2 investigators each year = $4000). In Year 4, we expect the investigators to travel to have more dissemination activities and have budgeted travel to 4 meetings at $2000 in these years ($2000 * 4 meetings = $8000).

Other Expenses

We request computing and operations fees for faculty/staff in the College of Public Health to cover computer software licenses and technical support (Gerald, Gerald, Carvajal, Stroupe, Project Coordinator, GRA, and Research Assistants). We have budgeted $75 per year per FTE for these costs.

We request computing and operations fees for Dr. Billheimer, Dr. Liu, and Mr. Davey to cover computer hardware, software licenses, reference material and continuing education. This cost is based on hours assigned at a rate of $6000/FTE-year.

We have budgeted for 3 cell phones for specific study use ($200 each at purchase) and $80 per month for toll charges to be used by study personnel in the field.

Participant incentives are an important part of this project since researcher will have to access the schools monthly to perform data collection. While no incentives are felt to be necessary to perform the program in schools, the collection of data required to evaluate the program does put an extra strain on schools and their personnel; therefore, we have budgeted $150 per semester for each school participating in the project (16 schools * 125 * 4 semesters = $8000; $2000 in Year 1; $4000 in Year 2 and $2000 in Year 3). We have also budgeted $20 per phone interview for parents (500 parents * 6 interviews * $20 = $60,000; $15,000 in Year 1; $30,000 in Year 2; and $15,000 in Year 3)

In year 1 we request the amount of $3500 to cover costs of a CEU course for the Tucson Unified School District. The course will provide information to all staff on the proposed project as well as asthma. This CEU course will take place over the lunch hour on teacher workdays

and will cover the costs of room rental and food. We are also requesting the amount of $1000 for meetings with school nurses and key personnel in Years 2 - 4.

We request the amount of $1000 in Years 2 and 3 for publication and presentation costs. In Year 4, we request the amount of $8000 to cover publication, presentation, dissemination, and data sharing preparation costs.

The proposed project will need to collect data on the medication use of children enrolled in the study. Arizona's Health Care Cost Containment System (AHCCS) Medicaid plan will abstract medical claims data for the children enrolled in the study. We expect that 30-50% of students will be covered by this plan. AHCCS will abstract the data and provide it to our Data Manager in an easy to use format. We request the amount of $40,000 in Year 2 and $40,000 in Year 4.

**We have applied a standard increase of 3% to salaries across each year.

Subcontract with the American Lung Association of Southern Arizona
The American Lung Association of Southern Arizona will conduct the intervention activities. Ms. Donna Bryson, is the Lung Health Educator for the ALA and is a registered nurse with extensive clinical and community experience in the area of asthma. She will coordinate all of the intervention activities. Ms. Bryson and the ALA have extensive experience in school based asthma screening, and providing Open Airways for Schools Education. She has also worked as a clinical nurse for one of the area's busiest pediatric pulmonary practices and has strong ties to primary care practices that care for patients with asthma. The ALA activities include conducting asthma screening (approximately 6400 children in 16 schools) in both the intervention and delayed intervention schools and implementing the intervention in the immediate intervention schools during Years 1 and 2 (8 schools) and both intervention and delayed intervention schools in Years 2 and 3 (16 schools). Intervention activities include: 1) measuring asthma control in each child, 2) facilitating physician follow-up, 3) ensuring asthma action plans and quick relief medication are on file for each child with asthma, 4) conducting Open Airways for Schools, and 5) facilitating the supervision of asthma controller medication at school. In addition, Ms. Bryson will attend all Investigator meetings. We request the following amounts in each year for these activities: Year 1 $27,824; Year 2 $92,537; Year 3 $94,509; Year 4 $27,824.

Subcontract with Todd Lee
Todd Lee, PharmD, PhD. Dr. Lee is an Associate Professor in the Departments of Pharmacy Practice, Pharmacy Administration and the Section of Pulmonary, Critical Care, Sleep and Allergy in the Department of Medicine at the University of Illinois at Chicago. In addition, Dr. Lee is a senior investigator at the Center for the Management of Complex Chronic Care (CMC3) at the Hines VA Hospital. Dr. Lee has expertise in economic evaluations of medical interventions to better understand the value of these new interventions. He has extensive experience with economic evaluations conducted alongside clinical trials as well as developing economic models, including decision-tree and Markov health state models. Dr. Lee also has experience in evaluating patient preferences utilizing several different elicitation techniques and was part of the team that developed the Pediatric Asthma Health Outcome Measure which will be used as the primary outcome measure for this cost-effectiveness analysis. Dr. Lee will supervise the cost-effectiveness analysis and work with the PI and Investigators on the data collection protocols for the cost data. He will also travel to the University of Arizona once each year to meet with the research team. These tasks will require 1.2 months effort each year.

RESEARCH & RELATED BUDGET - Cumulative Budget

		Totals ($)
Section A, Senior/Key Person		[redacted]
Section B, Other Personnel		1,039,272.00
Total Number Other Personnel	28	
Total Salary, Wages and Fringe Benefits (A+B)		1,879,385.00
Section C, Equipment		
Section D, Travel		34,417.00
1. Domestic	34,417.00	
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		780,209.00
1. Materials and Supplies	261,650.00	
2. Publication Costs		
3. Consultant Services	10,560.00	
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs	329,091.00	
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	178,908.00	
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		2,694,011.00
Section H, Indirect Costs		1,235,216.00
Section I, Total Direct and Indirect Costs (G + H)		3,929,227.00
Section J, Fee		

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 0201417760000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: American Lung Association

*** Start Date:** 12-01-2011 *** End Date:** 11-30-2012 **Budget Period: 1**

A. Senior/Key Person

Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Donna		Bryson		PD/PI		4.92			19,883.00	0.00	19,883.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **19,883.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	
						Total Salary, Wages and Fringe Benefits (A+B)	**19,883.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Tracking Number: GRANT10782528

OMB Number: 4040-0001
Expiration Date: 04/30/2008

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 0201417760000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: American Lung Association

*** Start Date:** 12-01-2011 *** End Date:** 11-30-2012 **Budget Period: 1**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)
Total funds requested for all equipment listed in the attached file	
Total Equipment	

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	173.00
2. Foreign Travel Costs	
Total Travel Cost	**173.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	**Total Participant/Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 0201417760000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: American Lung Association

*** Start Date:** 12-01-2011 *** End Date:** 11-30-2012 **Budget Period: 1**

F. Other Direct Costs	**Funds Requested ($)**
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Other Direct Costs/Expenses	5,239.00
Total Other Direct Costs	**5,239.00**

G. Direct Costs	**Funds Requested ($)**
Total Direct Costs (A thru F)	**25,295.00**

H. Indirect Costs

Indirect Cost Type	**Indirect Cost Rate (%)**	**Indirect Cost Base ($)**	*** Funds Requested ($)**
1. TDC	10.00	25,295.00	2,529.00
		Total Indirect Costs	**2,529.00**

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	**Funds Requested ($)**
Total Direct and Indirect Institutional Costs (G + H)	**27,824.00**

J. Fee	**Funds Requested ($)**

K. * Budget Justification	File Name: 1234-Budget Justification - Subcontract with the American Lung Association of Southern Arizona.pdf (Only attach one file.) Mime Type: application/pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

*** ORGANIZATIONAL DUNS:** 0201417760000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: American Lung Association

*** Start Date:** 12-01-2012 *** End Date:** 11-30-2013 **Budget Period: 2**

A. Senior/Key Person

Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Donna		Bryson		PD/PI		10.44			59,730.00	0.00	59,730.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **59,730.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
9	Temporary Employees				5,120.00	0.00	5,120.00
9	**Total Number Other Personnel**				**Total Other Personnel**		**5,120.00**
					Total Salary, Wages and Fringe Benefits (A+B)		**64,850.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Tracking Number: GRANT10782528

OMB Number: 4040-0001
Expiration Date: 04/30/2008

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

*** ORGANIZATIONAL DUNS:** 0201417760000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: American Lung Association

*** Start Date:** 12-01-2012 *** End Date:** 11-30-2013 **Budget Period: 2**

C. Equipment Description		
List items and dollar amount for each item exceeding $5,000		
	Equipment Item	*** Funds Requested ($)**
Total funds requested for all equipment listed in the attached file		
	Total Equipment	
Additional Equipment:	File Name:	Mime Type:

D. Travel	**Funds Requested ($)**
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	173.00
2. Foreign Travel Costs	
Total Travel Cost	**173.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)**
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	**Total Participant/Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

*** ORGANIZATIONAL DUNS:** 0201417760000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: American Lung Association

*** Start Date:** 12-01-2012 *** End Date:** 11-30-2013 **Budget Period: 2**

F. Other Direct Costs	Funds Requested ($)
1. Materials and Supplies	7,154.00
2. Publication Costs	48.00
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Other Direct Costs/Expenses	11,948.00
Total Other Direct Costs	**19,150.00**

G. Direct Costs	Funds Requested ($)
Total Direct Costs (A thru F)	**84,173.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1. TDC	10.00	84,173.00	8,364.00
		Total Indirect Costs	**8,364.00**

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	**92,537.00**

J. Fee	Funds Requested ($)

K. * Budget Justification	File Name: 1234-Budget Justification - Subcontract with the American Lung Association of Southern Arizona.pdf (Only attach one file.) Mime Type: application/pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

*** ORGANIZATIONAL DUNS:** 0201417760000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: American Lung Association

*** Start Date:** 12-01-2013 *** End Date:** 11-30-2014 **Budget Period: 3**

A. Senior/Key Person

Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Donna		Bryson		PD/PI		10.44			61,522.00	0.00	61,522.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **61,522.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
9	Temporary Employees				5,120.00	0.00	5,120.00
9	**Total Number Other Personnel**					**Total Other Personnel**	**5,120.00**
					Total Salary, Wages and Fringe Benefits (A+B)		**66,642.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Tracking Number: GRANT10782528

OMB Number: 4040-0001
Expiration Date: 04/30/2008

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

*** ORGANIZATIONAL DUNS:** 0201417760000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: American Lung Association

*** Start Date:** 12-01-2013 *** End Date:** 11-30-2014 **Budget Period: 3**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)

Total funds requested for all equipment listed in the attached file

Total Equipment

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	173.00
2. Foreign Travel Costs	
Total Travel Cost	**173.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	

Number of Participants/Trainees **Total Participant/Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 3

*** ORGANIZATIONAL DUNS:** 0201417760000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: American Lung Association

*** Start Date:** 12-01-2013 *** End Date:** 11-30-2014 **Budget Period: 3**

F. Other Direct Costs	Funds Requested ($)
1. Materials and Supplies	7,154.00
2. Publication Costs	48.00
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Other Direct Costs/Expenses	11,948.00
Total Other Direct Costs	**19,150.00**

G. Direct Costs	Funds Requested ($)
Total Direct Costs (A thru F)	**85,965.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1. TDC	10.00	85,965.00	8,544.00
		Total Indirect Costs	**8,544.00**

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	**94,509.00**

J. Fee	Funds Requested ($)

K. * Budget Justification	File Name: 1234-Budget Justification - Subcontract with the American Lung Association of Southern Arizona.pdf (Only attach one file.) Mime Type: application/pdf

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

*** ORGANIZATIONAL DUNS:** 0201417760000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: American Lung Association

*** Start Date:** 12-01-2014 *** End Date:** 05-31-2015 **Budget Period: 4**

A. Senior/Key Person

Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Donna		Bryson		PD/PI		4.92			21,726.00	0.00	21,726.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **21,726.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	
						Total Salary, Wages and Fringe Benefits (A+B)	**21,726.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Tracking Number: GRANT10782528

OMB Number: 4040-0001
Expiration Date: 04/30/2008

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

*** ORGANIZATIONAL DUNS:** 0201417760000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: American Lung Association

*** Start Date:** 12-01-2014 *** End Date:** 05-31-2015 **Budget Period: 4**

C. Equipment Description		
List items and dollar amount for each item exceeding $5,000		
	Equipment Item	*** Funds Requested ($)**
Total funds requested for all equipment listed in the attached file		
	Total Equipment	
Additional Equipment:	File Name:	Mime Type:

D. Travel	**Funds Requested ($)**
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	173.00
2. Foreign Travel Costs	
Total Travel Cost	**173.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)**
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	**Total Participant/Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 4

*** ORGANIZATIONAL DUNS:** 0201417760000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: American Lung Association

*** Start Date:** 12-01-2014 *** End Date:** 05-31-2015 **Budget Period: 4**

F. Other Direct Costs	**Funds Requested ($)**
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Other direct costs/expenses	3,396.00
Total Other Direct Costs	**3,396.00**

G. Direct Costs	**Funds Requested ($)**
Total Direct Costs (A thru F)	**25,295.00**

H. Indirect Costs

Indirect Cost Type	**Indirect Cost Rate (%)**	**Indirect Cost Base ($)**	*** Funds Requested ($)**
1. TDC	10.00	25,295.00	2,529.00
		Total Indirect Costs	**2,529.00**

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	**Funds Requested ($)**
Total Direct and Indirect Institutional Costs (G + H)	**27,824.00**

J. Fee	**Funds Requested ($)**

K. * Budget Justification	File Name: 1234-Budget Justification - Subcontract with the American Lung Association of Southern Arizona.pdf Mime Type: application/pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		**162,861.00**
Section B, Other Personnel		**10,240.00**
Total Number Other Personnel	18	
Total Salary, Wages and Fringe Benefits (A+B)		**173,101.00**
Section C, Equipment		
Section D, Travel		**692.00**
1. Domestic	692.00	
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		**46,935.00**
1. Materials and Supplies	14,308.00	
2. Publication Costs	96.00	
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1	32,531.00	
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		**220,728.00**
Section H, Indirect Costs		**21,966.00**
Section I, Total Direct and Indirect Costs (G + H)		**242,694.00**
Section J, Fee		

Budget Justification - Subcontract with the American Lung Association of Southern Arizona

The American Lung Association of Southern Arizona will conduct the intervention activities. Ms. Donna Bryson is the Lung Health Educator for the ALA and is a registered nurse with extensive clinical and community experience in the area of asthma. She will coordinate all of the intervention activities. Ms. Bryson and the ALA have extensive experience in school based asthma screening, and providing Open Airways for Schools Education. She has also worked as a clinical nurse for one of the area's busiest pediatric pulmonary practices and has strong ties to primary care practices that care for patients with asthma. The ALA activities include conducting asthma screening (approximately 6400 children in 16 schools) in both the intervention and delayed intervention schools and implementing the intervention in the immediate intervention schools during Years 1 and 2 (8 schools) and both intervention and delayed intervention schools in Years 2 and 3 (16 schools). Intervention activities include: 1) measuring asthma control in each child, 2) facilitating physician follow-up, 3) ensuring asthma action plans and quick relief medication are on file for each child with asthma, 4) conducting Open Airways for Schools, and 5) facilitating the supervision of asthma controller medication at school. In addition, Ms. Bryson will attend all Investigator meetings. We request the following amounts in each year for these activities: Year 1 $27,824; Year 2 $92,537; Year 3 $94,509; Year 4 $27,824.

