BEMSTS Response:

Rob, thanks for the opportunity to respond to this request for AZ-PIERS Data. This project addresses an important clinical and public health issue.

Once the applicant completes the two minor changes outlined below, the application is approved. The signature below allows the steering committee to move forward on the initiative without re-submitting the project to BEMSTS, though we do request a final copy of the initiative.

Request 1: Include a short paragraph in the SPECIFIC AIM section describing the initiative as a joint public health initiative between the Pima County Health Department, the Arizona Department of Health Services' Bureau of Women's and Children's Health and the Office of Children with Special Health Care Needs.

Rationale: While this content is included in the final page, it is better to clarify the joint public health nature of the project at the beginning of the document.

Proposal 1: Schedule a meeting with all the project leadership and analysis team to discuss the AZ-PIERS database. We can meet in person or over the phone.

Signed: ____________________________

Date: ____________________________
Request to Proceed with Project:

Evaluating the impact of stock albuterol program at school for children with asthma

This form is to be used to submit project proposals to the ADHS/U of A Research Collaboration Steering Group. The purpose of this form is to pre-screen your proposal to evaluate feasibility, and whether the data required can be made available within the data sharing agreement before you move ahead with your IRB review(s).

1) Please describe your proposed study. Include anticipated Public Health value of the study. If you already have an IRB review, please attach a copy, otherwise, it will be understood that no IRB review has yet been conducted.

Specific Aims.

In the US, 10% of children have asthma and 60% of these children will experience an exacerbation annually leading to 750,000 emergency department (ED) visits and 200,000 hospitalizations. Asthma leads to 10 million school absences each year. On average, students with asthma experience two more absences per year than students without asthma and some miss much more. Morbidity is higher among low-income and minority students, particularly those residing in urban areas.

National organizations recommend that schools ensure that quick relief medication (short-acting beta agonist, SABA) is readily available to all students with asthma. The National Asthma Education and Prevention Program (NAEPP) also recommends schools allow students to possess and self-administer asthma medications when appropriate. Nevertheless, many students still do not have access. For example, we recently documented that only 20% of students with asthma in a large urban school district had access. Barriers included difficulty obtaining medications from physicians and parents, ensuring school personnel had the requisite knowledge to safely administer SABAs, and having accessible asthma care within the community. Lack of SABA access at school jeopardizes the safety of children with asthma.

Under the supervision of a medical consultant, schools can implement a stock inhaler program, a single SABA inhaler shared among multiple students using a disposable or reusable holding chamber, as a practical solution to increase SABA access and provide a “fail safe” mechanism when students’ personal inhalers are not available. Stock inhalers are feasible, inexpensive, and well-accepted by schools and families; however, there is limited data to support their effectiveness.

We recently implemented a pilot program in two large urban school districts Sunnyside Unified (SUSD) and Tucson Unified School District (TUSD). In addition, we recently received a favorable score (89/100) on a HRSA Maternal and Child Health Bureau Research Program grant to expand and evaluate these programs throughout Pima County; however, reviewers were concerned that we would be unable to obtain from schools the data for our proposed outcomes (911 calls and EMS transports). Therefore, we propose to obtain AZ-PIERS (Arizona Pre-Hospitalization Information and EMS Registry System) data to demonstrate the feasibility of using these outcomes to evaluate the prior implementation of stock inhaler programs in SUSD and TUSD. We propose the following aims:

Aim 1. Use the AZ-PIERS database to identify general and asthma-related 911 calls and EMS transports originating from Pima County schools. We hypothesize that general and asthma-related calls and transports will be associated with school and area characteristics
such as minority enrollment, free or reduced lunch program eligibility, and diesel exposure.

**Aim 2.** Compare asthma-related 911 calls and EMS transports prior to and after stock inhaler program implementation in SUSD and TUSD. We hypothesize that asthma-related calls and transports will be lower in the post-intervention year.

**Aim 3.** Compare asthma-related 911 calls and EMS transports between SUSD and TUSD schools and matched controls. We hypothesize that intervention schools will have fewer calls and transports than non-intervention schools.

Successful completion of these aims will allow us to address reviewer concerns with our HRSA application and resubmit with greater confidence of future funding.

**Significance.**

National organizations recommend that schools ensure that SABAs are readily available to all students with asthma.\textsuperscript{12-16} The National Asthma Education and Prevention Program (NAEPP) also recommends schools allow students to possess and self-administer asthma medications when appropriate.\textsuperscript{14} Nevertheless, many students still do not have access. For example, we recently documented that only 20% of students with asthma in a large urban school district had access.\textsuperscript{17} Lack of SABA access at school jeopardizes the safety of children with asthma.