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 0989872170000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: University of Illinois

*** Start Date:** 12-01-2011 *** End Date:** 11-30-2012 **Budget Period: 1**

A. Senior/Key Person

Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Todd		Lee	PhD	PD/PI		1.20			12,121.00	0.00	12,121.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **12,121.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	
						Total Salary, Wages and Fringe Benefits (A+B)	**12,121.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 0989872170000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: University of Illinois

*** Start Date:** 12-01-2011 *** End Date:** 11-30-2012 **Budget Period: 1**

C. Equipment Description		
List items and dollar amount for each item exceeding $5,000		
	Equipment Item	*** Funds Requested ($)**
Total funds requested for all equipment listed in the attached file		
	Total Equipment	
Additional Equipment:	File Name:	Mime Type:

D. Travel	**Funds Requested ($)**
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	950.00
2. Foreign Travel Costs	
Total Travel Cost	**950.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)**
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	**Total Participant/Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 1

*** ORGANIZATIONAL DUNS:** 0989872170000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: University of Illinois

*** Start Date:** 12-01-2011 *** End Date:** 11-30-2012 **Budget Period: 1**

F. Other Direct Costs	Funds Requested ($)
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)
Total Direct Costs (A thru F)	**13,071.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1. TDC	57.00	13,071.00	7,450.00
		Total Indirect Costs	**7,450.00**

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	**20,521.00**

J. Fee	Funds Requested ($)

K. * Budget Justification	File Name: 1235-Budget Justification - Subcontract with Todd Lee.pdf Mime Type: application/pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 2

*** ORGANIZATIONAL DUNS:** 0989872170000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: University of Illinois

*** Start Date:** 12-01-2012 *** End Date:** 11-30-2013 **Budget Period: 2**

A. Senior/Key Person

Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Todd		Lee	PhD	PD/PI		1.20			12,651.00	0.00	12,651.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **12,651.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	
						Total Salary, Wages and Fringe Benefits (A+B)	**12,651.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Tracking Number: GRANT10782528

OMB Number: 4040-0001
Expiration Date: 04/30/2008

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 2

*** ORGANIZATIONAL DUNS:** 0989872170000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: University of Illinois

*** Start Date:** 12-01-2012 *** End Date:** 11-30-2013 **Budget Period: 2**

C. Equipment Description		
List items and dollar amount for each item exceeding $5,000		
	Equipment Item	*** Funds Requested ($)**
Total funds requested for all equipment listed in the attached file		
	Total Equipment	
Additional Equipment:	File Name:	Mime Type:

D. Travel	**Funds Requested ($)**
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	950.00
2. Foreign Travel Costs	
Total Travel Cost	**950.00**

E. Participant/Trainee Support Costs	**Funds Requested ($)**
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	
Number of Participants/Trainees	**Total Participant/Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 2

*** ORGANIZATIONAL DUNS:** 0989872170000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: University of Illinois

*** Start Date:** 12-01-2012 *** End Date:** 11-30-2013 **Budget Period: 2**

F. Other Direct Costs	Funds Requested ($)
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)
Total Direct Costs (A thru F)	**13,601.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1. TDC	57.00	13,601.00	7,754.00
		Total Indirect Costs	**7,754.00**

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	**21,355.00**

J. Fee	Funds Requested ($)

K. * Budget Justification	File Name: 1235-Budget Justification - Subcontract with Todd Lee.pdf Mime Type: application/pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 3

*** ORGANIZATIONAL DUNS:** 0989872170000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: University of Illinois

*** Start Date:** 12-01-2013 *** End Date:** 11-30-2014 **Budget Period: 3**

A. Senior/Key Person

Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Todd		Lee	PhD	PD/PI		1.20			13,033.00	0.00	13,033.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **13,033.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	
						Total Salary, Wages and Fringe Benefits (A+B)	**13,033.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 3

*** ORGANIZATIONAL DUNS:** 0989872170000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: University of Illinois

*** Start Date:** 12-01-2013 *** End Date:** 11-30-2014 **Budget Period: 3**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)

Total funds requested for all equipment listed in the attached file

Total Equipment

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	950.00
2. Foreign Travel Costs	
Total Travel Cost	**950.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	

Number of Participants/Trainees **Total Participant/Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 3

*** ORGANIZATIONAL DUNS:** 0989872170000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: University of Illinois

*** Start Date:** 12-01-2013 *** End Date:** 11-30-2014 **Budget Period: 3**

F. Other Direct Costs	Funds Requested ($)
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)
Total Direct Costs (A thru F)	**13,983.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1. TDC	57.00	13,983.00	7,970.00
		Total Indirect Costs	**7,970.00**

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	**21,953.00**

J. Fee	Funds Requested ($)

K. * Budget Justification	File Name: 1235-Budget Justification - Subcontract with Todd Lee.pdf Mime Type: application/pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION A & B, BUDGET PERIOD 4

*** ORGANIZATIONAL DUNS:** 0989872170000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: University of Illinois

*** Start Date:** 12-01-2014 *** End Date:** 05-31-2015 **Budget Period: 4**

A. Senior/Key Person

Prefix	* First Name	Middle Name	* Last Name	Suffix	* Project Role	Base Salary ($)	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
1.	Todd		Lee	PhD	PD/PI		1.20			13,425.00	0.00	13,425.00

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name: Mime Type: **Total Senior/Key Person** **13,425.00**

B. Other Personnel

* Number of Personnel	* Project Role	Cal. Months	Acad. Months	Sum. Months	* Requested Salary ($)	* Fringe Benefits	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
0	**Total Number Other Personnel**					**Total Other Personnel**	
						Total Salary, Wages and Fringe Benefits (A+B)	**13,425.00**

RESEARCH & RELATED Budget {A-B} (Funds Requested)

Tracking Number: GRANT10782528

OMB Number: 4040-0001
Expiration Date: 04/30/2008

RESEARCH & RELATED BUDGET - SECTION C, D, & E, BUDGET PERIOD 4

*** ORGANIZATIONAL DUNS:** 0989872170000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: University of Illinois

*** Start Date:** 12-01-2014 *** End Date:** 05-31-2015 **Budget Period: 4**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	* Funds Requested ($)

Total funds requested for all equipment listed in the attached file

Total Equipment

Additional Equipment: File Name: Mime Type:

D. Travel	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	950.00
2. Foreign Travel Costs	
Total Travel Cost	**950.00**

E. Participant/Trainee Support Costs	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other:	

Number of Participants/Trainees **Total Participant/Trainee Support Costs**

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, BUDGET PERIOD 4

*** ORGANIZATIONAL DUNS:** 0989872170000

*** Budget Type:** ❍ Project ● Subaward/Consortium

Enter name of Organization: University of Illinois

*** Start Date:** 12-01-2014 *** End Date:** 05-31-2015 **Budget Period: 4**

F. Other Direct Costs	Funds Requested ($)
Total Other Direct Costs	

G. Direct Costs	Funds Requested ($)
Total Direct Costs (A thru F)	**14,375.00**

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
1. TDC	57.00	14,375.00	8,193.00
		Total Indirect Costs	**8,193.00**

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	**22,568.00**

J. Fee	Funds Requested ($)

K. * Budget Justification	File Name: 1235-Budget Justification - Subcontract with Todd Lee.pdf Mime Type: application/pdf (Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)	
Section A, Senior/Key Person		**51,230.00**
Section B, Other Personnel		
Total Number Other Personnel		
Total Salary, Wages and Fringe Benefits (A+B)		**51,230.00**
Section C, Equipment		
Section D, Travel		**3,800.00**
1. Domestic	3,800.00	
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		
1. Materials and Supplies		
2. Publication Costs		
3. Consultant Services		
4. ADP/Computer Services		
5. Subawards/Consortium/Contractual Costs		
6. Equipment or Facility Rental/User Fees		
7. Alterations and Renovations		
8. Other 1		
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		**55,030.00**
Section H, Indirect Costs		**31,367.00**
Section I, Total Direct and Indirect Costs (G + H)		**86,397.00**
Section J, Fee		

Budget Justification - Subcontract with Todd Lee

Todd Lee, PharmD, PhD. Dr. Lee is an Associate Professor in the Departments of Pharmacy Practice, Pharmacy Administration and the Section of Pulmonary, Critical Care, Sleep and Allergy in the Department of Medicine at the University of Illinois at Chicago. In addition, Dr. Lee is a senior investigator at the Center for the Management of Complex Chronic Care (CMC3) at the Hines VA Hospital. Dr. Lee has expertise in economic evaluations of medical interventions to better understand the value of these new interventions. He has extensive experience with economic evaluations conducted alongside clinical trials as well as developing economic models, including decision-tree and Markov health state models. Dr. Lee also has experience in evaluating patient preferences utilizing several different elicitation techniques and was part of the team that developed the Pediatric Asthma Health Outcome Measure which will be used as the primary outcome measure for this cost-effectiveness analysis. Dr. Lee will supervise the cost-effectiveness analysis and work with the PI and Investigators on the data collection protocols for the cost data. He will also travel to the University of Arizona once each year to meet with the research team. These tasks will require 1.2 months effort each year.

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

1. Project Director / Principal Investigator (PD/PI)

Prefix:
* First Name: Lynn
Middle Name: B
* Last Name: Gerald
Suffix: Ph.D.

2. Human Subjects

Clinical Trial? ☐ No ☒ Yes

* Agency-Defined Phase III Clinical Trial? ☐ No ☒ Yes

3. Applicant Organization Contact

Person to be contacted on matters involving this application

Prefix: Ms.
* First Name: Sherry
Middle Name: L
* Last Name: Esham
Suffix:

* Phone Number: 520-626-6000
Fax Number: 520-626-4137
Email: sponsor@email.arizona.edu

* Title: Director, Sponsored Projects Services

* Street1: P.O. Box 3308
Street2:
* City: Tucson
County/Parish: Pima
* State: AZ: Arizona
Province:
* Country: USA: UNITED STATES
* Zip / Postal Code: 85722-3308

PHS 398 Cover Page Supplement

4. Human Embryonic Stem Cells

* Does the proposed project involve human embryonic stem cells? ☒ No ☐ Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://stemcells.nih.gov/research/registry/. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Cell Line(s): ☐ Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Tracking Number:GRANT10782528 Funding Opportunity Number:PAR-10-114 Received Date:2011-01-25T18:37:50-04:00

OMB Number: 0925-0001

PHS 398 Research Plan

1. Application Type:

From SF 424 (R&R) Cover Page. The response provided on that page, regarding the type of application being submitted, is repeated for your reference, as you attach the appropriate sections of the Research Plan.

*Type of Application:

☒ New ☐ Resubmission ☐ Renewal ☐ Continuation ☐ Revision

2. Research Plan Attachments:

Please attach applicable sections of the research plan, below.

1. Introduction to Application (for RESUBMISSION or REVISION only)		Add Attachment	Delete Attachment	View Attachment
2. Specific Aims	1249-SPECIFIC AIMS.pdf	Add Attachment	Delete Attachment	View Attachment
3. *Research Strategy	1250-Research Strategy.pdf	Add Attachment	Delete Attachment	View Attachment
4. Inclusion Enrollment Report		Add Attachment	Delete Attachment	View Attachment
5. Progress Report Publication List		Add Attachment	Delete Attachment	View Attachment

Human Subjects Sections

6. Protection of Human Subjects	1251-Protection of Human Sub	Add Attachment	Delete Attachment	View Attachment
7. Inclusion of Women and Minorities	1252-Inclusion of Women and	Add Attachment	Delete Attachment	View Attachment
8. Targeted/Planned Enrollment Table	1253-Targeted and Planned En	Add Attachment	Delete Attachment	View Attachment
9. Inclusion of Children	1254-Inclusion of Children.p	Add Attachment	Delete Attachment	View Attachment

Other Research Plan Sections

10. Vertebrate Animals		Add Attachment	Delete Attachment	View Attachment
11. Select Agent Research		Add Attachment	Delete Attachment	View Attachment
12. Multiple PD/PI Leadership Plan		Add Attachment	Delete Attachment	View Attachment
13. Consortium/Contractual Arrangements		Add Attachment	Delete Attachment	View Attachment
14. Letters of Support	1255-Letters of Support.pdf	Add Attachment	Delete Attachment	View Attachment
15. Resource Sharing Plan(s)	1256-Resource sharing plan.p	Add Attachment	Delete Attachment	View Attachment

16. Appendix Add Attachments | Remove Attachments | View Attachments

SPECIFIC AIMS

Asthma is a common chronic condition among children that is associated with significant morbidity.[1] Because medication non-adherence is an important cause of excess morbidity, the National Asthma Education and Prevention Program (NAEPP) guidelines and the American Academy of Asthma, Allergy, and Immunology (AAAAI) have called for the development of more effective adherence programs.[2,3] Schools represent a logical setting where adherence programs could reach the inner-city, low-income, and ethnically diverse populations that have the highest morbidity and lowest adherence. However, school-based programs must overcome barriers outside of the school setting to be effective. For example, school-based asthma screening (i.e. case identification) and education programs are necessary but not sufficient to improve asthma outcomes.[4, 5] Mechanisms must also exist to ensure that the students who are identified by screening are also evaluated by an experienced asthma clinician, are provided with inhaled corticosteroids (ICSs) when needed, and are monitored to ensure adherence.

We recently demonstrated that a school-based program that included the daily supervision of controller medication use was an efficacious approach to increase medication adherence and asthma control (R01 HL075043).[6] Borrowing a paradigm from tuberculosis control, the program implemented directly observed therapy (daily ICS use) in a low-income, urban elementary school system with a large African-American population. In a separate study, we established the theoretical framework to demonstrate that the program could be cost-effective as well as efficacious.[7] Our published results were accompanied by a call to prospectively validate our model under real-world conditions.[8] Therefore, we propose to:

Aim 1. **Conduct a randomized controlled trial to evaluate the effectiveness under real world conditions of a previously demonstrated efficacious school-based asthma program that includes the direct supervision of daily controller therapy.** Students within intervention schools are hypothesized to achieve better asthma control, as measured by the Juniper Asthma Control (ACQ) questionnaire,[9] than students within usual care schools. Secondary outcomes will include asthma symptom free days (ASFDs), parent and child quality of life (QoL), health care utilization, and school health events including absences.

The program is built upon previous school-based research,[10-13] recommendations from the Centers for Disease Control and Prevention (CDC)[14] and the NAEPP guidelines,[2] as well as our team's extensive school-based research experience.[6, 15-17] To evaluate the program's effectiveness under real-world conditions and to establish the feasibility of broader dissemination within other communities, the program will be administered by the American Lung Association of Southern Arizona (ALA) in collaboration with the Tucson Unified School District (TUSD). Key program components will include:

- Identifying children with previously diagnosed, but not well-controlled asthma
- Ensuring guideline-concordant care in coordination with the child's asthma care provider
- Providing comprehensive asthma education
- Monitoring asthma control over time
- Providing ready access to quick relief medication at school
- Providing direct supervision of daily controller therapy

Aim 2. **Conduct a cost-effectiveness analysis (CEA) from the societal perspective using dollars per quality-adjusted life year (QALY) gained.** Compared to usual care, the intervention is hypothesized to be cost-effective. Secondary outcomes will include dollars per ASFD gained. The CEA will be conducted using the gold standard reference case analysis in concordance with the well-established recommendations made by the Panel on Cost-Effectiveness in Health and Medicine.[18] This aim will provide critical information regarding the program's cost-effectiveness, feasibility, and sustainability. With this information, decision makers can optimize the use of scarce public health resources by adopting programs that efficiently maximize child health.

Aim 3. **Conduct a process evaluation including the assessment of the program's implementation fidelity and participants' experiences with the program.** Multilevel determinants will be identified and examined for their impact on implementation fidelity and overall program effectiveness and cost-effectiveness. Focus groups and key informant interviews will provide data on participants' experiences with the program. Data from the process evaluation will assist researchers, providers, and community partners in accelerating the successful adoption of a guideline-based, community implemented intervention that minimizes the impact of asthma among children in a primarily urban, low-income, and ethnically diverse population.

RESEARCH STRATEGY

SIGNIFICANCE

Epidemiology and economic burden: Approximately 9 million children in the US have asthma and nearly 4 million of them experience an exacerbation annually that leads to 725,000 emergency department (ED) visits and 200,000 hospitalizations.[1] Although rare, approximately 200 children die each year from asthma. The direct medical costs for children with asthma are approximately double those for children without asthma.[19] Among school-age children, the total cost of asthma is estimated to be 2 billion dollars annually.[20]

Adverse asthma outcomes are disproportionately concentrated among minority, low-income and urban populations.[1] In the Southwest, there is a unique population of primarily urban, low income Hispanic children with asthma. These children are at higher risk of poor asthma outcomes because they are more likely to be uninsured,[21] less likely to have a medical home,[22] and more likely to reside in poverty.[23] National data suggest that Hispanic children, as compared to non-Hispanic white children, are 20% less likely use primary care and 65% more likely to use the ED for their health care needs.[1,24] In the military health system, Hispanic elementary-age children are 40% more likely to have an asthma diagnosis, 40% more likely to experience a preventable asthma hospitalization, 25% more likely to experience an ED visit, and 25% less likely to have seen an asthma specialist in the past year than white children.[25] Hispanic children served by Medicaid are 40% less likely to report ICS use than white children.[26]

School-based asthma screening: Multiple school-based asthma screening methods exist. Questionnaire-based strategies are easily administered but have high false positive rates that lead to unnecessary and costly referrals.[16,27-31] Lung function testing can improve accuracy and reduce unnecessary referrals but it is resource intensive.[16,32-35] To evaluate the trade-offs between these approaches, we recently evaluated four mutually exclusive screening programs (2 questionnaire-based and 2 multi-method that included spirometry ± exercise testing) using a simulation model.[7] We found that under a wide range of assumptions, a questionnaire-based approach that identified children with previously diagnosed, but not well-controlled asthma was the most cost-effective approach.

De-emphasizing the importance of population-based screening to identify children with undiagnosed asthma is supported by a growing body of evidence. Children with undiagnosed asthma experience less frequent symptoms than children with previously diagnosed asthma; the symptoms they do experience rarely result in ED visits or hospitalizations.[36-38] In fact, we found that the rates of respiratory-related ED visits and hospitalizations among children with undiagnosed asthma were indistinguishable from those of children without asthma.[36] We concluded that screening for undiagnosed asthma might reduce symptoms in a few children, but it was unlikely to be a cost-effective strategy to improve population-level asthma control.[7]

School-based asthma management: A well-developed body of knowledge supports the efficacy of school-based interventions to improve asthma knowledge.[39] Schools are an ideal setting for asthma programs because children are geographically concentrated and because schools are strong advocates for children's health. The CDC recommends six key strategies for developing effective school-based asthma programs: support schools as they provide asthma services, increase access to health care services within schools, provide asthma education for students and staff, improve the school environment, encourage participation in school activities, and coordinate school, family and community efforts.[14]

Demonstrating the efficacy of school-based programs to improve asthma control has been more difficult. For these programs to work, they must address each step in the process between screening and improved asthma outcomes and overcome barriers outside of the school setting (Figure 1). Screening and education alone are not sufficient to improve asthma outcomes.[4,5] Mechanisms must also exist to ensure that students identified by screening are evaluated by experienced asthma clinicians, are provided inhaled corticosteroids (ICSs) when needed, and are monitored to confirm medication adherence. Failure to address any one of these steps diminishes the

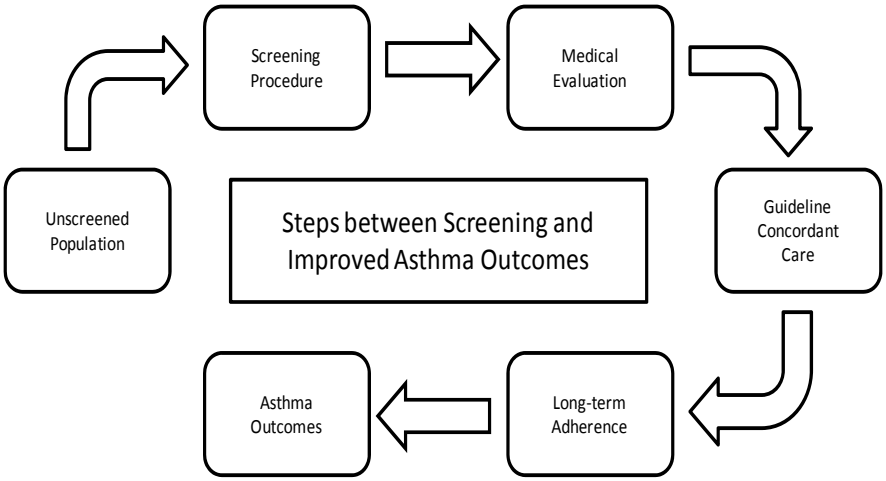

Figure 1. Steps between Screening and Improved Asthma Outcomes

program's ability to improve asthma outcomes.

Medication adherence: Despite the development of clinical guidelines, approximately 40% of children with asthma are not well-controlled at any given time.[40-42] Much of this is attributable to behavioral and health system factors that result in the underuse of controller medications. Because the daily use of controller medication offers considerable protection against exacerbations, the NAEPP guidelines and the AAAI have recommended the development of more effective adherence programs.[2, 3]

We recently developed and evaluated a school-based asthma program (supervised therapy) that implemented the daily supervision of ICS use at school among elementary-age students with persistent asthma. (R01 HL075043)[6] Supervised therapy incorporated the lessons learned from many years of school-based asthma research. It was designed as a comprehensive approach to address each of the steps in the process (Figure 1) and the many barriers that had been previously identified. To implement supervised therapy we identified children with persistent asthma, evaluated their asthma control status, optimized their medication regimen in collaboration with their primary asthma provider, and monitored its daily administration. Using a randomized controlled trial, we demonstrated that the program improved medication adherence and asthma control in an urban, low-income, primarily African-American population.

Demonstrating supervised therapy's efficacy is not likely to be sufficient to drive its widespread adoption. Given the scarcity of public health resources, it will also be important to demonstrate to key stakeholders that supervised therapy is effective and cost-effective when implemented under real-world conditions. To establish the theoretical framework to obtain this evidence, we developed a model to simulate the costs and outcomes of various school-based asthma screening and management programs.[7] Our results indicated that a cost-effective school-based asthma program would have to not only identify children with poorly controlled asthma, but also have to ensure that students would be evaluated clinically, provided controller therapy when needed, and monitored for adherence. Supervised therapy is a program that meets these general requirements.

Cost-effectiveness as an outcome: If children adhere with behavioral and pharmacologic treatment recommendations, good asthma control can be expected.[2] Despite this knowledge, many physicians, parents and children do not regularly follow these recommendations and as a result, many children experience poor asthma control.[43,44] This suggests that the key to better population-level asthma control is not developing new treatments but rather more consistently using the ones we have. New medications and technologies are often adopted once proven efficacious. However, third-party payers and public agencies are reluctant to adopt community-based, behavioral interventions without additional evidence demonstrating their "value."

Cost-effectiveness analysis (CEA) is a well-established tool to evaluate the value of health interventions.[45] It provides decision makers with the information to decide when the benefits of new interventions are likely to be worth their costs. Because CEA measures costs and health outcomes independently, it requires the same rigor as traditional effectiveness trials. In CEA, careful cost-accounting simply augments the evaluation of effectiveness and allows additional conclusions to be drawn regarding an intervention's value.

CEA is preferred to other types of economic analyses (e.g. cost-minimization and cost-benefit analysis) because it measures health outcomes in natural units of health (e.g. life years or symptom free days) instead of dollars. Cost-utility analysis is special case of CEA where the health outcome captures both the quality and quantity of life in a single measure (e.g. quality adjusted life years, QALYs). Compared to disease specific outcomes (e.g. asthma control), QALYs allow comparisons across a wider range of conditions. This ability is important to decision makers as they attempt to balance many competing needs simultaneously.

Improving knowledge and clinical practice: By including a cost-effectiveness analysis, our proposal will provide a greater understanding of the interplay between the efficacy, effectiveness and efficiency of supervised therapy. It will identify and quantify the important patient, physician, health system, and community barriers that contribute to the inefficient delivery of care to children with asthma. By addressing potential health system barriers that prevent the wider adoption of guideline concordant care among children with asthma, supervised therapy will help to accelerate the implementation of national asthma guidelines.[46]

INNOVATION

Using community-partners to implement school-based supervised therapy under real world conditions is a novel approach to improve asthma outcomes among children. Supervised therapy is a comprehensive approach that addresses each of the barriers that exist between the identification of children with poorly controlled asthma and improved asthma control. We extend the traditional school-based approach that emphasizes screening and education alone by also addressing co-existing health system barriers.

Prospectively incorporating CEA as an important outcome measure will also provide decision makers with the information needed to better understand the program's value and sustainability. Previously, CEA studies in

childhood asthma have been limited by the inability to use QALYs as an outcome;[47] however, our approach will use the newly developed Pediatric Asthma Health Outcome Measure (PAHOM) to directly measure QALYs as the primary CEA outcome.[48] The PAHOM is a multi-attribute measure that provides standard gamble derived utility (e.g. preference) weights for a set of 10 unique asthma health states. The ability to provide information regarding supervised therapy's value using a generalizable metric such as QALYs is an important methodologic step forward in the economic evaluation of interventions targeting children with asthma. By moving beyond the traditional evaluation of efficacy/effectiveness alone, this study will provide the critical piece of missing information needed to promote the program's widespread adoption.

APPROACH

A. Summary: We propose to conduct a prospective, randomized controlled trial to evaluate the effectiveness and cost-effectiveness of a comprehensive school-based asthma program that includes the direct supervision of daily controller medication. Sixteen elementary schools (grades K-5) from a single school system will be randomized to immediate or delayed intervention. Students in the immediate intervention group will be exposed to the intervention for two consecutive years; students in the delayed intervention group will be identified during the first year and exposed to the intervention during the second (Figure 2).

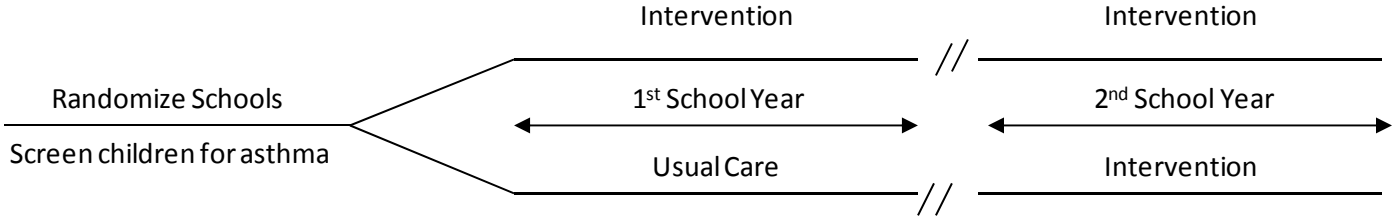

Figure 2. Study Design

A delayed intervention design was chosen to maximize school participation and ensure that all students with asthma could benefit from participation. Schools are often reluctant to participate in randomized trials when they may be assigned to a no treatment control group. Since the intervention has been previously shown to be efficacious, schools would be justified in questioning the appropriateness of such a design. To overcome these concerns, others have recommended and we have previously used cross-over designs;[6,17,49] however, this study is not well-suited to a cross-over design. Its comprehensive nature and high degree of coordination with the student's primary asthma provider may create significant carry-over effects in the immediate intervention group. In fact, we expect these carry-over effects to yield considerable gains in program efficiency during the second intervention year. Given the emphasis on cost-effectiveness, it is important to quantify any gains and evaluate their impact on the program's cost-effectiveness. Therefore, a delayed intervention design with two consecutive intervention years in one group is critical to ensure that the trial successfully obtains all of the data necessary to draw accurate and reliable conclusions.[50]

B. Preliminary Studies: This project is built upon the lessons our team has learned over the past 15 years of conducting school-based asthma research in urban, low-income, minority (primarily African-American) elementary schools. Our first study, the NHLBI-funded Improving Asthma Management and Prevention in Birmingham Public Schools study began in 1994.[15] For this study, we developed a school-based asthma screening protocol and screened 12,247 students in 54 elementary schools.[32] We also provided asthma education for faculty and staff (Managing Asthma: A Guide for Schools[51]), the general student body (Asthma Awareness: A Curriculum for the Elementary School Classroom[52]), and students with asthma (Open Airways for Schools[53]). The 736 students identified as having asthma were evaluated by an asthma specialist who created an individual asthma action plan that was shared with the school nurse and the student's asthma care provider.

The intervention improved asthma knowledge but not asthma outcomes (e.g. absences, grades, and health care utilization). We concluded that screening and education, while important components of school-based programs, were not sufficient to improve long-term asthma control.[15] We concluded that the individual asthma action plans were not effective because of the much larger problems we identified but were unable to address during the study. For example, few students actually had a primary asthma provider which meant that many went without daily controller medication as well as quick relief medication, particularly at school.

We were subsequently funded by NHLBI to validate the previously developed screening procedure. We screened 3,539 students in 10 elementary schools using four incrementally intensive screening strategies and **validated the results against the gold standard of physician-rated control** (Figure 3).[16] The most sensitive, but least specific strategy was a simple 5-item questionnaire (3 symptom-based questions and 2 prior diagnosis questions). Adding spirometry and exercise testing to the 5-item questionnaire increased its specificity but decreased its sensitivity. Students we identified as having undiagnosed asthma had relatively mild sequelae compared to those with previously diagnosed asthma (Figure 4).[36] This led us to question the use of a population-based approach to identify undiagnosed asthma.

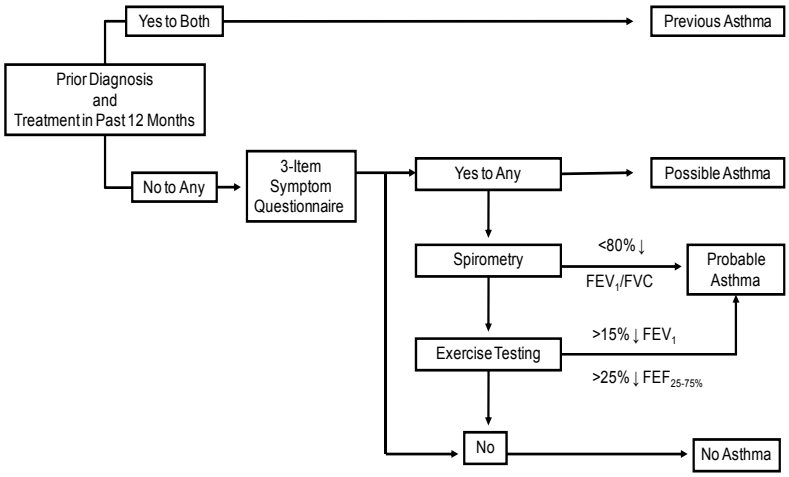

Figure 3. Asthma Screening Strategies

This concern was echoed in an ATS Workshop on Asthma Screening chaired by the PI of this proposal (LBG).[11] One of the recommendations called for a CEA of school-based asthma screening to determine if population-based asthma screening was cost-effective. To answer the question, we conducted a CEA of the four screening strategies above (Figure 3) using a novel Markov simulation that used dollars per QALY gained as the primary outcome.[7] The most cost-effective approach was to use a 2-item questionnaire to identify students with previously diagnosed, but not well-controlled, asthma. At $150,000 per QALY gained, this approach was the most cost-effective, but it was higher than the traditional $50,000 per QALY threshold. Sensitivity analyses demonstrated scenarios where school-based screening could be more cost-effective. Most importantly, we demonstrated that modest increases in just two parameters, the number of students clinically evaluated after screening (from 30% to 45%) and the number of students maintaining medication adherence (from 60% to 80%), would yield a CEA estimate <$100,000 per QALY. We believe supervised therapy could achieve even greater improvements in clinical evaluation and adherence than we estimated in our model. Because supervised therapy would likely improve other factors as well, it is reasonable to hypothesize that supervised therapy could even be cost-effective at $50,000 per QALY.

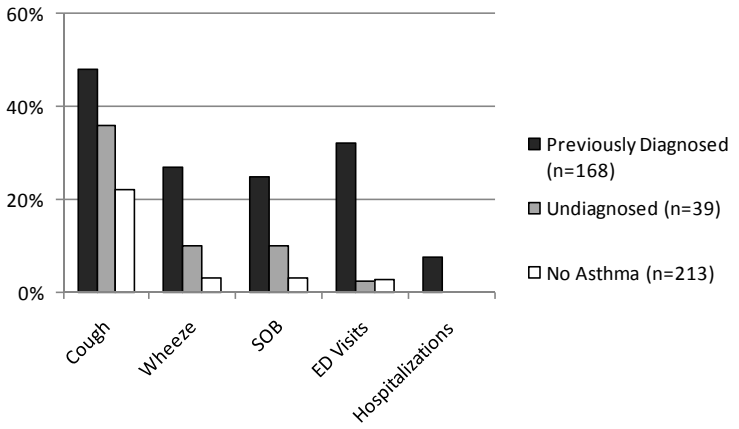

Figure 4. Asthma Outcomes among Children Screened (All comparisons significant at p<.0001)

Our CEA (unfunded) was conducted during the same time period as our NHLBI-funded efficacy trial of supervised therapy (R01 HL075043).[6] This trial was conducted in 36 elementary schools with 290 children with asthma. Students with persistent asthma were identified, provided asthma education and access to quick-relief medication at school, evaluated by an asthma specialist, provided a once daily controller medication regimen (Budesonide 200-800 mcg/day) coordinated with their primary asthma provider, and supervised as they took medication at school. Monthly exacerbations in the supervised therapy group decreased significantly (p=.006) while those in the usual care group did not (p=.04) (Figure 5). This effect was observed despite using a relatively insensitive composite measure of asthma control (respiratory absences, red/yellow peak flow meter readings, and increased use of quick-relief medication) and having substantial interaction with the usual care group throughout the study (internet delivered asthma education and daily monitoring of symptoms and peak flow). This experience led us to propose a more sensitive outcome measure and a less obtrusive involvement with the usual care group in this study. During the supervised therapy study, we found schools to be committed, community physicians to be adaptable, parents to be supportive, and students to be cooperative with a once daily, school-supervised medication program.

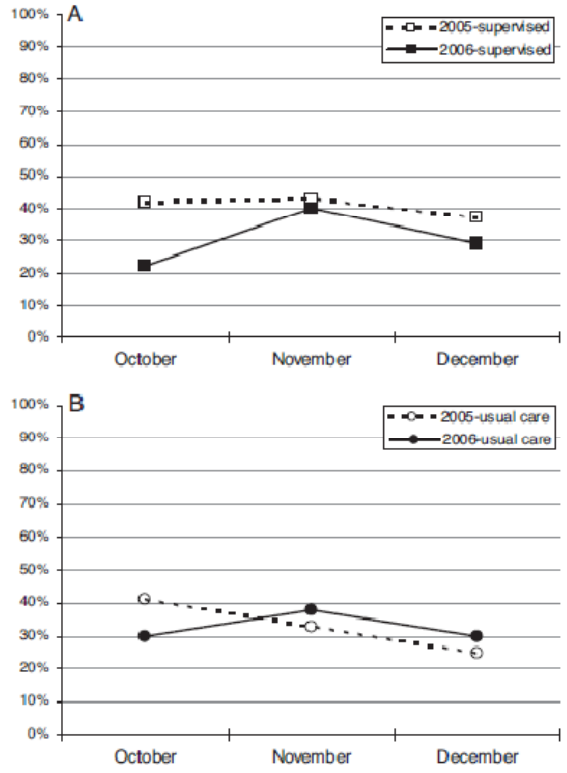

Figure 5. Exacerbations according to month for supervised therapy (A) and usual care (B). Supervised therapy, 2005 vs 2006, p=.0064; usual care, 2005 vs 2006, p=.94

Lastly it is important to document our experience using the PAHOM, a multi-attribute instrument designed to capture QALYs for CEA among children with asthma. In our ongoing study of health literacy and asthma outcomes among 250 caregivers of children with asthma (HRSA MCH 5 R40MC08728), we compared the measurement properties of the PAHOM to the Juniper Asthma Control Questionnaire (ACQ) as well as the gold standard of physician-rated asthma control.[54, 55] When administered to parents, the ACQ and the PAHOM had similar ability to identify students with poor asthma control (p=.08) (Figure 6). Student PAHOM responses did not perform as well as parental responses when compared to physician-rated control (p=.008). On average, parents reported worse outcomes, particularly symptoms, than their children (p<.0001).[56] In a study of hand sanitizer use and asthma outcomes in 30 elementary schools with 15,000 students (527 with asthma) (NIH 1 R01 HL086972), we compared student responses on the PAHOM with their daily diary reporting. We found that students reported more symptom days using daily diary reporting versus PAHOM recall (p=.04).[57] For these reasons, we will administer the PAHOM and the ACQ to both parents and children. Doing so will provide a comprehensive and valid measurement of asthma control/QALYs in the students.

In summary, our extensive school-based asthma research experience positions us to successfully conduct the proposed clinical trial of supervised asthma therapy.

C. Recruitment:

School system/schools: The Tucson Unified School District (TUSD) is a committed partner and has been actively involved in study planning (see Letter of Support). TUSD has 72 elementary schools with a total enrollment of 26,750 students.[58] Enrollment is 59% Hispanic, 26% white and 7% African-American; approximately 60% of students qualify for free lunches. Schools with high asthma prevalence and low socioeconomic status will be targeted for recruitment as these factors identify settings where supervised therapy is most likely to be cost-effective.[7] Participating schools will be matched on key factors (e.g., asthma prevalence and racial/ethnic mix) and then randomized in pairs. In our previous supervised therapy study, only 1 of 37 schools approached declined to participate. We expect TUSD schools to be similarly committed to participation.

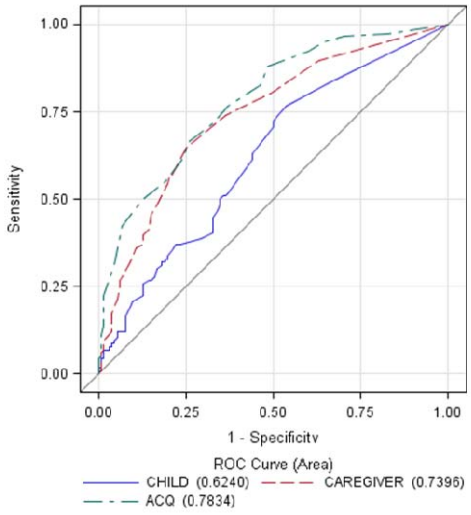

Figure 6. ACQ and PAHOM ROC Curves as compared to physician-rated asthma control

Students: Students with asthma will be identified using a 2-item questionnaire that will be provided in English and Spanish on pre-registration health cards that are required for TUSD school enrollment. The two questions are: (1) Has a doctor ever said your child has asthma? and (2) Has your child taken asthma medicine (e.g. pills, inhaler, puffer) prescribed by a doctor in the past 12 months? Responding "yes" to both questions will make students eligible for enrollment.

We have previously validated these questions[16] and shown them to represent the most cost-effective approach to identifying students who can benefit from further evaluation and treatment.[7] These questions identify the students who experience the greatest burden of symptoms and health care use due to their asthma and therefore stand to gain the most from the intervention (see Section B. Preliminary Studies, Figure 4, previously diagnosed category). Because health cards may be incomplete or inaccurate, school nurses will follow-up on incomplete cards; they may also refer students to the program during the school year.

We considered restricting enrollment to students with study-confirmed persistent asthma, but three considerations led us to include all students identified by the 2-item questionnaire. First, even students with intermittent/mild asthma should be known to the school, be provided asthma education, and have access to quick relief medication at school. Second, our previous experience suggests that schools do not want to turn away students who request help but do not meet study criteria. Third, we wanted to minimize involvement with the delayed intervention group; requiring this group to be physician-evaluated would be a significant intervention that might bias their treatment and outcomes during their usual care year. Students enrolled but not offered medication supervision are unlikely to consume significant study resources or to experience significant morbidity. Including them may bias the effectiveness estimate towards the null, but should have minimal impact on costs. We will conduct subgroup analysis to determine the impact of this decision.

Parents will be contacted by school nurses to determine their interest in the program and obtain permission for research personnel to contact them. Written informed consent (parents) and assent (students) will be obtained by research personnel. Program availability will also be announced on the school's web-page and in take-home materials and school nurses will be able to refer students to the program throughout the year based on school absences and health room visits.[12] Despite these efforts, some children with asthma will be missed; however, a trade-off exists between higher sensitivity and the added resources needed to achieve it. Adding symptom-based questions would increase sensitivity, but the additional costs to confirm the asthma diagnosis among the false positive cases would exceed the expected benefits.[7,16,36] To maximize data collection, schools and parents will be provided small incentives (health room supplies and gift cards, respectively).

D. Intervention: The intervention will be conducted by the American Lung Association (ALA) of Southern Arizona in partnership with the TUSD (see Letters of Support). The ALA's commitment to school-based asthma interventions, such as the Open Airways for Schools program (OAS), makes it well-suited to deliver the proposed program. If supervised therapy is shown to be cost-effective, the ALA would be a strong partner to support its national adoption. The six major intervention components are described below.

(1) **Identify children with previously diagnosed, but not well-controlled asthma.** Under the direction of the ALA, certified school nurse substitutes will contact parents who responded "yes" to both asthma questions on the school's health cards. This collaboration between TUSD and the ALA will allow parents to be contacted in accordance with the Family Educational Rights and Privacy Act (FERPA) while removing the burden from full-time school nurses. Parents expressing interest will be contacted by study personnel who will provide study information, offer enrollment, and make arrangements to obtain written consent.

(2) **Ensure guideline-concordant care in coordination with the child's asthma care provider.** Students in intervention schools will be evaluated by a study-provided asthma specialist during early morning or late afternoon school-based asthma clinics. This strategy has been acceptable to schools, feasible for practitioners, and well-attended by parents.[15,16,32,49] At the visit, asthma control will be assessed both by the physician and using the ACQ. A personalized asthma action plan will be created and as well as an appropriate once-daily controller medication regimen. If the once-daily regimen requires a change to the student's existing regimen, the change will be coordinated with the child's primary asthma care provider by Dr. Grad (pediatric pulmonologist, study investigator) and Dr. Clemens (pediatrician, Medical Director for TUSD, study investigator). The community physician will remain the student's usual source of asthma care.

(3) **Provide comprehensive asthma education.** During the intervention years, the ALA will provide the OAS asthma education program to all students enrolled in the study.[53] OAS is based on prior NHLBI research and has become one of the nation's most successful school-based asthma education programs.[59,60,53] It teaches students how to detect asthma warning signs, avoid triggers and make better health decisions using a fun and interactive approach to asthma self-management. It has been approved and recommended by the National Association of School Nurses, honored with a Health Education Research Award from the NAEPP, and cited by the CDC as an effective childhood asthma management program. This program reaches hundreds of thousands of students with asthma in more than 40,000 elementary schools across the country.[53] While this program was developed for children in grades 3-5, we have successfully used it in grades K-2.[15]

(4) **Monitor asthma control over time.** Because asthma control varies over time, passive surveillance during the school year will be conducted by the school nurse using factors such as school absences, visits to the health room, non-participation in physical education and early school dismissals.[12] If a student at risk of poor control is identified, the school nurse will contact the student's parents and the TUSD medical director. Because TUSD already electronically tracks these health events, a passive, rather than active, surveillance strategy was deemed to be most feasible and appropriate. This decision is also consistent with CDC recommendations for school health.[14] In 2009-2010, asthma care was the 11th most frequent TUSD health

event, accounting for 2,354 of 75,894 documented health actions. The presence of a pre-existing and well-utilized health tracking system makes it difficult to justify adding additional resource intensive tracking measures such as daily peak flow meter or symptom monitoring.

(5) **Provide ready access to quick relief medication at school.** The ALA will coordinate with school nurses, parents and the student's primary asthma provider to ensure access to quick relief medication and an asthma action plan at school. Access could include self-carry, a second inhaler supervised by the school nurse, or a stock inhaler. This is an important initiative because our research has shown that few students with asthma (<15%) have quick relief medication available at school.[61] This program will help overcome many of the previously identified barriers to accessing quick relief medication at school such as non-compliance with state-mandated medication forms and obtaining a second inhaler from third party payers.

(6) **Provide direct supervision of daily controller therapy.** All students will receive asthma education and access to quick relief medication at school during intervention years, but only students deemed to require daily controller therapy will be offered daily medication supervision at school. We expect >90% of students identified will require daily controller medication.[16] Supervision of once-daily controller medication ensures adherence during the school year, is well-received by students, parents, schools and physicians, and reduces asthma exacerbations.[6] Use of daily controller medication will be supervised at school using protocols previously developed by the investigators.[6, 49] Supervision will be provided by a school employee who will be trained to recognize appropriate inhaler technique. Students will continue to use their controller medication at home, on weekends, and during school breaks. Because this protocol will require a second inhaler and since third-party payers rarely pay for them, the study will provide a second inhaler at no cost. For students whose regimen cannot be changed to once-daily dosing, they will be offered supervision of at least one of their doses at school. In our previous supervised therapy study, we used a standardized medication (budesonide) with a variable dose (200-800 mcg) dependent on the student's needs. Since this study emphasizes effectiveness under real-world conditions, and not efficacy, we will not require all students to be placed on a standardized, once-daily regimen. Therefore we will need to purchase a variety of asthma medications for in-school use.

E. Delayed intervention: Students in the delayed intervention group will be identified and enrolled using the same methods as the intervention group; however, they will not be exposed to any intervention initiatives (e.g. education, physician evaluation, medication supervision) until the second year of the study. Schools assigned to delayed intervention will continue their usual care practices with regard to asthma care. Data collection methods and intervals for the intervention and delayed intervention groups will be the same.

Our previous experience suggests that it is difficult to conduct a pure usual care group in school-based asthma research resulting in varying levels of bias towards the null. To minimize this bias, we aim to limit study contact with the usual care (delayed intervention) group during Year 1. There will only be 3 opportunities for study interaction: (1) initial recruitment/enrollment telephone contact (2) periodic assessments of asthma outcomes obtained from both parents and students, and (3) a score of ≥1.50 on the ACQ[62] Parents of children scoring ≥1.50, indicating poor asthma control, will be contacted by mail and advised to seek care from their child's primary asthma provider. Providing this notification will meet our duty to warn, but it is unlikely to improve the child's asthma care and subsequently bias the study outcome.[4,5] This is an unfortunate but realistic assessment that, in part, justifies programs like the one we are proposing for this study.

F. Outcomes and Data Collection Procedures:

Aim 1: **Conduct a randomized controlled trial to evaluate the effectiveness under real world conditions of a previously demonstrated efficacious school-based asthma program that includes the direct supervision of daily controller therapy.**

Primary Outcome: The primary outcome will be the score on the Juniper Asthma Control Questionnaire (ACQ).[9] Scores range from 0 to 7 with lower scores indicating better asthma control. The ACQ is a 7-item questionnaire that asks 5 symptom-related questions, assesses recent short-acting beta-agonist (SABA) use, and measures pulmonary function (FEV_1). It can be interviewer-administered to children between the ages of 6-10 years. It is available in English and Spanish. For this study, we will use the 6-item score (without FEV_1) as it has equal or better measurement properties than the 7-item score, particularly for measuring change over time.[9] Using the 6-item score also avoids the need to perform labor intensive spirometry. We considered, but decided against, using the Asthma Control Test (ACT) because it must be administered concurrently to both parents and children for children <11 years making it logistically impractical to coordinate for a school-based study with 500 children.

The methodology for administering the ACQ is consistent with the instrument's original design and validation;[9] however, our work with this instrument (and the PAHOM) suggests that different outcomes may be obtained when administered to parents instead of children (see Preliminary Studies, Figure 6). There is considerable evidence that differing responses are to be expected on instruments that assess asthma control.[63-71] The direction of these differences is inconsistent across instruments; on some parents report more symptoms, on others children report more. This proxy problem appears to be most problematic for children of intermediate age, like those in our study, where they are semi-independent. Unfortunately, there is not enough data to know which group, parents or children, provide the "best" answers. Because of this problem, we believe it is important to administer the ACQ (and the PAHOM) to both parents and students. This will provide a more robust study and will allow us to more fully investigate and report on the important proxy problem.

Secondary outcomes: Secondary outcomes will include asthma symptom free days (ASFDs), parent and child quality of life (QoL), health care utilization, and school health events such as absences. ASFDs will be measured using the PAHOM (see Aim 2, Primary Outcome). Parent and child QoL will be measured using the Pediatric Asthma Caregiver's Quality of Life Questionnaire *(PACQLQ)* and the Standardized Pediatric Asthma Quality of Life Questionnaire (PAQLQ(S)). The PACQLQ measures the problems that are most troublesome to the primary caregivers of children with asthma.[72] It has 13 questions in two domains: activity limitation and emotional function. The PAQLQ(S) measures functional problems that are most troublesome to children with asthma.[73] It has 23 questions in 3 domains: symptoms, activity limitation and emotional function. The PAQLQ(S) has been shown to have good measurement properties and validity in children.[48] Both instruments are available in English and Spanish.[74] Health care utilization will be collected as described under Aim 2 (see Secondary Outcomes) and school outcomes (e.g. absences and health room visits) will be collected via TUSD's existing electronic health event reporting system.

Data collection: All outcome data will be collected by research staff based on the schedule in Table 1. Parents (via telephone) and students (interviewer-administered) will be interviewed four times a year (August, November, February, and May). School-reported outcomes will be obtained annually from TUSD.

Table 1. Data Collection Schedule for Aims 1 and 2.

	2012					2013											2014				
	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M
ACQ‡	X			X			X			X			X			X			X			X
PAHOM‡	X			X			X			X			X			X			X			X
PAQLQ(S)*	X			X			X			X			X			X			X			X
PACQLQ#	X									X			X									X
Health care utilization#,§	X									X			X									X
School health events†										X												X

*Student-reported only; #Parent-reported only; ‡both-reported; †school-reported; §claims data

Aim 2**: Conduct a cost-effectiveness analysis (CEA) from the societal perspective using dollars per quality-adjusted life year (QALY) gained.**

Primary Outcome: The primary outcome will be dollars per QALY gained in children with asthma. QALYs will be obtained using the Pediatric Asthma Health Outcome Measure (PAHOM).[48] The PAHOM measures symptom burden, emotional impairment, and activity limitation in children with asthma. Based on responses to the 4-item PAHOM, children can be assigned to one of 10 health states for each of the previous 7 days. Each health state is associated with a standard gamble derived preference weight that represents society's estimation of the desirability of that health state on a scale of 0 (death) to 1 (perfect health).[75] The weights can be summed to derive total QALYs over the one week period. The PAHOM was designed to be interviewer-administered to students 7 to 12 years of age.

We have previously used the preference weights of the PAHOM health states to estimate the cost-effectiveness of school-based asthma screening in a simulation model.[7] We have also reported on the comparability of the PAHOM with a standard measure of asthma control, the ACQ, and the comparability of parent and child PAHOM responses (see Preliminary Studies, Figure 6).[54,55] Our experience with this instrument suggests that is a valid instrument, but it is susceptible (like other instruments) to the proxy report problem. On the PAHOM, parents tend to report more symptoms (and fewer QALYs) than their children. When these responses are compared to physician-rated control, parental responses show better congruence (see Preliminary Studies, Figure 6). The implication of this differential reporting is that student responses may yield higher cost-effectiveness estimates (less cost-effective) than parent responses. The reason is because

student responses have, on average, less room to improve. These differences may or may not be meaningful, but the importance of the CEA aim makes it prudent to obtain both parent and student PAHOM responses.

The unique capabilities that the PAHOM brings to CEA cannot be overstated. It is the only instrument that can directly measure standard gamble derived QALYs in children with asthma. Measuring QALYs is an absolute requirement to conduct a gold-standard, reference case cost-effectiveness analyses.[76] QALYs are preferred because they are generalizable and can be compared against a universal standard (e.g. $50,000 per QALY). Previously, the major weakness of cost-effectiveness studies in childhood asthma has been the lack of a standardized, generalizable outcome.[47] Other advantages of the PAHOM include its ability to measure asthma symptom free days (ASFDs) and its comparability to the ACQ, a measure of asthma control.[54]

Secondary outcomes: A secondary outcome will be dollars per ASFD gained in children with asthma. From our previous modeling work, symptom days are likely to be the most important driver of cost-effectiveness in asthma.[7] Even though symptom days are not viewed as severe (e.g. low preference weight), they are so frequent that when summed over the year they can result in significant impairment. Therefore, ASFDs are an important CEA outcome as well as being clinically meaningful. The major limitation of ASFDs is their lack of generalizability when compared to cost-effectiveness estimates outside of asthma.

Cost-accounting: While standardized methodologies to measure asthma costs[77] and randomized trial costs[78] have not been formalized, recommendations for best practices exist.[79] One recommendation is to take a societal perspective where all relevant costs (and outcomes) are considered.[75] The time horizon should also be consistent with the time period over which the important costs (and outcomes) occur. Therefore, all asthma-related costs over the first and second year of study will be measured. This will include the direct costs of the intervention as well as the direct (e.g. medication, outpatient visits, ED visits, and hospitalizations) and indirect (e.g. parental productivity and school absences) costs of asthma. Discounting future costs will not be necessary due to the short time horizon of the study. The delayed intervention design with two consecutive intervention years in one group will allow us to quantify any gains in efficiency and evaluate their impact on the program's cost-effectiveness.

All resources used at the school-level and by the ALA including the implementation of school-based clinics, personnel time for medication supervision, facility use, supplies and missed class time will be measured. Health care utilization costs will be tracked using a gross-costing method, where costs are bundled by service type (e.g. single ED visit) versus micro-costing method where costs are individually aggregated (e.g. nursing time, medication, procedure costs at each ED visit).[78,79] Gross-costing is more practical and reliable than micro-costing when a wide variety of service events and locations are being measured.[78]

For a study of this type, the biggest challenge will be to accurately estimate health care costs. A number of approaches can be taken including self-report and third-party claims data. Our primary method will be to use parental self-report data regarding the frequency of four major health care events: medication refills, out-patient visits (scheduled and unscheduled), ED visits and hospitalizations. Self-report data has been validated as a reliable source of health care utilization frequency by one of our investigators (TAL).[80] While individual-level differences may exist between self-report and claims data, at the population-level these differences are small enough that self-report data is appropriate for use in clinical trials. Health care utilization data will be collected from parents during telephone interviews conducted four times a year. This schedule should be frequent enough to maximize recall even of less salient events such as medication refills and routine outpatient visits.

To estimate costs, the frequency of each health event will be multiplied by a cost estimate (e.g. 4 ED visits x $350 = $1400). Several methods will be used to estimate accurate and generalizable costs. Releases will be solicited from a subset of parents to obtain medical records/charges for reported health events. Charges will be discounted to obtain actual costs. We will also obtain third-party claims data from students enrolled in the Arizona's Health Care Cost Containment System (AHCCCS), Arizona's Medicaid plan. Data from AHCCCS is available on a cost-recovery basis upon request. Because Arizona has a highly fragmented insurance market where no health plan has >20% market share, it is not possible to obtain claims data for all students.[81] Even so, we expect approximately 50% of students will be enrolled in the Medicaid program. AHCCCS data will be compared with self-report data and, if necessary, correction factors will be estimated to adjust systematic over- or under-reporting of utilization. Lastly, we will compare our cost estimates to similar estimates from the literature and other published sources.

Aim 3**: Conduct a process evaluation including the assessment of the program's implementation fidelity and participants' experiences with the program.**

Our team has experience conducting large, randomized, school-based trials where process evaluation and assessment of intervention fidelity were important outcomes.[82-84] Given the size and stability of TUSD and the

good will between the system and the ALA, we expect to have a strong and viable research/community partnership. Throughout the study we will maintain close communication with our community partners and will include them as key stakeholders in meetings and decision-making. We will employ a process evaluation coordinator (PEC) to keep us informed of site specific concerns and to identify challenges in cooperation between the various partners to effectively implement the program as intended.

One of the major challenges to conducting randomized controlled trials in the community setting is minimizing contamination within the control group. Despite appropriate precautions, the mere presence of project staff at the site or unrelated secular events within the local community can threaten study integrity. We will attempt to minimize contamination between intervention and usual care schools and increase intervention fidelity by offering multiple training sessions for all involved staff and partners, including training on the scientific aims, issues of contamination, and human subjects protocols. To the extent possible, schools will maintain separate staff at intervention versus delayed intervention schools and data collection will be conducted by research staff blinded to intervention condition.

Despite these precautions, implementation of behavioral interventions in non-clinical settings presents unique challenges to study integrity that are often not faced in clinically-based randomized controlled trials.[85-87] To identify and measure potential threats to study validity, we will create intervention fidelity monitoring tools which will follow the recommendations outlined by the NIH Behavior Change Consortium Workgroup.[85] One of our primary goals will be to ensure consistent intervention delivery and document any variation in: (1) the identification of students with previously diagnosed asthma, the assessment of their control status, and the offer of daily medication supervision; (2) the appropriate provision of guideline-concordant care and the level of coordination with the child's primary asthma provider; (3) the complete and effective delivery of the OAS asthma education program; (4) the consistency of surveillance for poor asthma control; (5) the ready access to quick relief medication at school; and 6) the adequacy of direct supervision of daily medication at school. We will also monitor usual care schools for evidence that any of these, or related activities, are being implemented.

In addition to monitoring intervention fidelity, we will also collect data to identify challenges to intervention delivery as well as participant experiences with the intervention. This data will allow us to determine barriers and challenges to implementation and dissemination of the program.

Outcomes: All intervention steps as well as school-provided information, reminder cards and referrals will be documented. Participant records will include documentation of all attempts to recruit, contacts with project staff (intervention and research), consent and HIPAA forms, and data on follow-up phone calls (date, content, and outcome). Additional data from the following sources will be collected and extracted to monitor any concerns about intervention fidelity as well as site specific/partner specific disruptions: (1) Internal logs and clinical notes from school nurses and ALA staff who are engaged in testing and treatment activities (2) study clinician/school nurse notes from initial assessment as well as any follow-up contacts or health encounters. Communication logs between parents, nurses, the ALA, and physicians will be examined to explore communication regarding the child's asthma management.

A series of program exposure assessments specific to the intervention objectives will be conducted with students and parents at baseline and the end of each school year to monitor secular changes in asthma knowledge/treatment, variation in procedures for asthma knowledge/treatment delivery between intervention schools, and unintentional exposures to asthma knowledge/treatment activities within usual care schools.

The PEC will visit each school site frequently to make subjective assessments and conduct key informant interviews to identify site challenges that could compromise data collection or intervention delivery. Weekly meetings between the process evaluator and key investigators will be conducted to review findings from site visits. If variations in study protocols are identified, recommendations will be made regarding additional training or other corrective actions for project personnel and/or community partners. The PEC will periodically assess the activities of school nurses, clinical specialists and ALA personnel. She will also review and extract data from the logs and notes. These data extractions will be discussed at regular staff meetings and include input from all key investigators. The PEC will also take inventory of available asthma medications during site visits. At the end of the study, the PEC will conduct focus groups and key informant interviews to gather participant thoughts and opinions regarding their experiences with the intervention. See Appendix A for complete list of evaluative measures.

G. Data Management, Sample Size, and Statistical Analysis Plan*:*

Data Management: A web database application using open source components including Java, Apache Tomcat, and the PostgreSQL database will be built to house instrument, interview, and organizational data for the project. Interview data will be entered directly into the database at the time of the interview and school and

medical claims data will be integrated directly into the study database. To facilitate analysis, the application(s) will include the ability to generate custom reports and to export them to other statistical and data management applications as needed. The application(s) will be supported throughout the lifetime of the project and when needed, new functionality will be added. Summary reporting of entered data will be conducted monthly to ensure satisfactory data quality and timeliness of reporting.

Sample Size: Our study design is a two-arm, group-randomized trial. Sixteen schools will be paired according key factors such as asthma prevalence and racial/ethnic mix. One school from each pair will be randomly assigned to receive immediate intervention and the other will be subsequently assigned to the delayed intervention. TUSD elementary schools average approximately 400 students per school and we expect that approximately 10% of students will meet our screening definition of asthma. If we achieve 85% enrollment and 90% completion, we expect 245 students per treatment arm (~31 students per school) will complete the 2-year program. Statistical power will be estimated separately for the effectiveness outcome (Aim 1, ACQ) and the cost-effectiveness outcome (Aim 2, dollars per QALY).

Aim 1: **Conduct a randomized controlled trial to evaluate the effectiveness under real world conditions of a previously demonstrated efficacious school-based asthma program that includes the direct supervision of daily controller therapy.** The ACQ will be the primary outcome for evaluating program effectiveness. Secondary outcomes include ASFDs, parental and child quality of life, health care utilization events, and school outcomes such as absences. Descriptive numerical and graphical summaries will be constructed for all recorded outcomes. These include frequencies for categorical measures and summary statistics (e.g. means and standard deviations) for continuous measures, as well as, density plots conditional on school, observation time, and student-related factors.

The primary statistical analysis evaluates the mean effect of the intervention vs. usual care (point estimate and 95% confidence interval) on asthma control as measured by the ACQ in students with asthma. A linear mixed-effects model will be used to estimate the mean effect of intervention. The mixed model accounts for sources of variability between schools, between children (within a school), and between multiple observations for each child. The student's age, sex, and baseline ACQ values will be included as covariates in the mixed model. The bootstrap[88,89] will be used to compute a 95% confidence interval for the mean intervention effect. This method will supplement the interval computed from the Gaussian-based mixed effects model. Because our design enrolls students with well-controlled symptoms who are unlikely to experience significant morbidity, we will conduct a secondary analysis omitting these students. In addition, we will investigate potential discrepancies in parent and child reporting for the ACQ and PAHOM. Again, the linear mixed-effects model will be used in evaluating parent-child differences.

Statistical Power: We anticipate study completion for 245 children per arm (8 schools per arm). Preliminary data from children aged 7-12 years indicate that the difference of ACQ scores per child exhibit a standard deviation of 0.61[90]. Scores are also skewed such that most student will report low scores (well-controlled asthma) and subsequently fewer will report higher scores (poorly controlled asthma). In addition, we examined a range of intraclass correlation coefficients (ICCs) from 0 to 0.15 to account for within schools correlation. Using cluster randomization power calculations[91] we compute minimum detectable differences ranging from 0.15-0.37 (power 0.8, 0.05 significance level). Clinically relevant differences in ACQ occur at 0.50.[92] Thus with minimum detectable differences less than 0.5, we believe this study is well-powered to detect clinically relevant changes associated with the intervention.

Aim 2**: Conduct a cost-effectiveness analysis (CEA) from the societal perspective using dollars per quality-adjusted life year (QALY) gained.**

The primary outcome (dollars per QALY) is computed from the total costs (intervention costs, health care utilization costs, and indirect student/parent costs) and the PAHOM (QALYs). The intervention-associated difference in mean PAHOM score will be the method for computing QALYs. The PAHOM assigns students to a specific asthma-related health state for each of 7 days reported. The health state assignment is based on responses to 4 questions in three domains (symptoms, activity limitation, and emotional impairment). Each day is associated with a standard gamble-derived preference weight between 0 (death) and 1 (perfect health). These weights can be summed, multiplied and divided. The sum of the 7 preference weights represents the number of quality-adjusted life days experienced in the past week. This amount can be multiplied by 52 to obtain the number of QALYs.

Based on preliminary data, the PAHOM data is expected to have a similar structure to that of the ACQ described in Aim 1 (many students with high scores indicating good control/QoL, few students with low scores). The linear mixed effects model will be used as the basis for statistical inference. As above, bootstrap methods

will be used to compute a 95% confidence interval for differences in mean PAHOM scores between the intervention vs. usual care groups. This method will supplement the standard analysis from the Gaussian-based mixed effects model.

The primary analysis will compare the difference in the mean per child costs between intervention and usual care schools divided by the mean difference in per child QALYs achieved in intervention and usual care schools. The bootstrap[88,89] will be used to compute a 95% confidence interval for the resulting cost-effectiveness ratio. In addition, we will conduct the traditional one-way sensitivity analysis of cost and health outcome parameters to identify the most influential variables. We will also use our previously developed 5-Health State Markov[7] model to conduct probabilistic sensitivity analysis to obtain a simulated 95% confidence interval based on the distribution of cost-effectiveness ratios from repeated model iterations in a simulated population with characteristics derived from this study.

Statistical Power: The incremental cost-effectiveness ratio (ICER, dollars per QALY) includes the intervention associated PAHOM mean difference in the denominator of the equation. As a consequence, we take special care to ensure that this mean difference (and associated confidence interval) is bounded greater than zero. As one might expect, near zero numbers in the denominator of a ratio outcome make the outcome unstable. Our preliminary data from our simulation model indicate that a PAHOM difference of 0.05-0.06 is clinically significant.[7] Data re-sampling (100 re-sampled data sets), and use of the linear mixed effects model is summarized in Figure 7, which shows the relationship between increasing sample size and estimated half-width of the 95% confidence interval. With 16 schools (31 students per school) the half-width is slightly less than 0.026, and the lower bound of 95% confidence interval is approximately two standard errors greater than zero. Since the estimated intervention effect is well above zero, we anticipate that a reliable ICER can be estimated.

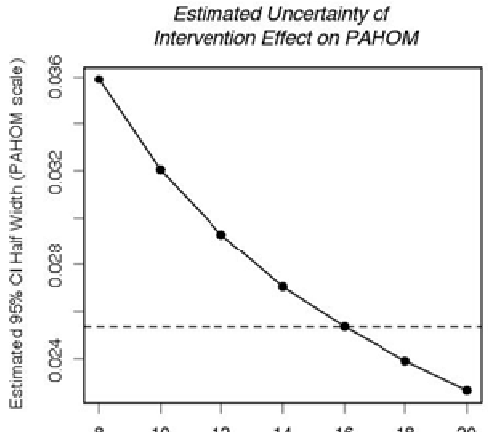

Figure 7. Relationship between half-width of 95% Confidence Interval and School Sample Size

Aim 3**: Conduct a process evaluation including the assessment of the program's implementation fidelity and participants' experiences with the program.** The process evaluation will collect both quantitative and qualitative data. Quantitative data will include observation data collected using checklists, as well as data collected to quantify any variation in the components of the intervention (i.e. health cards returned, quick relief medication, receive supervised therapy) and data to monitor secular changes in asthma knowledge or treatment. Quantitative data will be summarized using rates and relative frequencies (with confidence intervals) for categorical outcomes, and measures of location (e.g., mean, median) and dispersion (standard deviation, range) for measured outcomes. Summaries will be reported globally and by school for each measurement period. Qualitative data will include communication logs, key informant interviews and focus groups. NVivo software will be used to assist with content analysis of these data[93, 94].

H. Timetable:

The proposed project is scheduled to be completed in three and a half years (See Table 2).

Table 2. Timeline for Proposed Research Project.

Activity	Year 1				Year 2				Year 3				Year 4	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
Hire/train project staff														
Recruit schools														
Randomization														
Intervention in half the schools														
Intervention in all schools														
Data cleaning & analysis														
Final health care use data available														
Manuscript & report generation														
Preparation of data for sharing														

PROTECTION OF HUMAN SUBJECTS

The proposed project meets the NIH definition of a clinical trial and will be registered in http://clinicaltrials.gov. All study personnel will obtain and maintain up to date training in the protection of human subjects.

A. Risks to the Subjects

Human Subjects Involvement, Characteristics, and Design The subjects for the proposed research will be elementary school children with asthma. These children will be ages 5-12 with physician diagnosed asthma. We expect the children to be 40% female and 60% Hispanic white. Other minority groups expected to enroll include approximately 3% American Indian and 7% black. This racial/ethnic composition is representative of the Tucson Unified School District (TUSD).

Schools will be randomized to immediate or delayed intervention and children will be assigned intervention status based upon the school in which they are enrolled. A delayed intervention design was chosen for two reasons: 1) to maximize school participation, and 2) for ethical considerations. Prior experience indicates that recruiting schools to participate in randomized trials is difficult when some will be assigned to a no treatment control group. Previously, we have used cross-over designs instead of delayed intervention designs to address this issue. However, this project is not well-suited to a crossover design because we expect significant carry-over effects. The comprehensive nature of the intervention and high degree of coordination between the child's primary care physician and the school are expected to create persistent changes in care. Furthermore, we believe that the use of a no-treatment control group would be ethically challenging as our intervention has been proven efficacious in a different setting. Therefore, we chose a delayed intervention design which is considered to be a critical design element for successful community based randomized trials.

All children enrolled will have their asthma control status determined at baseline. If children in the usual care group have poor asthma control, as indicated by a score of ≥1.50 on the Juniper Asthma Control Questionnaire, a written letter will be mailed to the parent's address advising them to seek care from their child's primary asthma care provider. Children in the intervention group will have their asthma control assessed and those with poor control or on daily medication will be recommended to see the asthma specialist at an after-hours school based clinic. At the visit, asthma control will be re-assessed, a personalized asthma action plan will be created, and controller medication recommendations will be made. If changes to the student's existing regimen are recommended, they will be coordinated with the child's primary asthma care provider who will remain the child's usual source of asthma care. Only children who require controller medication will be offered supervised therapy at school. We will ensure that all children in the intervention group have access to quick relief medication and an asthma action plan at school and they will receive asthma education through the Open Airways for Schools program. Passive surveillance during the school year will be conducted by the school nurse using factors such as school absences, visits to the health room, non-participation in physical education class and early dismissals from school. When a student is identified as having poor control, the school nurse will contact the student's parents and the program's asthma specialist.

Sources of Materials The research materials collected from the children will include interview data on asthma control, asthma symptom free days, and quality of life which will be collected quarterly by study staff at the child's school. Other research data will include twice yearly parent interviews to collect data on the child's asthma control, parental quality of life, and health care utilization. Data on school absences, health room visits, early dismissal due to illness, and missed physical education will also be collected from the child's school. Health care

claims data will be collected on a subset of children from the Arizona Health Care Cost Containment System.

Potential Risks The major risks to the study are related to asthma medications which are administered at school. The majority of children receiving daily medication at school will be on an inhaled corticosteroid. The primary risk from inhaled corticosteroids is oropharyngeal candidiasis. Children will be taught to rinse their mouth after taking their inhaled steroid to reduce this risk. Rare instances of glaucoma, increased intraocular pressure, and cataracts have been reported following the administration of corticosteroids. There is also the possibility of systemic absorption of inhaled corticosteroids that could lead to hypercorticism and adrenal suppression. In children, there is the possibility of a reduction in growth velocity. Therefore, children will be administered the lowest dose that controls their asthma. Adverse events that occurred at a rate of greater than or equal to 3% in persons on inhaled steroids that were more common than in the placebo group include: respiratory infection, pharyngitis, sinusitus, voice alteration, headache, flu syndrome, pain, back pain, fever, oral candidiasis, dyspepsia, gastroenteritis, and nausea. Rare adverse events that have been published in the literature include: immediate and delayed hypersensitivity reactions including rash, contact dermatitis, urticaria, angioedema and bronchospasm, symptoms of hypocorticism and hypercorticism; psychiatrics symptoms including depression, aggressive reactions, irritability, anxiety, and psychosis. Children will also be taking quick relief medication (albuterol) as needed. Albuterol can cause jitteriness and dizziness after administration and can raise the heart rate. School nurses will be educated on the risks of all asthma medications to reduce risks to the children.

B. Adequacy of Protection Against Risks

Recruitment and Informed Consent We will recruit children from the TUSD using health cards that identify children with asthma. Program availability will be announced on the school's web-page and in take-home materials and school nurses will also conduct passive surveillance throughout the year (e.g. absences and health room visits) to identify students who may have been missed but are still eligible. Parents of these children will be contacted by school personnel (part-time district nurses hired by the ALA) to determine their interest. Because the school nurse is often assigned to several schools and this follow-up may present an unreasonable burden on her time, the ALA will hire TUSD certified nurse substitutes to perform this duty. This will allow us to contact the children following the rules of the Family Educational Rights and Privacy Act (FERPA) while removing the research burden from the school nurse. Those interested will be referred to the research team. The research team will explain the project to the parents and obtain informed consent. The study will also be explained to each child and assent will be obtained. Copies of the informed consent will be provided to each school principal.

Protections Against Risk All study information will be confidential. Privacy risks will be minimized by appropriate protection of all study data. Paper data will be stored in a locked file cabinet within a locked office and computerized data will be stored on a secure server with password protection. Access to study data will only be given to study investigators. Data will only be published in aggregate form such that no individuals can be identified.

The study will have a Data Safety and Monitoring Board which will help to ensure patient safety (see plan below) and will set the rules and protocols for medical intervention.

C. Potential Benefits of The Proposed Research to The Subjects And Others. There are only minimal risks to the children involved in the proposed project. The benefits for the children may include an increased knowledge about their asthma and how to control it as well as improved asthma control. The delayed intervention design will allow all children enrolled to benefit from the intervention. In addition, the benefits for society include increased knowledge about methods that may improve asthma control. Integrating a gold-standard, reference case cost-effectiveness analysis using QALYs will inform key stakeholders about the program's effectiveness, value, and sustainability. Given the scarcity of funding for public health,

demonstrating the program's value may be one of the most important drivers of its future adoption. The risk/benefit ratio is favorable to individual patients as the risks are minimal and the likely benefit is high. The proposed study is testing the effectiveness of a previously demonstrated efficacious intervention in a community setting.

D. Importance of the Knowledge Gained The benefits to society include increased knowledge about school based programs that may improve asthma control. The project will also provide information regarding the cost of this program. Poor asthma control is a major cause of morbidity among school age children. The risk/benefit ratio is favorable to individual patients as well as to society as the risks are minimal and the likely benefit is high. The proposed study is testing the effectiveness of a previously demonstrated efficacious intervention in a community setting.

E. Data Safety and Monitoring Plan This study meets the NIH definition of a clinical trial. Therefore, it is our intention to create a three member Data Safety and Monitoring Board of persons not affiliated with the research project. Names will be submitted to NHLBI for approval. The DSMB will be created prior to the beginning of the study and will consist of at least two individuals outside of our program and a third who is outside of our institution. One of these individuals will have statistical expertise. Prior to initiation of the trial, the DSMB will approve the consent form. The DSMB will meet once a year and have interim conference calls if needed. Official minutes will be taken by the project statistician, Dr. Dean Billheimer, and will be forwarded to the NHLBI after each meeting. The major functions of the DSMB will be to review project performance and monitor patient safety. The DSMB will review recruitment and data collection to ensure project goals are met. The DSMB will also approve all changes to the protocol. At its initial meeting, members of the DSMB will decide what data points they need to monitor to ensure patient safety and if they need *a priori* stopping rules or guidelines.

At each meeting, the DSMB will vote whether to continue the trial. Reasons for early termination of the trial may include concerns about safety of the treatments, an early convincing beneficial effect of treatment, or such poor performance by the investigators that successful completion of the trial is unlikely. The DSMB may also recommend amendments to the study protocol if it appears they are necessary for safety or scientific validity of the trial.

A special responsibility of the DSMB is to review serious adverse events (SAEs), as defined by deaths, life-threatening conditions, hospital admissions, cancer, or events that require the permanent discontinuation of the intervention. No SAEs are anticipated as the intervention is using FDA approved medications; however all SAEs will be reported to NHLBI and the UAB Institutional Review Board in the standard manner with follow-up reporting until the event has terminated. SAEs will be reported to the DSMB by the procedures they determine.

Inclusion of Women and Minorities

We expect children to be 40% female; therefore, females will be adequately represented. We expect that approximately 60% of the children who enroll will be Hispanic, 3% American Indian, and 7% black; therefore, minorities will be over-represented in this research. This population represents that of the Tucson Unified School District and targets minority groups who often have the poorest asthma control.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: The Cost-Effectiveness of School-Based Supervised Asthma Therapy

Total Planned Enrollment: 500

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	118	177	295
Not Hispanic or Latino	82	123	205
Ethnic Category: Total of All Subjects *	200	300	500
Racial Categories			
American Indian/Alaska Native	6	9	15
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	14	21	35
White	180	270	450
Racial Categories: Total of All Subjects *	200	300	500

* The “Ethnic Category: Total of All Subjects” must be equal to the “Racial Categories: Total of All Subjects.”

Inclusion of Children

All of the proposed participants will be children because this is a school based study examining methods to improve asthma control among elementary school children.

BIBLIOGRAPHY & REFERENCES

1. Akinbami L. The state of childhood asthma, United States, 1980-2005. *Adv Data*. 2006(381):1-24.
2. National Asthma Education and Prevention Program. National Heart, Lung, and Blood Institute. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. US Department of Health and Human Services; 2007.
3. American Academy of Allergy Asthma, and Immunology. Pediatric Asthma: Promoting best practice a guide for managing asthma in children. Rochester, NY: American Academy of Allergy, Asthma, and Immunology; 1999.
4. Yawn B. P., Wollan P., Scanlon P., Kurland M. Are we ready for universal school-based asthma screening?: An outcomes evaluation. *Arch Pediatr Adolesc Med*. 2002;156(12):1256-1262.
5. Yawn B. P., Wollan P., Scanlon P. D., Kurland M. Outcome results of a school-based screening program for undertreated asthma. *Ann Allergy Asthma Immunol*. 2003;90(5):508-515.
6. Gerald L.B., McClure L.A., Mangan J.M., Harrington K.F., Gibson L., Erwin S., et al. Increasing adherence to inhaled steroid therapy among schoolchildren: randomized, controlled trial of school-based supervised asthma therapy. *Pediatrics*. 2009;123(2):466-474.
7. Gerald J. K., Grad R., Bailey W. C., Gerald L. B. Cost-effectiveness of school-based asthma screening in an urban setting. *J Allergy Clin Immunol*. 2010;125(3):643-650, 650 e641-650 e612.
8. McElligott S., Polsky D. The opportunity costs of screening children for asthma. *J Allergy Clin Immunol*. 2010;125(3):651-652.
9. Juniper E. F., Gruffydd-Jones K., Ward S., Svensson K. Asthma Control Questionnaire in Children: Validation, Measurement Properties, Interpretation. *Eur Respir J*. 2010.
10. Wheeler L. S., Merkle S. L., Gerald L. B., Taggart V. S. Managing asthma in schools: lessons learned and recommendations. *J Sch Health*. 2006;76(6):340-344.
11. Gerald L. B., Sockrider M. M., Grad R., Bender B. G., Boss L. P., Galant S. P., et al. An official ATS workshop report: issues in screening for asthma in children. *Proc Am Thorac Soc*. 2007;4(2):133-141.
12. Wheeler Lani, Buckley Rebekah, Gerald L. B., Merkle Sarah, Morrison Teresa Ann. Working With Schools to Improve Pediatric Asthma Management. *Ped Asthma Allergy Immunol*. 2010;22(4):197-207.
13. Merkle S. L., Wheeler L. S., Gerald L. B., Taggart V. S. Introduction: learning from each other about managing asthma in schools. *J Sch Health*. 2006;76(6):202-204.
14. Centers for Disease Control and Prevention. Strategies for addressing asthma within a coordinated school health program, with updated resources. National Center for Chronic Disease Prevention and Health Promotion. Atlanta, GA; 2006.
15. Gerald L. B., Redden D., Wittich A. R., Hains C., Turner-Henson A., Hemstreet M. P., et al. Outcomes for a comprehensive school-based asthma management program. *J Sch Health*. 2006;76(6):291-296.
16. Gerald L. B., Grad R., Turner-Henson A., Hains C., Tang S., Feinstein R., et al. Validation of a multistage asthma case-detection procedure for elementary school children. *Pediatrics*. 2004;114(4):e459-468.
17. Gerald L. B., Gerald J.K., McClure L. A., Harrington K. F., Erwin S., Bailey W. C. Redesigning a Large School-Based Clinical Trial in Response to Changes in Community Practice. *Clinical Trials*. 2010;Under review/revise and resubmit.

18. Weinstein M. C., Siegel J. E., Gold M. R., Kamlet M. S., Russell L. B. Recommendations of the Panel on Cost-effectiveness in Health and Medicine. *JAMA*. 1996;276(15):1253-1258.
19. Lozano P., Sullivan S. D., Smith D. H., Weiss K. B. The economic burden of asthma in US children: estimates from the National Medical Expenditure Survey. *J Allergy Clin Immunol*. 1999;104(5):957-963.
20. Wang L. Y., Zhong Y., Wheeler L. Direct and indirect costs of asthma in school-age children. *Prev Chronic Dis*. 2005;2(1):A11.
21. Canino G., Koinis-Mitchell D., Ortega A. N., McQuaid E. L., Fritz G. K., Alegria M. Asthma disparities in the prevalence, morbidity, and treatment of Latino children. *Soc Sci Med*. 2006;63(11):2926-2937.
22. Raphael J. L., Guadagnolo B. A., Beal A. C., Giardino A. P. Racial and ethnic disparities in indicators of a primary care medical home for children. *Acad Pediatr*. 2009;9(4):221-227.
23. Ramirez R., de la Cruz G. Patricia. The Hispanic Population in the United States. Department of Commerce; 2003.
24. Moorman J. E., Rudd R. A., Johnson C. A., King M., Minor P., Bailey C., et al. National surveillance for asthma--United States, 1980-2004. *MMWR Surveill Summ*. 2007;56(8):1-54.
25. Stewart K. A., Higgins P. C., McLaughlin C. G., Williams T. V., Granger E., Croghan T. W. Differences in Prevalence, Treatment, and Outcomes of Asthma Among a Diverse Population of Children With Equal Access to Care: Findings From a Study in the Military Health System. *Arch Pediatr Adolesc Med*.
26. Lieu T. A., Lozano P., Finkelstein J. A., Chi F. W., Jensvold N. G., Capra A. M., et al. Racial/ethnic variation in asthma status and management practices among children in managed medicaid. *Pediatrics*. 2002;109(5):857-865.
27. Bauer E. J., Lurie N., Yeh C., Grant E. N. Screening for asthma in an inner-city elementary school in Minneapolis, Minnesota. *J Sch Health*. 1999;69(1):12-16.
28. Clark N. M., Brown R., Joseph C. L., Anderson E. W., Liu M., Valerio M., et al. Issues in identifying asthma and estimating prevalence in an urban school population. *J Clin Epidemiol*. 2002;55(9):870-881.
29. Maier W. C., Arrighi H. M., Morray B., Llewllyn C., Redding G. J. The impact of asthma and asthma-like illness in Seattle school children. *J Clin Epidemiol*. 1998;51(7):557-568.
30. Mvula M., Larzelere M., Kraus M., Moisiewicz K., Morgan C., Pierce S., et al. Prevalence of asthma and asthma-like symptoms in inner-city schoolchildren. *J Asthma*. 2005;42(1):9-16.
31. Webber M. P., Carpiniello K. E., Oruwariye T., Appel D. K. Prevalence of asthma and asthma-like symptoms in inner-city elementary schoolchildren. *Pediatr Pulmonol*. 2002;34(2):105-111.
32. Gerald L. B., Redden D., Turner-Henson A., Feinstein R., Hemstreet M. P., Hains C., et al. A multi-stage asthma screening procedure for elementary school children. *J Asthma*. 2002;39(1):29-36.
33. Nicholas S. W., Jean-Louis B., Ortiz B., Northridge M., Shoemaker K., Vaughan R., et al. Addressing the childhood asthma crisis in Harlem: the Harlem Children's Zone Asthma Initiative. *Am J Public Health*. 2005;95(2):245-249.
34. Joseph C. L., Foxman B., Leickly F. E., Peterson E., Ownby D. Prevalence of possible undiagnosed asthma and associated morbidity among urban schoolchildren. *J Pediatr*. 1996;129(5):735-742.
35. Schneider D., Freeman N. C., McGarvey P. Asthma and respiratory dysfunction among urban, primarily Hispanic school children. *Arch Environ Health*. 2004;59(1):4-13.

36. Gerald J. K., Sun Y., Grad R., Gerald L. B. Asthma morbidity among children evaluated by asthma case detection. *Pediatrics*. 2009;124(5):e927-933.
37. Joseph C. L., Havstad S., Anderson E. W., Brown R., Johnson C. C., Clark N. M. Effect of asthma intervention on children with undiagnosed asthma. *J Pediatr*. 2005;146(1):96-104.
38. van Gent R., van Essen L. E., Rovers M. M., Kimpen J. L., van der Ent C. K., de Meer G. Quality of life in children with undiagnosed and diagnosed asthma. *Eur J Pediatr*. 2007;166(8):843-848.
39. Mangan J. M., Merkle S, Gerald L. B. Asthma in the Schools. In: Harver A, Kotses H, editors. *Asthma, Health and Society*. New York: Springer; 2010.
40. Nathan R. A., Sorkness C. A., Kosinski M., Schatz M., Li J. T., Marcus P., et al. Development of the asthma control test: a survey for assessing asthma control. *J Allergy Clin Immunol*. 2004;113(1):59-65.
41. Schatz M., Sorkness C. A., Li J. T., Marcus P., Murray J. J., Nathan R. A., et al. Asthma Control Test: reliability, validity, and responsiveness in patients not previously followed by asthma specialists. *J Allergy Clin Immunol*. 2006;117(3):549-556.
42. Schmier J. K., Manjunath R., Halpern M. T., Jones M. L., Thompson K., Diette G. B. The impact of inadequately controlled asthma in urban children on quality of life and productivity. *Ann Allergy Asthma Immunol*. 2007;98(3):245-251.
43. Finkelstein J. A., Lozano P., Farber H. J., Miroshnik I., Lieu T. A. Underuse of controller medications among Medicaid-insured children with asthma. *Arch Pediatr Adolesc Med*. 2002;156(6):562-567.
44. Riekert K. A., Butz A. M., Eggleston P. A., Huss K., Winkelstein M., Rand C. S. Caregiver-physician medication concordance and undertreatment of asthma among inner-city children. *Pediatrics*. 2003;111(3):e214-220.
45. Gold M.R., Siegel J.E., Russell L.B., Weinstein M. C., editors. Cost-Effectiveness in Health and Medicine. New York: Oxford University Press; 1996.
46. Gupta R. S., Weiss K. B. The 2007 National Asthma Education and Prevention Program Asthma Guidelines: Accelerating their implementation and facilitating their impact on children with asthma. *Pediatrics*. 2009;123 Suppl 3:S193-198.
47. Griebsch I., Coast J., Brown J. Quality-adjusted life-years lack quality in pediatric care: a critical review of published cost-utility studies in child health. *Pediatrics*. 2005;115(5):e600-614.
48. Chiou C.F., Weaver M.R., Bell M.A., Lee T.A., Krieger J.W. Development of the multi-attribute Pediatric Asthma Health Outcome Measure (PAHOM). *International Journal for Quality in Health Care*. 2005;17(1):23-30.
49. Gerald L.B., McClure L.A., Harrington K., Mangan J.M, Gibson L., Atchison J., et al. Design of the supervised asthma therapy study: Implementing an adherence intervention in urban elementary schools. *Contemporary Clinical Trials*. 2008;29:304-310.
50. Research Triangle Institute. Community Based Participatory Research: Assessing the Evidence, a report for the Agency for Health Care Research and Quality. Rockville, MD: AHRQ; 2004.
51. National Institutes of Health. National Asthma Education Program. Managing Asthma: A Guide for Schools. US Department of Health and Human Services; National Institutes of Health Publication 91-2650;1991.
52. National Asthma Education Program. Asthma Awareness: Curriculum for the Elementary Classroom. US Department of Health and Human Services; National Institutes of Health Publication 93-2894; 1991.
53. Association American Lung. Open Airways for Schools. New York: American Lung Association; 1992.

54. Gerald J.K., McClure L. A., Harrington K.F., Moore T., Gerald L. B. Can asthma control and quality-adjusted life years be captured with a single instrument? *J Allergy and Clin Immunology*. 2010;Under review.
55. Gerald J.K., McClure L. A., Harrington K., Lee T. A., Gerald L. B. The Pediatric Asthma Health Outcome Measure, Not Just Quality of Life? In: *Am J Respir Crit Care Med*; 2009. p. A4312.
56. Gerald J.K., McClure L.A., Harrington K., Lee T. A., Gerald L. B. Parent Child Agreement on the Pediatric Asthma Health Outcome Measure. *Am J Respir Crit Care Med*. 2009;179(April):A2457.
57. Gerald Joe K., Harrington Kathleen F., McClure Leslie, Bailey William C., Gerald Lynn B. Daily Respiratory Symptom Reporting Versus Two-Week Recall In Children With Asthma. *Am J Respir Crit Care Med*.181(1_MeetingAbstracts):A5805.
58. Department of Accountability and Research. TUSDStats Main Page; http://tusdstats.tusd.k12.az.us/ accessed 12/15/10.
59. Clark N. M., Feldman C. H., Freudenberg N., Millman E. J., Wasilewski Y., Valle I. Developing education for children with asthma through study of self-management behavior. *Health Educ Q*. 1980;7(4):278-297.
60. Evans D., Clark N. M., Feldman C. H., Rips J., Kaplan D., Levison M. J., et al. A school health education program for children with asthma aged 8-11 years. *Health Educ Q*. 1987;14(3):267-279.
61. Gerald L.B., Gerald J.K., McClure L. A., Grad R. Quick Relief Medication Orders at School. *American Journal of Respiratory and Critical Care Medicine*. 2009;179:A2454.
62. Juniper E. F., Bousquet J., Abetz L., Bateman E. D. Identifying 'well-controlled' and 'not well-controlled' asthma using the Asthma Control Questionnaire. *Respir Med*. 2006;100(4):616-621.
63. Theunissen N. C., Vogels T. G., Koopman H. M., Verrips G. H., Zwinderman K. A., Verloove-Vanhorick S. P., et al. The proxy problem: child report versus parent report in health-related quality of life research. *Qual Life Res*. 1998;7(5):387-397.
64. Braun-Fahrlander C., Gassner M., Grize L., Minder C. E., Varonier H. S., Vuille J. C., et al. Comparison of responses to an asthma symptom questionnaire (ISAAC core questions) completed by adolescents and their parents. SCARPOL-Team. Swiss Study on Childhood Allergy and Respiratory Symptoms with respect to Air Pollution. *Pediatr Pulmonol*. 1998;25(3):159-166.
65. Lara M., Duan N., Sherbourne C., Lewis M. A., Landon C., Halfon N., et al. Differences between child and parent reports of symptoms among Latino children with asthma. *Pediatrics*. 1998;102(6):E68.
66. le Coq E. M., Boeke A. J., Bezemer P. D., Colland V. T., van Eijk J. T. Which source should we use to measure quality of life in children with asthma: the children themselves or their parents? *Qual Life Res*. 2000;9(6):625-636.
67. Hedman L., Lindgren B., Perzanowski M., Ronmark E. Agreement between parental and self-completed questionnaires about asthma in teenagers. *Pediatr Allergy Immunol*. 2005;16(2):176-181.
68. Magzamen S., Mortimer K. M., Davis A., Tager I. B. School-based asthma surveillance: a comparison of student and parental report. *Pediatr Allergy Immunol*. 2005;16(8):669-678.
69. Wittich A. R., Li Y., Gerald L. B. Comparison of parent and student responses to asthma surveys: students grades 1-4 and their parents from an urban public school setting. *J Sch Health*. 2006;76(6):236-240.
70. Taggart V. S., Wittich A. R., Yawn B. Comparison of parent and student responses to asthma surveys: 2 different experiences with similar results. *J Sch Health*. 2006;76(6):235.

71. Yawn B. P., Wollan P., Kurland M., Bertram S. Comparison of parent and student responses to asthma surveys: students grades 3-12 and their parents from a suburban private school setting. *J Sch Health*. 2006;76(6):241-245.
72. Juniper E. F., Guyatt G. H., Feeny D. H., Ferrie P. J., Griffith L. E., Townsend M. Measuring quality of life in the parents of children with asthma. *Qual Life Res*. 1996;5(1):27-34.
73. Juniper E. F., Guyatt G. H., Feeny D. H., Ferrie P. J., Griffith L. E., Townsend M. Measuring quality of life in children with asthma. *Qual Life Res*. 1996;5(1):35-46.
74. Qoltech. Measurment of health-related quality of life and asthma control. 2010.
75. Gold M.R., Patrick D.L., Torrance G.W., Fryback D.G., Hadorn D.C., Kamlet M.S., et al. Identifying and Valuing Outcomes. In: Gold M.R., Russell L.B., Siegel J.E., Weinstein W.C., editors. *Cost-Effectiveness in Health and Medicine*. New York: Oxford University Press; 1996.
76. Mandelblatt JS, Fryback DG, Weinstein MC, Russell L.B., Gold M.R., Hadorn D.C. Assessing the Effectiveness of Health Inteventions. In: Gold M.R., Siegel J.E., Russell L.B., Weinstein M.C., editors. *Cost-Effectiveness in Health and Medicine*. New York: Oxford University Press; 1996.
77. Sculpher M. J., Price M. Measuring costs and consequences in economic evaluation in asthma. *Respir Med*. 2003;97(5):508-520.
78. Polsky D., Glick H. Costing and cost analysis in randomized controlled trials: caveat emptor. *Pharmacoeconomics*. 2009;27(3):179-188.
79. Luce B.R, Manning W.G., Siegel J.E., Lipscomb J. Estimating costs in cost-effectiveness analysis. In: Gold M.R., Siegel J. E., Russell L. B., Weinstein M. C., editors. *Cost-Effectiveness in Health and Medicine*. New York: Oxford University Press; 1996.
80. Lee T. A., Fuhlbrigge A. L., Sullivan S. D., Finkelstein J. A., Inui T. S., Lozano P., et al. Agreement between caregiver reported healthcare utilization and administrative data for children with asthma. *J Asthma*. 2007;44(3):189-194.
81. Baumgarten A. Arizona health care market report 2008. In; 2008.
82. Bassen-Engquist K.B., Coyle K., Parcel G.S., Kirby D., Banspach S., Carvajal S.C., et al. Schoolwide effects of a multicomponent HIV, STD, and pregnancy prevention program for high school students. *Health Education and Behavior*. 2001;28:166-185.
83. Coyle K., Basen-Engquist K., Kirby D., Parcel G.S., Banspach S., Collins J.L., et al. Long-term impact of a multi-component school-based HIV, other STD and pregnancy prevention program. *Public Health Rep*. 2001;116:82-93.
84. Gritz E.R., Tripp M.K., James A.S., Carvajal S.C., Harrist R.B., Mueller N.H., et al. An intervention for parents to promote preschool children's sun protection: Effects of sun protection is fun! *Preventive Medicine*. 2005;41:357-366.
85. Bellg A.J., Borrelli B., Resnick B., Hecht J., Minicucci D.S., Ory M., et al. Enhancing treatment fidelity in health behavior change studies: Best practices and recommendations from the NIH behavior change consortium. *Health Psychology*. 2004;23:443-451.
86. Davidson K.W., Goldman M., Kaplan R. M., Kaufmann P.G., Knatterud G.L., Orleans C.T., et al. Evidenced-based behavioral medicine: What is it and how do we achieve it? *Annals of Behavioral Medicine*. 2003;26:161-171.
87. Kraemer H.C., Kuchler T., Spiegel D. Use and misuse of Consolidated Standards of Reporting Trials (CONSORT) Guidelines to assess research findings: Comment on Coyne, Stefanek, and Palmer (2007). *Psychological Bulletin*. 2009;135:173-178.
88. Efron B., Tibshirani R.J. *An Introduction to the Bootstrap.* New York: Chapman and Hall; 1993.
89. Davidson A.C., Hinkley D.V. *Bootstrap Methods and Their Application*. Cambridge: Cambridge University Press; 1997.

90. The American Lung Association Asthma Clinical Research Centers. Randomized Comparison of Strategies for Reducing Treatment in Mild Persistent Asthma. *New England Journal of Medicine*. 2007;356(20):2027-2039.
91. Donner A., Birkett N., Buck C. Randomization by Cluster: Sample size requirements and analysis. *American Journal of Epidemiology*. 1981;114(9):906-914.
92. Juniper E. F., Svensson K., Mork A. C., Stahl E. Measurement properties and interpretation of three shortened versions of the asthma control questionnaire. *Respir Med*. 2005;99(5):553-558.
93. Patton M. *Qualitative research and evaluation methods*. 3rd ed. Thousand Oaks, CA: Sage Publications; 2002.
94. Krippendorff KH. *Content Analysis: An introduction to its methodology*. 2nd ed. Thousand Oaks, California: Sage Publications; 2004.

AMERICAN LUNG ASSOCIATION®
IN ARIZONA

2819 East Broadway
Tucson, AZ 85716
Phone: (520) 323-1812
Fax: (520) 323-1816
www.lungarizona.org

Southern Arizona

January 3, 2011

Lynn B. Gerald, PhD, MSPH
Canyon Ranch Endowed Chair/Professor
Mel and Enid Zuckerman College of Public Health
Arizona Respiratory Center
1295 N Martin Avenue
PO Box 245163
Tucson, AZ 85724-5163

Dear Dr. Gerald,

The American Lung Association in Arizona enthusiastically supports your grant "The Cost-Effectiveness of a Comprehensive School-Based Asthma Screening and Management Program". As you know, we have extensive experience both locally and nationally in implementing asthma screening, management and education programs in elementary schools.

The American Lung Association in Arizona's southern office serves the counties of Cochise, Pima, and Santa Cruz and we are supported by legions of dedicated volunteers, a professional staff and leading experts in lung disease. Our mission is "to save lives by improving lung health and preventing lung disease." We strive to meet our mission through research, education, and public advocacy.

We are excited to be a part of this important project which will answer several important questions identified in the recent ATS workshop on screening for asthma in children by carefully quantifying not only the effects of such a comprehensive intervention, but also its costs. The six components that compose the intervention have all been proven effective in improving asthma outcomes but have not been combined and evaluated in a systematic manner. Furthermore, there are no studies examining the cost-effectiveness of any of these school based interventions. Given limited public health funds to conduct interventions, there are opportunity costs that arise to implementing any intervention. As a non-profit organization whose mission includes promoting lung health, we are very interested in the results of this project.

Our staff is well suited to perform the intervention activities that you have outlined in the proposed application. Ms. Donna Bryson, who is our Lung Health Educator, is a registered nurse with extensive clinical and community experience. She has worked

Fighting For Air

extensively with the Tucson Unified School District in conducting Open Airways for Schools, the ALA's Asthma Education Program. Ms. Bryson will coordinate the intervention activities for the proposed project.

We look forward to collaborating with you and your team on this important project.

Sincerely,

Stacey Mortenson
Executive Director

TUSD
Celebrate the US!

School Health Services
Donna Johnson, RN, BSN
Director
102 North Plumer Street
Tucson, Arizona 85719
(520) 225-3284

January 3, 2011

Lynn B. Gerald PhD, MSPH
University of Arizona
Mel and Enid Zuckerman College of Public Health
1295 N Martin Ave.
PO Box 245163
Tucson, AZ 85724

Dear Dr. Gerald,

We would like to express our enthusiastic support of your proposed project. Asthma is a major health concern for children in our school system and we are excited about collaborating with your team to determine the cost-effectiveness of a comprehensive school-based approach to asthma identification and management. We understand that the program has six major components that include:

1) Identify children with previously diagnosed asthma and make initial assessment of asthma control status.

2) Implement guideline-concordant care under the supervision of an asthma specialist in coordination with the child's primary care provider.

3) Provide comprehensive asthma education.

4) Undertake periodic monitoring of asthma control status.

5) Provide ready access to quick relief medication at school.

6) Provide direct supervision of daily controller therapy at school, if needed.

We agree to work with your team to ensure the implementation of the proposed study and are excited about the potential impacts it may have on the health of our student body. We have had previous successful collaborations with University of Arizona researchers and look forward to this new venture.

We wish you the best of luck in your proposal.

Sincerely,

Donna Johnson, RN, BSN, MA
Director
School Health Services

Conrad Clemens, MD, MPH
Medical Consultant for Tucson Unified School District
Associate Professor of Clinical Pediatrics
Director, Pediatric Residency Program
University of Arizona

STATEMENT OF INTENT

Prime PI: **Lynn Gerald, PhD** Prime Institution: **Arizona Board of Regents, University of Arizona**
Project Title: **: Cost-Effectiveness of a Comprehensive School-Based Asthma Screening and Management Program**

Cooperating Institution: University of Illinois at Chicago
PI Name: **Todd Lee, PharmD, PhD** ERA Commons ID: **toddlee**
Tel: **312-355-5140** Fax: **312-996-0379** Email:**toddlee@uic.edu**
Project Period: **7/1/2011 – 6/30/2015** Direct Costs: **$55,031** F&A Costs: **$31,367**
Performance site: **University of Illinois at Chicago**

Cooperating Institutional Business Contact Information:
Name: **Luis Vargas**
Address: **1737 W. Polk Street, 310 AOB M/C 672 Chicago, IL 60612**
Tel: **312-996-2862** Fax: **312-996-9005** Email: **awards@uic.edu**

Project information:	Yes	No	Assurance#:	Approval Date or Pending:
Human subjects:		X		
Vertebrate animals:		X		
Human Embryonic Stem Cells:		X		
Inventions and Patents: *(for renewal applications)*		X		
Program Income:		X		

Certifications:

In signing below and offering to participate in this research program, the Cooperating Institution certifies that neither they nor their principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from receiving funds from any federal department or agency and are not delinquent on any federal debt; they are in compliance with the Drug Free Workplace Act of 1988; they are in compliance with U.S. Code, Section 1352, restrictions on the use of federal funds for the purpose of lobbying; they have filed annually with the Office of Scientific Integrity a PHS form 6349 governing Misconduct in Science; they have filed with DHHS compliance offices certification forms governing Civil Rights (441), Handicapped Individuals (641), Sex Discrimination (639-A), and Age Discrimination (680); they are in compliance with PHS policy governing Program Income; they have established policies in compliance with 45 CFR Part 46, Subpart A (protection of human subjects); the Animal Welfare Act (PL-89-544 as amended) and the Health Research Exchange Act of 1985 (Public Law 99-158); and that they are in compliance with NIH guidelines regarding human pluripotent stem cell research, transplantation of fetal tissue, recombinant DNA and human gene transfer research, and inclusion of women, children & minorities in research.

The appropriate programmatic and administrative personnel of each institution involved in this grant application are aware of the PHS-NIH consortium grant policies and are prepared to establish the necessary inter-institutional agreements consistent with those policies. In signing below, the Cooperating Institution certifies it has implemented and is enforcing a written policy of conflicts of interest consistent with the provisions of 42 CFR Part 50, Subpart F & 45 CFR Subtitle A, Part 94. If a conflict is identified by the Cooperating Institution during the period of the award contemplated under this agreement, the Cooperating Institution will report to the Prime Awardee the existence of the conflict, including the grant title, PI (if different from the investigator with the financial interest) and the specific method the Cooperating Institution adopts for addressing the conflict (managing, reducing, or eliminating it). The Cooperating Institution will rely on the Prime Awardee to report the existence of the conflict to NIH.

Cooperating Institution Business Official:

Joe G.N. Garcia, MD (Vice Chancellor for Research)
Typed Name & Title

Joe G.N. Garcia, M.D.
Signature

8-4-10
Date

Program Director/Principal Investigator (Last, First, Middle): Lee, Todd

CHECKLIST

TYPE OF APPLICATION *(Check all that apply.)*

☒ NEW application. *(This application is being submitted to the PHS for the first time.)*

☐ RESUBMISSION of application number: _____
(This application replaces a prior unfunded version of a new, renewal, or revision application.)

☐ RENEWAL of grant number: _____
(This application is to extend a funded grant beyond its current project period.)

☐ REVISION to grant number: _____
(This application is for additional funds to supplement a currently funded grant.)

☐ CHANGE of program director/principal investigator.
Name of former program director/principal investigator: _____

☐ CHANGE of Grantee Institution. Name of former institution: _____

☐ FOREIGN application ☐ Domestic Grant with foreign involvement List Country(ies) Involved:

INVENTIONS AND PATENTS *(Renewal appl. only)* ☐ No ☐ Yes
If "Yes," ☐ Previously reported ☐ Not previously reported

1. PROGRAM INCOME ***(See instructions.)***
All applications must indicate whether program income is anticipated during the period(s) for which grant support is request. If program income is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)

2. ASSURANCES/CERTIFICATIONS ***(See instructions.)***
In signing the application Face Page, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the application instructions when applicable. Descriptions of individual assurances/certifications are provided in Part III and listed in Part I, 4.1 under Item 14. If unable to certify compliance, where applicable, provide an explanation and place it after this page.

3. FACILITIES AND ADMINSTRATIVE COSTS (F&A)/ INDIRECT COSTS. See specific instructions.

☐ DHHS Agreement dated: _____ ☐ No Facilities And Administrative Costs Requested.

☐ DHHS Agreement being negotiated with _____ Regional Office.

☒ No DHHS Agreement, but rate established with Office of Naval Research Date 7/1/07

CALCULATION* *(The entire grant application, including the Checklist, will be reproduced and provided to peer reviewers as confidential information.)*

a. Initial budget period:	Amount of base $	13,071	x Rate applied	57.00	% = F&A costs	$	7,450
b. 02 year	Amount of base $	13,603	x Rate applied	57.00	% = F&A costs	$	7,754
c. 03 year	Amount of base $	13,983	x Rate applied	57.00	% = F&A costs	$	7,970
d. 04 year	Amount of base $	14,374	x Rate applied	57.00	% = F&A costs	$	8,193
e. 05 year	Amount of base $		x Rate applied		% = F&A costs	$	
					TOTAL F&A Costs	$	31,367

*Check appropriate box(es):

☐ Salary and wages base ☒ Modified total direct cost base ☐ Other base *(Explain)*

☐ Off-site, other special rate, or more than one rate involved *(Explain)*

Explanation *(Attach separate sheet, if necessary.):*

4. DISCLOSURE PERMISSION STATEMENT: If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)? ☐ Yes ☐ No

STATEMENT OF WORK

Dr. Lee is an Associate Professor in the Departments of Pharmacy Practice, Pharmacy Administration and the Section of Pulmonary, Critical Care, Sleep and Allergy in the Department of Medicine at the University of Illinois at Chicago. In addition, Dr. Lee is a senior investigator at the Center for the Management of Complex Chronic Care (CMC3) at the Hines VA Hospital. Dr. Lee has expertise in economic evaluations of medical interventions to better understand the value of these new interventions. He has extensive experience with economic evaluations conducted alongside clinical trials as well as developing economic models, including decision-tree and Markov health state models. Dr. Lee also has experience in evaluating patient preferences utilizing several different elicitation techniques and was part of the team that developed the Pediatric Asthma Health Outcome Measure which will be used as the primary outcome measure for this cost-effectiveness analysis. Dr. Lee will supervise the cost-effectiveness analysis and work with the PI and Investigators on the data collection protocols for the cost data. These tasks will require 1.2 months effort each year. He will also travel to the University of Arizona once each year to collaborate on study related activities.

Principal Investigator/Program Director (Last, First, Middle):

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Todd A. Lee, PharmD, PhD	Associate Professor
eRA COMMONS USER NAME toddlee	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Drake University, Des Moines, IA	PharmD	1997	Pharmacy
University of Washington, Seattle, WA	PhD	2001	Outcomes Research/ Pharmacoeconomics

A. Personal Statement

The specific aim of the proposed project is to evaluate the cost-effectiveness of a comprehensive school-based asthma screening and management program. I will serve as a co-investigator on this project and provide expertise in the conduct of the cost-effectiveness analysis alongside the clinical trial. I have expertise in economic evaluations of medical interventions aimed at better understand the value of these new interventions. I have extensive experience with economic evaluations conducted alongside clinical trials as well as developing economic models, including decision-tree and Markov health state models. Importantly, I was involved in the cost-effectiveness analysis of the Pediatric Asthma Care PORT which will provide valuable experience for conducting the economic evaluation proposed as part of this study. In addition, I also have experience in evaluating patient preferences utilizing several different elicitation techniques and was part of the team that developed the Pediatric Asthma Health Outcome Measure which will be used as the primary outcome measure for this cost-effectiveness analysis. Given this experience, I am well-suited to collaborate with the study team on the evaluation of the cost-effectiveness of the school-based asthma program.

B. Positions and Honors

Positions and Employment

2001-present Research Scientist, Center for Management of Complex Chronic Care (CMC3), Hines VA Hospital, Hines, IL
2002-2008 Research Assistant Professor, Institute for Healthcare Studies and Division of General Internal Medicine, Northwestern University Feinberg School of Medicine, Chicago, IL
2007-present Director, CMC3 HSR&D Post-Doctoral Fellowship, Hines VA Hospital, Hines, IL
2009-present Associate Professor, Departments of Pharmacy Practice and Pharmacy Administration, University of Illinois at Chicago, Chicago, IL
2009-present Assistant Director, Center for Pharmacoeconomic Research, University of Illinois at Chicago, Chicago, IL

Other Experience and Professional Membership

2005 VA HSR&D Scientific Merit Review Board (SMRB), Chronic Disease Management and Behavioral Processes Review Group, Ad hoc reviewer
2005 VA HSR&D Scientific Merit Review Board (SMRB), Quality Measurement and Effectiveness Review Group, Ad hoc reviewer
2005 Michael Smith Foundation for Health Research, Career Awards, External reviewer
2005 – 2009 VA HSR&D Scientific Merit Review Board (SMRB), Chronic Diseases and Quality Measurement & Effectiveness, Member
2007 AHRQ, Centers for Education and Research in Therapeutics Special Emphasis Panel (CERTs SEP), Reviewer

Honors and Awards

1991 - 1996	Drake University Trustee Scholarship
1997 - 1999	Achievement Rewards for College Scientists (ARCS) Fellowship
1999	Best Contributed Poster Presentation – Student ISPOR 4th Annual International Meeting
1999 - 2001	AFPE – Pre-Doctoral Fellowship
2003	American Foundation for Pharmaceutical Education (AFPE) Scholar and Fellow
2005	Center Director's Award, Midwest Center for Health Services and Policy Research
2007	ISPOR Bernie J. O'Brien New Investigator Award

C. Selected peer-reviewed publications (From a total of 66 publications)

Publications relevant to current application

1. **Lee TA**, Hollingworth W, Sullivan SD. Comparison of directly elicited preferences to preferences derived from the SF-36 in adult asthmatics. *Med Decis Making*. 2003; 23(4): 323-334.
2. Chiou CF, Weaver MR, Bell MA, **Lee TA**, Krieger JW. Development of a multi-attribute pediatric asthma health outcome measure (PAHOM). *Int J Qual Health Care*. 2005; 17(1): 23-30.
3. Pickard AS, Wang Z, Walton SM, **Lee TA**. Are decisions using cost-utility analyses robust to choice of SF-36/SF-12 preference-based algorithm? *Health Qual Life Outcomes*. 2005; 3(11).
4. Sullivan SD, **Lee TA**, Blough DK, Finkelstein JA, Lozano P, Inui TC, Fuhlbrigge AL, Carey VJ, Wagner E, Weiss KB. A multi-site randomized trial of the effects of physician education and organizational change in chronic asthma care: Cost-effectiveness analysis of the Pediatric Asthma Care PORT. *Arch Pediatr Adolesc Med*. 2005; 159(5): 428-434.
5. **Lee TA**, Hacek DM, Stroupe KT, Collins SM, Peterson LR. Three surveillance strategies for vancomycin-resistant enterococci in hospitalized patients: detection of colonization and a cost-effectiveness model. *Infect Control Hosp Epidemiol*. 2005; 26(1): 39-46.
6. **Lee TA**, Fuhlbrigge AL, Sullivan SD, Finkelstein JA, Inui TS, Lozano P, Weiss KB. Agreement between caregiver reported healthcare utilization and administrative data for children with asthma. *J Asthma*. 2007; 44(3): 189-194.
7. Khare RK, Courtney DM, Powell ES, **Lee TA**. Sixty-four slice computed tomography of the coronary arteries: cost-effectiveness analysis of patients presenting to the ED with low risk chest pain. *Ann Emerg Med*. 2008; 15: 623-632.
8. Scheetz MH, Bolon MK, Postelnick M, Noskin GA, **Lee TA**. Cost effectiveness analysis of an antimicrobial stewardship team on blood stream infections: a probabilistic analysis. *J Antimicrob Chemother*. 2009; 63(4): 816-825.

Other recent publications

9. **Lee TA**, Pickard AS, Au DH, Bartle B, Weiss KB. Risk of deaths associated with medications for recently diagnosed chronic obstructive pulmonary disease. *Ann Intern Med*. 2008; 149(6): 380-390.
10. **Lee TA**, Wilke CT, Joo M, Stroupe KT, Krishnan J, Schumock GT, Pickard AS. Outcomes associated with tiotropium use in COPD patients. *Arch Intern Med*. 2009; 169(15): 1403-1410.
11. **Lee TA**, Pickard AS, Bartle B, Schumock GT. Mortality risk in patients receiving drug regimens with theophylline for chronic obstructive pulmonary disease. *Pharmacotherapy*. 2009; 29(9): 1039-1053.
12. Joo MJ, Au DH, Fitzgibbon ML, **Lee TA**. Inhaled corticosteroids and risk of pneumonia in newly diagnosed COPD. *Respir Med*. 2010; 104(2): 246-252.
13. Nielsen R, Johannessen A, Benediktsdottir B, Gislason T, Buist AS, Gulsvik A, Sullivan SD, **Lee TA**. Present and future costs of COPD in Iceland and Norway: Results from the BOLD study. *Eur Respir J*. 2009; 34(4): 850-857.
14. Joo MJ, Au DH, **Lee TA**. Use of spirometry in the diagnosis of COPD and efforts to improve quality of care. *Transl Res*. 2009; 154(3): 103-110.
15. Ogale SS, **Lee TA**, Au DH, Boudreau DM, Sullivan SD. Cardiovascular events associated with ipratropium bromide in COPD. *Chest*. 2010; 137(1): 13-19.

D. Research Support

Ongoing

1RC2HL101618-01	Lee (Co-PI)	9/09 - 8/11

NHLBI
CONCERT-Clinical Effectiveness Research (CONCERT-CER)
The goal of this project is to develop infrastructure for comparative effectiveness studies in patients with chronic obstructive pulmonary disease.
Role: Co-PI

HHSP23320045013XI Hidalgo (PI) 10/08 – 9/10
Department of Defense
Complex chronic care among Tricare beneficiaries: cost effective treatment strategies
The objective of this study is to compare the prevalence and healthcare use of patients with multiple chronic conditions among VA and DOD beneficiaries.
Role: Project Lead Investigator

IIR 08-354 Hynes (PI) 5/09 – 4/12
VA HSR&D
Clinical guidelines for ESA use in cancer: impacts on clinical practice
The objective of this study is to evaluate the impact of clinical practice guidelines on the use of ESA in patients with cancer and to examine the association between ESA use and adverse effects.
Role: Co-Investigator

R21HS017635-01 Jordan (PI) 9/08 – 8/10
AHRQ
Effect of chronic illness complexity on evidence-based depression treatment
The goal of this project is to evaluate the association between multiple chronic conditions and the receipt of evidence-based depression treatment among those with new onset major depressive disorder.
Role: Co-Investigator

RWJ Weiss (PI) 12/07 – 8/10
Characterizing costs and episodes of care
The objective of this project is to create a process for defining episodes of care for chronic illnesses and to estimate costs associated with 20 chronic conditions as test cases for the process.
Role: Co-Investigator

VA HSR&D Jordan (PI) 11/09 – 10/11
Depression care facility-level variation for persons with multimorbidity
The goal of this study is to examine facility and system characteristics associated with provision of evidence-based depression care.
Role: Co-I

IIR 05-293 Lee (PI) 07/06 – 12/10
VA HSR&D
NSAID related adverse events: evaluating risk using clinical information
The objective of this study is to evaluate the impact of clinical enriched datasets when examining the association between NSAID use and adverse events.
Role: PI

IIR 07-178 Lee (PI) 07/10 – 06/12
VA HSR&D
Management and control of co-existing chronic disease in COPD patients
The objective of this study is to evaluate the management and control of key co-existing conditions in patients with COPD and compare the outcomes of patients based on management strategies for the co-existing conditions.
Role: PI

Completed

HHSA290-2005-0038-I-TO4-WA2 Pickard (PI) 11/08 – 12/09
AHRQ
Development of a multicenter prospective study to assess the effectiveness of treatment for COPD
The objective of this project was to develop a prioritized list of comparative effectiveness research topics through stakeholder input and design a prospective study to address the highest ranking priority area.
Role: Project Lead Investigator

IIR 03-307 Lee (PI) 10/04 – 09/07
VA HSR&D
Outcomes assessment associated with salmeterol use in obstructive lung disease
The objective of this study was to evaluate the outcomes associated with salmeterol use in VA patients with asthma and COPD, specifically looking at the risk of mortality in users versus non-users.
Role: PI

HHSA29020050038I-TO4-WA1 Pickard (PI) 8/07 – 12/08
AHRQ
Comparative effectiveness of anticholinergic medications in patients with chronic obstructive pulmonary disease
The goal of this project was to examine the comparative benefits and harms of ipratropium and tiotropium in the management of patients with COPD
Role: Project Lead Investigator

IIR 01-074 Valenstein (PI) 3/04 – 10/06
VA HSR&D
Improving antipsychotic adherence among patients with serious mental illness
This was a multi-site randomized controlled trial of a pharmacy based intervention aimed at improving the overall medication adherence of patients with schizophrenia and bipolar disorder that were previously non-adherent to medication therapy.
Role: Co-I (site PI)

2R01HS008368-07A1
AHRQ Weiss (PI) 9/02 – 3/05
Outcomes assessment in pediatric asthma
The Pediatric Asthma Care Port II study was conducted to test the cost-effectiveness of national asthma care guidelines as implemented via two alternative methods, a peer leader implemented model and a practice redesign implemented model. The project evaluated the effectiveness and cost-effectiveness of the methods tested in a multi-site randomized controlled trial.
Role: Co-Investigator

Resource Sharing Plan

Data sharing. The PI and Investigators of this proposal concur that data sharing is the foundation for many important goals of the scientific community, including encouraging open scientific inquiry, promoting new research, enabling the exploration of topics beyond those originally envisioned by the investigators, and permitting the creation of new datasets by combining data from multiple sources. We agree to make our data available to the scientific community in a timely manner so other researchers can use this resource.

The proposed research will include data from approximately 500 elementary school children with asthma from an urban school district. Information contained will include self-reported demographic and asthma control data from interviews with the children and parents as well as health utilization data from medical claims. Upon completion of data collection and the acceptance for publication of the main findings from the dataset, this database will be made available to other investigators. We are in agreement with NIH data-sharing policy, in that data from human subjects derived from these studies will be shared only if the identity and privacy of the research participants can be protected. De-identification of data will be meticulously completed with awareness that our participants' privacy must be protected in agreement with all applicable laws and regulations. Data will be stripped of identifiers that would permit linkages to individual research participants and will exclude variables that could lead to deductive disclosure of the identity of individual subjects. Even though the final dataset will be stripped of identifiers prior to release for sharing, we believe that there remains the possibility of deductive disclosure of subjects with unusual characteristics. Thus, we will make the data and associated documentation available to users only under a data-sharing agreement that provides for: (1) a commitment to using the data only for research purposes and not to identify any individual participant; (2) a commitment to securing the data using appropriate computer technology; and (3) a commitment to destroying or returning the data after analyses are completed. We have included funds in our budget to create a limited access dataset to be submitted to the NHLBI BioLINCC after completion of the study. Dr. Billheimer (the project statistician) will work with Dr. Gerald and the NHLBI to create the limited access dataset and ensure full compliance with all requirements while preserving the privacy of individual participants.

Dissemination plan. Results of this study will provide important information for dissemination to several key interests groups: scientists/clinicians, school/communities, and health care payers. Study results will be distributed to these groups using different modes of communication. The project will provide a resource manual which contains the information necessary for a school or community to implement the program.

Scientists and clinicians will be reached primarily through presentations at local, regional, and national scientific meetings (such as the American Thoracic Society and American Academy of Asthma, Allergy, and Immunology meetings) as well as publication of journal articles. Journal articles will be deposited into PubMed Central according to the NIH Public Access Policy. To ensure that information reaches the clinical practitioner in addition to the clinical researcher, local and regional meetings will be included as a means of dissemination. Study results will also be available on the Arizona Respiratory Center's web site.

Information will be distributed to *schools and communities* through local and national meetings and professional organizations (such as the American Association of School Administrators, the National Association of School Nurses, Asthma Coalitions, and the American Lung Association) using both presentations and the written distribution of information. School nurses are an important means of dissemination of health information within schools and will be important participants in our plans. The Medical Director for the Tucson Unified School District (Dr. Clemens) and the Director of Health (Ms. Johnson) will assist us in our dissemination efforts to these groups. Dr. Gerald has close ties with the American Lung Association (ALA) at the national, regional, and local levels and will work with their leadership to

distribute information regarding results of the project to their constituency. If the program is successful and proves to be cost-effective, the ALA is the ideal organization to implement the program given its long history of adopting proven effective interventions (i.e. Open Airways for Schools, developed by Dr. Noreen Clark and colleagues at Columbia University and Breathe Well, Live Well developed by Dr. William Bailey and colleagues at the University of Alabama at Birmingham, Lung Health Center).

Sharing of information with *health care payers* will also be a key dissemination effort. Investigators will meet with the leaders of the Arizona Health Care Cost Containment System (AHCCCS), Arizona's Medicaid agency, to share information as a large percentage of the children in this project will be covered by this agency. Investigators also plan to distribute this information to Medicaid and each state's children's health insurance program through presentations at national conferences such as the Medicare and Medicaid Conference or through provision of written materials to health care payers.

Drs. Lynn and Joe Gerald will oversee the dissemination plan and we have included funds in our budget to accomplish the above goals.

PHS 398 Checklist

OMB Number: 0925-0001

1. Application Type:

From SF 424 (R&R) Cover Page. The responses provided on the R&R cover page are repeated here for your reference, as you answer the questions that are specific to the PHS398.

* Type of Application:

☒ New ☐ Resubmission ☐ Renewal ☐ Continuation ☐ Revision

Federal Identifier: GRANT10782520

2. Change of Investigator / Change of Institution Questions

☐ Change of principal investigator / program director

Name of former principal investigator / program director:

Prefix:
* First Name:
Middle Name:
* Last Name:
Suffix:

☐ Change of Grantee Institution

* Name of former institution:

3. Inventions and Patents (For renewal applications only)

* Inventions and Patents: Yes ☐ No ☐

If the answer is "Yes" then please answer the following:

* Previously Reported: Yes ☐ No ☐

4. * Program Income

Is program income anticipated during the periods for which the grant support is requested?

☐ Yes ☒ No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

5. * Disclosure Permission Statement

If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?

☒ Yes ☐ No