Under the supervision of a medical consultant, schools can implement a stock inhaler program, a single SABA inhaler shared among multiple students using a disposable or reusable holding chamber, as a practical solution to increase SABA access and provide a "fail safe" mechanism when students' personal inhalers are not available. Stock inhalers are feasible, inexpensive, and well-accepted by schools and families; however, there is limited data to support their effectiveness. We recently evaluated a pilot program in the Sunnyside Unified Schools District and documented a reduction in 911 calls (20% fewer) and EMS transports (40% fewer)\textsuperscript{24}.

The proposed project aligns with two of the AHSC's areas of excellence: Health Disparities and Population Based Health. This project is being conducted in Pima County, an area with high health disparities and limited access to health care, particularly primary care.

**Health Disparities.** Hispanics are the fastest growing ethnic group in the US.\textsuperscript{25} The Census Bureau projects that 25% of the population will identify as Hispanic by 2050 as 40% of the Hispanic population is under 20 years of age.\textsuperscript{26} While this population is geographically, racially and economically diverse,\textsuperscript{25} in Tucson, Mexican-Americans represent the largest Hispanic subgroup. Mexican-Americans are disproportionately represented among the poor and poverty is related to asthma prevalence.\textsuperscript{27} Hispanics are twice as likely to be poor than non-Hispanic whites, 25% versus 13%, respectively.\textsuperscript{28} Educational attainment among Hispanics is also low with 25% of adults having less than a 9th grade education and only 12% holding a Bachelor's degree.

Many Mexican-Americans lack health insurance.\textsuperscript{29} Thirty percent of Hispanics are uninsured compared to 20% of blacks and 10% of non-Hispanic whites.\textsuperscript{28} Currently, 12% of Arizona's children are uninsured compared to a national average of 7%, giving AZ the 3\textsuperscript{rd} highest rate in the country.\textsuperscript{30} Fifteen percent of Arizona's Hispanic children are uninsured compared to 12% nationally.\textsuperscript{31} The Children's Health Insurance Program (SCHIP) provides coverage for many low-income Hispanic children, but Arizona is the only state with an inactive SCHIP.\textsuperscript{32} Because of gaps in health insurance, more than 25% of Hispanics lack a usual source of care including 49% of recent immigrants.

Hispanics with asthma are less likely to be prescribed or adhere to controller medication than other racial/ethnic groups.\textsuperscript{33-35} Mexican-Americans are 40% less likely to use preventative medications than
whites even after accounting for health insurance. Hispanics are also less likely to access asthma specialists as compared to non-Hispanic whites. Those treated for an asthma exacerbation in the emergency department are less likely to receive follow-up care even among children in the Military Health System, which provides comprehensive health insurance to all its members, indicating these differences are not just a matter of having health insurance. Language barriers, lack of health insurance, inadequate health literacy, cultural beliefs, and non-adherence to controller medications may contribute to higher asthma morbidity among Hispanics.

While this proposed project focuses on health disparities among Mexican Americans that are present in Tucson, the proposed intervention can address health disparities in other populations as well. Asthma health disparities are linked to socioeconomic factors which often prevent children from having access to a SABA at school. If proven effective, our proposed intervention can be implemented in schools throughout the country.

Population Health. While stock inhaler programs address health disparities (low-income minority children standing to benefit most), they also address population health as all children are at risk of sudden, unpredictable asthma exacerbations. While low-income, minority children often lack an inhaler to use at school, all children are at risk of forgetting or losing their inhaler. In fact, a recent survey indicated that 86% of children (regardless of income) have at some time been without an inhaler at school. If children do not have access to a SABA at school, schools have no recourse except to active the EMS system.

Innovation.

Under the supervision of a medical consultant, schools can implement a stock inhaler program, a single SABA inhaler shared among multiple students using a disposable or reusable holding chamber, as a practical solution to increase SABA access and provide a “fail safe” mechanism when students’ personal inhalers are not available. However, few schools are currently implementing this simple intervention. The proposed project will allow us to demonstrate the feasibility of using AZ-PIERS data to evaluate this intervention. Our long-term goal is to estimate the impact of stock inhaler use in a variety of schools and develop the evidence to promote widespread adoption of these programs state-wide and throughout the country.

Approach.

The proposed project will use the AZ-PIERS database to collect preliminary data and show proof-of-concept for a resubmission to the HRSA/MCHB Research Program. The AZ-PIERS data will also serve as the final source of evaluation for Aims 2 and 3. As indicated in Section 4, we are asking for annual updates to the AZ-PIERS data through 2018 to allow for a robust evaluation of the stock inhaler program after its final implementation in the TUSD elementary schools in the 2015-2016 school year.

Description of Data Set. AZ-PIERS is a quality assurance initiative developed by the Arizona Department of Health Services to optimize EMS care in Arizona. It was launched in August 2011 and is a free, web-based, pre-hospital registry that gives EMS agencies an ability to generate and transmit electronic Patient Care Reports on scene, in the hospital, or at station. Currently, participation is voluntary and not mandated by the State of Arizona. The system allows EMS agencies to collect and submit the Arizona dataset for quality assurance and to improve the public’s health. The AZ-PIERS dataset is well documented with a 300 page data dictionary. Data can be filtered by geographical area; for this project, we will request all data from Tucson City and Pima County.

Aim 1: Use the AZ-PIERS database to identify general and asthma-related 911 calls and EMS transports originating from Pima County schools. We hypothesize that general and asthma-related calls and transports will be associated with school and area characteristics such as minority enrollment, free or
reduced lunch program eligibility, and presence and training of on-site health personnel. Records for 911 calls and EMS transports from schools will be selected using the “incident location type” variable and verified with the “scene GPS location”, “incident facility name”, and “incident street address” variables. Using the variables, “complaint reported by dispatch”, “problem of complain by patient or report provider”, and “primary symptom”, we will categorize calls as “asthma” or “no asthma”. School characteristics such as minority enrollment, percent free and reduced lunch program availability, and presence and training of on-site health personnel are readily available from school websites or administrators. Records for school-based 911 calls and EMS transports will be tabulated for each school and year, and will be summarized numerically and graphically to characterize distributions and their evolution through time. Exploratory analyses will evaluate associations between school demographics/risk factors and 911 calls and EMS transports.

Aim 2: Compare asthma-related 911 calls and EMS transports prior to and after stock inhaler program implementation in SUSD and TUSD. We hypothesize that asthma-related calls and transports will be lower in the post-intervention year. The AZ-PIERS database was started in 2011. SUSD implemented the stock inhaler program in the school year of 2013-2014. TUSD implemented their stock inhaler program in middle and high schools in 2014-2015 and in elementary schools in 2015-2016. Generalized linear mixed models (GLMMs; e.g., Poisson regression) will be used to evaluate the reduction in 911 calls and transports following stock inhaler implementation. We anticipate that covariates identified in Aim 1, such as % free and reduced lunch, may be important factors for reducing variability in observed data.

Aim 3: Compare asthma-related 911 calls and EMS transports between SUSD and TUSD schools and matched controls. We hypothesize that intervention schools will have fewer calls and transports than non-intervention schools. The GLMM approach will be used to evaluate the 911 call and transport rate reduction between stock inhaler schools and matched controls. Matching will be based on school demographics from Aim 1.

2) Please indicate which data you are requesting access to for your study. Be as detailed as possible to the extent known. Please include which data set, and which data elements you are requesting.

We are requesting the AZ-PIERS from 2011-2018. Data can be filtered by geographical area; for this project, we will request all data from Tucson City and Pima County.

Table 1: ADHS Data Sets Requested

<table>
<thead>
<tr>
<th>DATA SET</th>
<th>YEARS</th>
<th>PII</th>
<th>PHI</th>
<th>Data Elements</th>
</tr>
</thead>
<tbody>
<tr>
<td>AZ-PIERS</td>
<td>2000 - 2015</td>
<td>Y</td>
<td>Y</td>
<td>All available data elements for Tucson City and Pima County including identified data.</td>
</tr>
</tbody>
</table>

In compliance with the AZ-PIERS Data System Rights and Obligations, no individual provider or agency will be identified in the analysis results.

3) Please list all of the persons involved in the study who will have access to the data, and identify the lead investigator:

Lead Investigator: Lynn B. Gerald, PhD, MSPH, Professor/Canyon Ranch Endowed Chair, Health Promotion Sciences Department, Mel & Enid Zuckerman College of Public Health, & Associate Director,
Clinical Research, Asthma and Airways Disease Research Center, University of Arizona - (520) 626-3243 - lgerald@email.arizona.edu

Dean Billheimer, PhD, Professor, Biostatistics, Mel and Enid Zuckerman College of Public Health, & Director, Statistical Consulting Unit, University of Arizona

Don Saner, MS, Associate Chief Knowledge Officer, Senior VP Health Sciences, University of Arizona

Additional investigators who will not directly access the data include:

Joe K. Gerald, MD, PhD, Associate Professor, Public Health Policy and Management, Mel & Enid Zuckerman College of Public Health, University of Arizona.

Francisco Garcia, MD, Director, Pima County Health Department

Mary Ellen Cunningham, Chief, Bureau of Women’s and Children’s Health, Arizona Department of Health Services

Katharine Levandowsky, Chief, Office of Children with Special Health Care Needs

CB2 will act as the Honest Broker in the data transfer. Identifiable data will reside on the Server to which Don Saner and his team as well as Dean Billheimer and a designated analyst have access. Dr. Gerald will not have access to identified data.

U of A, ADHS and PCHD will collaborate on this project through the following:

- Sharing code;
- Sharing the development and review of the project throughout the stages of the analysis;
- Sharing with authorship of the manuscript.

In compliance with the MOU, the data elements and analysis of the data sets provided by ADHS will be limited to the scope of this project and not utilized for other research. The U of A will share progress on project evaluation through brief update reports and/or conference calls with ADHS as determined by the project team.

4) Please indicate how often your study will be requesting data from ADHS, and what options you can accept for secure data transfer.

This is an initial request for AZ-PIERS data from 2011 through the most recently available year. We also request annual updates as they become available up to and including the 2018. The University of Arizona Health Sciences Center (AHSC) has implemented Ipswitch’s MOVEit secure FTP Managed File Transfer system on its server.

5) Please describe the measures your project will have in place to secure and protect the data from unauthorized use, or access by unauthorized persons. You should describe any data encryption measures you plan to use.

UA Information Security (UAIS) is responsible for coordinating the development and dissemination of
information security policies, standards, and guidelines for the University. UAIS is also responsible for coordinating various regulatory compliance efforts as they relate to information technology systems.

The University of Arizona’s Cybersecurity Framework is based on NIST’s Framework for Improving Critical Infrastructure Cybersecurity. The Framework is a risk-based approach to managing cybersecurity risk.

High level statements, equivalent to organizational law, that drive decision making within the University. University policies are subject to a rigorous review process. We will comply with the University of Arizona’s information security policies including:

- Information Security Policy (IS-100)
- Computer and Network Access Agreement (IS-700)
- Acceptable Use of Computers Policy (IS-701)
- Electronic Privacy Statement Policy (IS-1000)
- Data Classification and Handling Standard (IS-2321)

Honest Broker

The Honest Broker will be the Biomedical Informatics Service (BIS) group directed by Don Saner. Mr. Saner is the Associate Chief Knowledge Officer in the Senior VP Health Sciences office at the University of Arizona. He and his team have developed and directed the University-wide services for PHI anonymization at three institutions and maintained HIPAA-compliance computer servers for analysis of limited or identified PHI: The University of Chicago (2009-2014), The University of Illinois at Chicago (2011-2013) and the University of Arizona Health Sciences (2014-present). BIS employs a group of IT professionals who have been designated as Honest Brokers to facilitate the de-identification and transfer of data to researchers in a compliant manner. BIS will designate one dedicated IT professional in addition to Don Saner to have access to the ADHS identified data. Among other entities, BIS currently serves as the Honest Broker for identified University of Arizona Health Plan claims and enrollment data and identified Banner University Medical Center EMR data.

BIS has established a Secure Analysis Server (Server) which is running 64 bit RedHat Linux, with 16 cores, 64 GB Ram and 1 TB of disk space. The Server is running in a virtualized environment which will permit expansion of cores, ram and disk space as needed. Authentication will be performed using the University’s Centralized CATNET Active Directory. Authorization to access data sets will be performed utilizing groups (roles) locally on the Server. Users of the server will be given access to the minimum necessary data sets required for their projects. In order to ensure availability of the computational resources of the server, scheduling software has been installed which will queue long running analyses.

All access to data will be logged on the server at the file level and will be monitored regularly to ensure compliance with Server utilization policies. Disk-based backup of the Server is implemented with data from the Server being isolated from other data to facilitate easy destruction of the data per any data use agreements.
Appendix A – References:


