ARIZONA DEPARTMENT OF HEALTH SERVICES BUREAU OF EMERGENCY MEDICAL SERVICES AND TRAUMA SYSTEM

Data & Quality Assurance Section

Data Request Packet

Issue 1.0

February 2, 2012

TO SERVE IN EVALUATING THE ARIZONA EMS AND TRAUMA SYSTEM THROUGH THE COLLECTION, ANALYSIS, AND CONTROLLED RELEASE OF DATA

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February 2, 2012 **Issue 1.0**

PART I
DATA & QUALITY ASSURANCE SECTION HISTORY & MISSION

The Data and Quality Assurance (DQA) Section was established as a distinct operating section of the Arizona Department of Health Services (ADHS) Bureau of EMS and Trauma System (BEMSTS) in 2006 when the BEMSTS implemented the Premier EMS Agency Program (PEAP), a statewide quality assurance initiative (discussed more fully below). The administrative structure of the DQA Section includes a section chief, a state trauma registry manager, an EMS and trauma care biostatistician, and an EMS and trauma data manager. *Diagram–1* depicts the DQA Section hierarchy within the BEMSTS administrative structure. The DQA Webpage link is: http://www.azdhs.gov/bems/DQA.htm

DQA SECTION MISSION STATEMENT:

The mission of the DQA Section is:

"To Serve in Evaluating the Arizona EMS and Trauma System through the Collection, Analysis, and Controlled Release of Data"

PART II
DATA AND QUALITY ASSURANCE SECTION STAFFING

The following BEMSTS staff members comprise the DQA Section:

SECTION CHIEF:

Dr. David James Harden, JD, NREMT-B
DQA Section Chief
Ph. (602) 364-3188
Fx. (602) 364-3568
hardend@azdhs.gov

Profile:

Dr. David James Harden holds a Juris Doctor from Trinity University School of Law, a Bachelor of Science in Public Health from California State University – Long Beach, and an NREMT-Basic certification. Dr. Harden has more than 25 years experience in prehospital- and hospital-based emergency medicine including for an EMS 9-1-1 System ambulance, county EMS system administration, poisoning management and prevention at the University of California Irvine Regional Poison Control Center, and cardiac monitoring at a Level-I Trauma Center. Dr. Harden's tenure with the ADHS includes seven years in the Bureau of EMS and Trauma System, initially as the Trauma Registry Manager, then the Trauma System Coordinator, EMS and Trauma Data and Quality Assurance Manager, and presently as the DQA Section Chief.

EMS AND TRAUMA DATA BIOSTATISTICIAN:

Vatsal Chikani, MPH
Ph. (602) 364-3191
Fx. (602) 364-3568
chikanv@azdhs.gov

Profile:

Vatsal Chikani holds an MPH from Northern Illinois University, DeKalb, Illinois. She also holds a Bachelor of Homeopathic Medicine and Surgery (Physician in Alternative Medicine) from C.M.P.H. Medical College, Mumbai, India. Ms. Chikani is a Biostatistician at the BEMSTS, providing assistance to internal and external entities regarding research and statistical analysis, managing databases, designing questionnaires and survey instruments, data cleaning, linking and manipulating datasets to monitor data collection, developing analysis plans and research strategies. She provides advanced statistical analysis of quantitative data using SAS/SPSS. Ms. Chikani has experience working with large population-based studies and has published several manuscripts on chronic diseases as a first author, coordinated a number of major research and statistical projects on chronic diseases, children with special health care needs, cardiac arrest, and stroke.

EMS AND TRAUMA DATA EPIDEMIOLOGIST:

Odalys Colon-Rentas, MS
Ph. (602) 364-3165
Fx. (602) 364-3568
colono@azdhs.gov

Profile:
Odalys Colon-Rentas holds a Masters in Statistics from ASU and a BS in Mathematics from the University of Puerto Rico. Her background in public health includes application of two statistical surveillance methods on the 2010 Dengue Fever epidemic in Puerto Rico, and working for the Mathematical and Theoretical Biology Institute. As the EMS and Trauma Data Epidemiologist, Odalys provides advanced statistical analysis of quantitative data to facilitate data requests submitted to the DQA Section, increase the DQA Section's data reporting and analysis capabilities and expand the Bureau's capabilities to utilize EMS and trauma data to lead the Bureau's efforts in system-wide quality improvement, treatment protocol development and evaluation, injury prevention, and collaborative data integration with the Governor's Office of Highway Safety and the Arizona Department of Transportation.

STATE TRAUMA REGISTRY MANAGER:

Anita Ray Ng, BA
Ph. (602) 542-1245
Fx. (602) 364-3568
raya@azdhs.gov

Profile:

Anita Ray Ng holds a Bachelor of Arts in Psychology and a minor in Spanish from Arizona State University, and completed the graduate-level Public Health Epidemiology Certification program from Arizona State University, W.P. Carey School of Business. Her 12-year tenure with the State of Arizona includes three years with the Department of Economic Security and nine years with the ADHS. At ADHS, her first four years were in the Newborn Screening Program, and for the past five years she has served in the BEMSTS as the Arizona State Trauma Registry Manager. As the State Trauma Registry Manager, Anita serves as the primary liaison with Arizona trauma centers to ensure conformance with data collection/reporting regulations, and data reporting accuracy by implementing comprehensive validation processes and data entry specifications. She also oversees software processes and upgrades, and coordinates the Trauma Registry User Group (TRUG) that meets quarterly.

EMS AND TRAUMA DATA MANAGER:

Anne Vossbrink, MS, BS
Ph. (602) 364-3164
Fx. (602) 364-3568
vossbra@azdhs.gov

Profile:
Anne Vossbrink holds a Master of Science in Microbiology from Arizona State University, a Bachelor of Arts in International Affairs from Northern Arizona University. She also completed the graduate-level Public Health Epidemiology Certification program from Arizona State University, W.P. Carey School of Business. Ms. Vossbrink has more than ten years experience in public health as an Infectious Disease Epidemiologist, a Public Health Scientist with the Arizona State Laboratory, and for the past two years has been working as the DQA Section's EMS and Trauma Data Manager. Ms. Vossbrink's publications include: *Public Health Surveillance for Coccidioidomycosis in Arizona*, Vossbrink et al, Annals of the New York Academy of Sciences, Volume 1111, pp. 96 – 102, September 2007. Coccidioidomycosis Sixth International Symposium.

PART III
DATA COLLECTION & SUBMISSION

ASTR DATA COLLECTION:

Presently, trauma data are the only data being collected by the DQA Section. The collection of EMS data will be added to the DQA Section's responsibilities after the Statewide EMS Database becomes fully operational in early 2011.
Designated trauma centers are required to submit and non-designated facilities may submit records of patients who satisfy the following trauma registry inclusion criteria specified in Title 9, Ch. 25, Article 14, § R9-25-1402(A) of the Arizona Administrative Code:

1. A. A patient with injury or suspected injury who is triaged from a scene to a trauma center or ED based upon the responding EMS provider's trauma triage protocol;
   B. A patient with injury who is transported via EMS transport from one acute care hospital to another acute care hospital; or
2. A patient with injury or suspected injury for whom a trauma team activation occurs; or
3. A patient with injury who
   A. Is admitted as a result of the injury or who dies as a result of the injury, who has an ICD-9-CM N-code within categories 800 through 959, and who does not only have:
      a. Late effects of injury or another external cause, as demonstrated by an ICD-9-CM N-code within categories 905 through 909;
      b. A superficial injury or contusion, as demonstrated by an ICD-9-CM N-code within categories 910 through 924;
      c. Effects of a foreign body entering through an orifice, as demonstrated by an ICD-9-CM N-code within categories 930 through 939;
      d. An isolated femoral neck fracture from a same-level fall, as demonstrated by:
         i. An ICD-9-CM N-code within category 820; and
         ii. An ICD-9-CM E-code within category E885 or E886;
      e. An isolated distal extremity fracture from a same level fall, as demonstrated by:
         i. An ICD-9-CM N-code within categories 813 through 817 or within categories 823 through 826; and
         ii. An ICD-9-CM E-code within category E885 or E886;
   f. An isolated burn, as demonstrated by an ICD-9-CM N-code within categories 940 through 949.

The Arizona State Trauma Registry Rules and the Guide to Trauma Patient Inclusion Criteria can be retrieved from the following respective links on the BEMSTS: Trauma Registry Rules

There are 168 required data elements (the ASTR Full Dataset) that designated Levels I, II, and III trauma centers must collect and submit (Level IV trauma centers may also submit the ASTR Full Dataset). The 168 data elements for Level I Trauma Centers includes AIS 2005 and 164 data elements for non-Level I hospitals submitting the full data set does not include AIS 2005. There are 40 required data elements (the ASTR Reduced Dataset) that designated Level IV trauma centers are required to collect and submit; non-designated facilities may collect and submit. The Required Data Elements (ASTR Full and Reduced) and their respective data dictionaries are available on the BEMSTS website:

ASTR 2008-2010 Required Data Elements;

ASTR Full Dataset 2008-2010 Data Dictionary;

ASTR Reduced Dataset 2009-2010 Data Dictionary

Trauma data records from ASTR-participating hospitals are collected on a quarterly basis. Participating hospitals are required to submit their respective trauma data no later than 90 days of the close of the immediately preceding quarter. The ASTR data submission guidelines and the ASTR export instructions can be retrieved from the following respective links on the BEMSTS website:

The ASTR Data Submission Guidelines;

ASTR Export Instructions

PART IV
REQUESTING BUREAU OF EMS & TRAUMA SYSTEM DATA

CONFIDENTIALITY STATEMENT AND OTHER DATA REQUEST FORMS:

All requests for data from the following databases/registries must be made using the DQA Section Data Request Forms and signed Confidentiality Statements:

- Arizona State Trauma Registry (ASTR);
- Arizona Prehospital Information & EMS Registry System (AZ-PIERS) – data availability pending;
- STEMI Database;
- Out-of-Hospital Cardiac Arrest (OHCA) Database;
- Stroke Database (data availability pending)

All individuals seeking data from any of the above listed databases/registries must complete and sign the applicable data request form, confidentiality statement, and Public Records Request Form. If the requested data will be used for commercial purposes, the Public Records Request Form must also be signed by a Notary Public in the prescribed section.

Appendix – B of this Guidebook includes the DQA Section Data Request Packet, containing all of the necessary data request forms, confidentiality statements, and hyperlinks to download HSRB documents for the requesting party to submit requests for data.

Requests for data that contain non-de-identified protected health information (PHI) must also be approved by the ADHS Human Subjects Review Board (HSRB) before the DQA Section Chief can approve the request. HRSB forms are included in Appendix – C of this Guidebook. Complete instructions, contacts, policies, and on-line forms are available at the ADHS/Office of Administrative Counsel & Rules website.

APPENDIX – A
DQA SECTION DATA REQUEST FORMS

ARIZONA DEPARTMENT OF HEALTH SERVICES/BUREAU OF EMS AND TRAUMA SYSTEM

DATA & QUALITY ASSURANCE (DQA) SECTION DATA REQUEST FORM

Mail /Fax Completed Form To:

Arizona Department of Health Services/Bureau of EMS & Trauma System
Attn: DQA Section Chief
150 N. 18th Avenue, Suite 540, Phoenix, AZ 85007-3248
Phone: (602) 364-3188 Fax: (602) 364-3568

REQUEST DATE INFORMATION	
Date of Request:	Date Report Needed:

DATA CATEGORY REQUESTED			
☐ **TRAUMA DATA**	☐ **EMS DATA (Pending)**	☐ **STEMI DATA**	☐ **OHCA DATA**
☐ Non-Confidential Aggreg.	☐ Non-Confidential Aggreg.	☐ Non-Confidential Aggreg.	☐ Non-Confidential Aggreg.
☐ Non-Confidential Pt. Level	☐ Non-Confidential Pt. Level	☐ Non-Confidential Pt. Level	☐ Non-Confidential Pt. Level
☐ Confidential Pt. Level	☐ Confidential Pt. Level	☐ Confidential Pt. Level	☐ Confidential Pt. Level

REQUESTOR'S INFORMATION			
☐ Hospital Researcher	☐ Univ. Researcher	☐ ADHS Researcher	☐ Other Govt. Agency
☐ Public Request	☐ Other (Specify):		

Requestor's Name:	Title:	
Requesting Agency:	Phone:	Fax:
Address:	Email:	

TYPE OF INFORMATION REQUESTED	
Data Elements/Date Range/Report Requested (Please list all data elements/report requested for the applicable data registries:	
Trauma Registry:	Date Range:
EMS Registry: (Still in Production)	Date Range:
STEMI Registry:	Date Range:
OHCA Registry:	Date Range:

PREFERRED METHOD OF RECEIPT		
☐ Mail	☐ Fax	☐ Email/Electronic

Purpose of Data Request *(attach additional pages as needed)*:

Intended Use of Report *(attach additional pages as needed)*:

Signature of Requestor:

DQA SECTION ADMINISTRATION USE ONLY		
Date Request Received:	Report Prepared By:	Approved: ☐ Yes ☐ No
Reason Request Disapproved:		
DQA Section Chief Name: Dr. David James Harden, JD, BS, NREMT-B		
DQA Section Chief Signature:		
Date Report Sent:	DQA Section Staff Signature:	

Data may be used only for purposes stated in this request. Any changes in planned use of data must be re-submitted for ADHS approval.

EMS and Trauma System data are confidential pursuant to ARS §§ 36-2220 and 36-2403.
Data analysis is limited to the accuracy of data submitted and the number of providers reporting to the Registry. The statistics are generated from patients meeting criteria for inclusion in the registry. For further information, please contact the Data Registry Manager.

ARIZONA DEPARTMENT OF HEALTH SERVICES/BUREAU OF EMS AND TRAUMA SYSTEM
DATA AND QUALITY ASSURANCE (DQA) SECTION
INTERNAL DATA REQUEST FORM

This is a request for electronic data. All identifying information will be kept confidential in accordance with A.R.S. §36-2220. Publications using these data will be discussed with the program prior to submission.

REQUEST DATE INFORMATION			
Date of Request:		Date Report Needed:	
DATA CATEGORY REQUESTED			
☐ **TRAUMA DATA**	☐ **EMS DATA (Pending)**	☐ **STEMI DATA**	☐ **OHCA DATA**
☐ Non-Confidential Aggreg.	☐ Non-Confidential Aggreg.	☐ Non-Confidential Aggreg.	☐ Non-Confidential Aggreg.
☐ Non-Confidential Pt. Level	☐ Non-Confidential Pt. Level	☐ Non-Confidential Pt. Level	☐ Non-Confidential Pt. Level
☐ Confidential Pt. Level	☐ Confidential Pt. Level	☐ Confidential Pt. Level	☐ Confidential Pt. Level
Will this be a continuing request for data?	☐ Yes ☐ No	If yes, please send updated version every:	
REQUESTOR'S INFORMATION			
Requesting Program/Office:			
Requestor's Name:		Phone:	
Title:		Email:	
TYPE OF INFORMATION REQUESTED			
Data Elements/Date Range/Report Requested (Please list all data elements/report requested for the applicable data registries:			
Trauma Registry:	All Identifiers Needed: ☐ Yes ☐ No	Date Range:	
EMS Registry: (Still in Production)	All Identifiers Needed: ☐ Yes ☐ No	Date Range:	
STEMI Registry:	All Identifiers Needed: ☐ Yes ☐ No	Date Range:	
OHCA Registry:	All Identifiers Needed: ☐ Yes ☐ No	Date Range:	
PREFERRED FORMAT (SELECT ONE)			
☐ DBF	☐ MS Access	☐ MS Excel	☐ ASCII
☐ Other (Specify):			
Purpose of Data Request *(attach additional pages as needed)*:			
Intended Use of Report *(attach additional pages as needed)*:			
Data will be destroyed/ returned by:		Procedure used to destroying the data:	
If data to be destroyed, a signed Certificate of Data Destruction must be submitted to the DQA Section Chief			
I agree that all data provided will be used solely by the requesting program for the purpose requested and will not be shared. I certify that all data will be destroyed or returned by the date listed above.			
Signature of Requestor:		Date:	
DQA SECTION ADMINISTRATION USE ONLY			
Date Request Received:	Report Prepared By:	Approved: ☐ Yes ☐ No	
Reason Request Disapproved:			
Date Report Sent:	Data Registry Manager Signature:		
DQA Section Chief Signature:		Date:	
BEMSTS Bureau Chief Signature:		Date:	

Data may be used only for purposes stated in this request. Any changes in planned use of data must be re-submitted for ADHS approval.
EMS and Trauma System data are confidential pursuant to ARS §§ 36-2220. Data analysis is limited to the accuracy of data submitted and the number of providers reporting . The statistics are generated from patients meeting criteria for inclusion in the registry. For further information, please contact the Data Registry Manager.

Please send a signed copy back to the Requesting Party

Arizona Department of Health Services

Public Records Request Form

Date of Request:

To be Completed by ADHS Employee Processing Request

Employee Processing Request:	
Name:	**Phone Number:**
ADHS Division/Bureau/Office or Program Providing Records:	

To be Completed by Requesting Party

Individual Requesting:	**If applicable, name of agency, company, department, etc. requesting records:**
Records requested to be copied or reproduced (specifically identify):	
These records are to be used for the following purpose(s):	
Will the records be used for commercial purposes? ☐ **Yes** ☐ **No**	

Signature of Requesting Party **(Sign in the presence of a Notary if the records will be used for commercial purposes.)** **Date**

To be Completed by a Notary if Records will be used for Commercial Purposes

I,_____, do hereby certify that _____
(name of notary) **(name of requesting party)**

personally appeared before me and affirmed the contents of the above request. In witness whereof, I have signed and affixed my official seal this _____ day of _____, _____.

Signature
Notary Public in and for the County of _____, State of _____.

My commission expires on the _____ day of _____, _____.

To be Completed by ADHS Employee Processing Request

Estimated net monetary gain expected from the use of these records will be as follows (if applicable):	**$**
Cost to the State for obtaining the original document or information contained in the document:	**$**
Value of reproduction on the commercial market, if known, or an estimated value, if not known:	**$**
In the program's opinion, is the proposed purpose a misuse of the record or abuse of the right to receive the record? If so explain below:	

ARIZONA DEPARTMENT OF HEALTH SERVICES/BUREAU OF EMS AND TRAUMA SYSTEM

DATA AND QUALITY ASSURANCE (DQA) SECTION RESEARCH/DATA REQUEST PUBLIC-USE DATA AGREEMENT

It is of utmost importance to protect the privacy of patients that have been reported to the various data registries of the Arizona Department of Health Services (ADHS) Bureau of EMS and Trauma System (BEMSTS). Every effort has been made to ensure the confidentiality of the Data Registry patient records via exclusion of identifying information from the computer files. Certain demographic information such as sex, race, etc. has been included for research purposes. Published research results MUST be presented in a manner which ensures that no individual can be identified. Users shall not attempt to identify individuals from any computer file nor shall they link with a computer file containing patient identifiers. All Identifying information will be kept confidential in accordance with A.R.S. §§36-2220 and 36-2401 et seq., and HIPAA.

IN ORDER FOR THE BEMSTS TO PROVIDE A PUBLIC-USE OR ANOTHER VERSION OF THE REQUESTED DATA, THE REQUESTOR MUST AGREE TO THE FOLLOWING PROVISIONS:		
1	The Requestor will not use nor permit others to use the data in any way other than those identified in the request form which stated the purpose and intended use.	
2	The Requestor will not present/publish data in which an individual can be identified.	
3	The Requestor will not attempt to link nor permit others to link the data with individually identified records in another database.	
4	The Requestor will not attempt to learn the identity of any person whose EMS data is contained in the supplied file(s).	
5	If the identity of any person is discovered inadvertently, the following must be done:	
	A	No use will be made of this knowledge,
	B	The BEMSTS Data & Quality Assurance Section Chief will be notified of the incident,
	C	No one else will be informed of the discovered identity.
6	The Requestor will not release nor permit others to release the data in full or in part to any person except with the written approval from the Arizona State EMS Data Registry.	
7	If accessing the data from a centralized location on a time-sharing computer system, LAN, or another statistical package, you will not share your logon name and password with any other individuals. You will also not allow any other individuals to use your computer account after you have logged on with your logon name and password.	
8	The source of information should be cited in all publications in the following format:	
	EMS Data	"Source: Arizona State EMS Data Registry, YYYY". ("YYYY" = 4-digit year of the data or range of years for multiple years.)
	Trauma Data	"Source: Arizona State Trauma Registry, YYYY". ("YYYY" = 4-digit year of the data or range of years for multiple years.)
	STEMI Data	"Source: Arizona State STEMI Data Registry, YYYY". ("YYYY" = 4-digit year of the data or range of years for multiple years.)
	OHCA Data	"Source: Arizona State Out of Hospital Cardiac Arrest Data Registry, YYYY". ("YYYY" = 4-digit year of the data or range of years for multiple years.)

THE REQUESTOR'S SIGNATURE INDICATES THAT HIS/HER AGREEMENT TO COMPLY WITH THE ABOVE STATED PROVISIONS.	
Requestor's Signature:	Date:
PLEASE FAX THIS SIGNED AND DATED AGREEMENT TO: THE DQA SECTION CHIEF 602-364-3568	

DQA SECTION USE ONLY			
Data Registry Manager Name:			Date:
DQA Section Chief Signature:			Date:
REQUEST TYPE			
☐ **TRAUMA DATA**	☐ **EMS DATA (Pending)**	☐ **STEMI DATA**	☐ **OHCA DATA**
☐ Non-Confidential Aggreg.	☐ Non-Confidential Aggreg.	☐ Non-Confidential Aggreg.	☐ Non-Confidential Aggreg.
☐ Non-Confidential Pt. Level	☐ Non-Confidential Pt. Level	☐ Non-Confidential Pt. Level	☐ Non-Confidential Pt. Level
☐ Confidential Pt. Level	☐ Confidential Pt. Level	☐ Confidential Pt. Level	☐ Confidential Pt. Level

ARIZONA DEPARTMENT OF HEALTH SERVICES/BUREAU OF EMS AND TRAUMA SYSTEM

DATA & QUALITY ASSURANCE (DQA) SECTION
DATA CONFIDENTIALITY AGREEMENT & USER AFFIRMATION STATEMENT

Mail /Fax Completed Form To:

Arizona Department of Health Services/Bureau of EMS & Trauma System
Attn: DQA Section Chief
150 N. 18th Avenue, Suite 540, Phoenix, AZ 85007-3248
Phone: (602) 364-3188 Fax: (602) 364-3568

I have been made aware and understand that all individuals who are approved to have access to the Arizona Department of Health Services (DHS) data are bound by applicable laws, rules and DHS directives and are responsible for DHS data.

I agree to abide by all applicable laws, rules and DHS directives, and I pledge to refrain from any and all of the following:

1. Revealing DHS data to any person or persons outside or within DHS who have not been specifically authorized to receive such data.
2. Attempting or achieving access to DHS data not germane to my mandated job duties or contract specifications.
3. Entering/altering/erasing DHS data for direct or indirect personal gain or advantage.
4. Entering/altering/erasing DHS data maliciously or in retribution for real or imagined abuse, or for personal amusement.
5. Using DHS workstations, printers, and/or other equipment for other than approved purposes.
6. Using another person(s) personal logon ID and password.
7. Revealing my personal logon ID and password to another person.
8. Asking another person to reveal his/her personal DHS logon ID and password.

In relation to my responsibilities regarding the proprietary rights of the authors of computer software utilized by DHS, I recognize that:

1. DHS licenses the use of computer software from a variety of outside companies. DHS does not own this software or its related documentation and, unless authorized by the software developer, does not have the right to reproduce it.
2. When used on a local area network or on multiple machines, employees or contractors shall use the software in accordance with the license agreement.
3. Employees or contractors who know of any misuse of software or related documentation within the agency shall notify the appropriate manager or supervisor, or the Department security administrator.
4. Employees or contractors making, acquiring or using unauthorized copies of computer software, or using personal non-DHS software are subject to punitive action in accordance with agency guidelines and applicable contract provisions appropriate to the circumstances.
5. According to U. S. Copyright Law, 17 USC Sections 101 and 506, illegal reproduction of software can be subject to criminal damages up to $250,000 and/or up to 5 years imprisonment.
6. In the event that an employee is sued or prosecuted for the illegal reproduction of software, he/she will not be represented by the Department of the Attorney General.
7. Contractors working for DEPARTMENT are responsible for penalties arising from their acts or omissions in the performance of work for the State of Arizona and are subject to exclusion as an accepted vendor for a contractor's violation of this policy.

Appropriate action will be taken to ensure that applicable federal and state laws, regulations, and directives governing confidentiality and security are enforced. A breach of procedures which occur pursuant to this policy or misuse of Department property including computer programs, equipment, and/or data, may result in disciplinary action including dismissal, and/or prosecution in accordance with any applicable provision of law including Arizona Revised Statutes, Section 13-2316.

My signature below confirms that I have read this form and accept responsibility for adhering to all applicable laws, rules, and DHS directives. Failure to sign this statement will mean that I will be denied access to DHS data, computer equipment, and software.

NAME ***(Last, First, M.I.)*** **PRINT OR TYPE**	**SIGNATURE**	**PHONE**	**DATE**
NAME OF SUPERVISOR ***(Last, First, M.I.)***	**SIGNATURE**	**PHONE**	**DATE**

Intended for use only in the BEMSTS Quality Assurance Process

ARIZONA DEPARTMENT OF HEALTH SERVICES/BUREAU OF EMS AND TRAUMA SYSTEM

DATA & QUALITY ASSURANCE (DQA) SECTION
CERTIFICATE OF DESTRUCTION FORM

Mail /Fax Completed Form To:

Arizona Department of Health Services/Bureau of EMS & Trauma System
Attn: DQA Section Chief
150 N. 18th Avenue, Suite 540, Phoenix, AZ 85007-3248
Phone: (602) 364-3188 Fax: (602) 364-3568

DAT/REQUEST RELATED INFORMATION		
Data Request PIN #:	Study Name:	
PRINCIPAL REQUESTOR INFORMATION		
Investigator's Name:	Title:	
Investigator's Agency:	Phone:	Fax:
Address:	Email:	
TYPE OF DOCUMENT OR MEDIUM OF DATA		
Paper Printed Report:	Electronic via SFTP:	Electronic File via CD-R, Disk:
Other Method/Medium (Describe):		
DATE, TIME, AND METHOD OF DESTRUCTION		
Date:	Time:	
Method:		
INVESTIGATOR'S SIGNATURE		
DQA Section Staff Signature:	Date:	

APPENDIX – B

ADHS
HUMAN SUBJECTS REVIEW BOARD
(HSRB) PACKET

SECTION I. GENERAL ADMINISTRATION

PART 4 HUMAN SUBJECTS REVIEW BOARD PROCEDURES

1. Charge

The Arizona Department of Health Services (ADHS) Human Subjects Review Board (HSRB) is charged to formally review study proposals/protocols and requests for ADHS data from any entity. The HSRB will approve or disapprove such proposals/protocols/requests on the basis of protection of the human subjects' privacy, maintenance of data confidentiality and personal safety from any test, procedure or interview. The HSRB will neither review funding needs nor scientific merit nor make recommendations in these areas, which are the primary responsibility of the submitting organization.

2. Duration

The HSRB shall run concurrent with ADHS or until terminated by the Director, Arizona Department of Health Services (ADHS).

3. Membership

The HSRB shall be comprised of a Chairperson and at least five ADHS members, but no more than one member from any service unit. The exception is the Assistant Registrar and **a representative from the Office of Administrative Counsel and Rules, Division of Operations**. The term membership shall be specified by the Director of ADHS. **The HSRB shall have at least one community member and a designated alternate to serve on the Board.**

4. Definitions

Unless otherwise defined, the terms set forth below shall have the following meanings:

A. "Board" means the ADHS, Human Subjects Review Board (HSRB).

B. "Department" means the Arizona Department of Health Services (ADHS).

C. "Human subject" means any individual living or dead about whom an investigator (whether professional or student) conducting research obtains:
   1. data through intervention or interaction with the individual, or
   2. identifiable private information.

D. "Institution" means any corporation, organization or entity seeking approval for ADHS data use or a research project from the HSRB.

E. "Interaction" includes communication or interpersonal contact between investigator and subject.

F. "Intervention" includes both physical procedures by which data is gathered and manipulations of the subject or subject's environment that are performed for research purposes.

G. "Legally authorized representative" means an individual or group authorized to present a proposed study protocol or seek data for approval from the HSRB.

H. "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

I. "Private information" includes information about behavior that is obtained in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g. a medical record, birth or death certificate). Private information must be individually identifiable so that the identity of the subject is or may readily be ascertained by the investigator, or associated with the information in order to obtain the information to constitute research involving human subjects.

J. "Protocol" means a plan detailing the purpose, methods, and expected results of a specific research study or project.

K. "Research" means any systematic investigation, evaluation or study designed to develop or contribute to general knowledge.

L. "Rules" shall mean all administrative rules adopted by the ADHS pursuant to the Arizona Administrative Procedures Act, 1986 A.R.S. Title 41, Chapter 6 and the Protection of Human Subjects, 4S CFR 46 revised April 1, 1977 as appropriate.

M. "Secretary" means the Secretary of the United States Department of Health and Human Services (HHS) and any officer or employee to whom authority to do business has been delegated.

5. Purpose of the Board

The HSRB is formed pursuant to the provisions of Section 474 of the National Research Act (Public Law 93-348) and Regulations (45 CFR 46.101. et. seq.) , to review biomedical and behavioral research involving human subjects conducted, funded, sponsored or using data collected and maintained by the ADHS in order to protect the rights of the human subjects of such research.

6. Nature of Research Requests to be Reviewed

All scientific or behavioral studies or investigations and use of data maintained by the ADHS shall be considered under the purview of the HSRB. This means all new projects developed by ADHS personnel and all outside requests for data but not necessarily projects submitted for funding under state or federal programs unless specifically requested by the funding organization and accepted by the HSRB.

The Chairperson shall assign projects to be reviewed by a Primary Reviewer. The reviewer will submit a Summary Form to the Chairperson with their recommendations.

7. Meetings

The Board shall meet at least quarterly at such time and place determined by the Chairperson. The Chairperson may also convene as many meetings as is necessary to conduct reviews of research submitted or conduct any other business coming before the Board.

A. Notice of Board Meetings.
The Chairperson shall determine the time and place of each meeting and provide written notice two calendar weeks before the meeting or as agreed to in the prior meeting.

B. Agenda

An agenda shall be provided and furnished to each Board member along with copies of proposed projects/protocols or data requests to be considered at the meeting.

C. Board Records

The HSRB shall prepare and maintain adequate documentation of all HSRB activities, including the following:

1. Copies of all research proposals reviewed, scientific evaluation, if any, that accompany proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
2. Copies of correspondence related to submission, approval or denial of a project.
3. Minutes of meetings which shall be sufficiently detailed to show attendance at the meetings, actions taken, the vote on these actions, including the number of members voting for, against, and abstaining, the basis for requiring changes in or disapproving research, and a written summary of the discussion of controverted issues and their resolution.
4. Records of continuing review activities.
5. Copies of all correspondence between the HSRB and the research investigators.
6. A current list of all Board members and their addresses.
7. Written procedures for the HSRB as required by regulations adopted by the Secretary.
8. Statements of significant new findings provided to subjects as required by regulations adopted by the Secretary.
9. All records maintained by the HSRB shall be maintained at the Chairperson's office and shall be preserved for at least five years following HSRB action and 7 years in state archives. All records shall be available for inspection and review at reasonable times by authorized representatives of the Secretary or Department.
10. A report of projects received, approved or denied will be sent to each ADHS Assistant Director for information and circulation to their service area.

8. Board Action

Unless otherwise specified, the HSRB shall review research and data requests and take action only at a meeting in which at least two-thirds (5) of the members are present. Research proposals and data requests shall be approved, returned for clarification or disapproved by vote of a majority of the members present.

A. Submission for Review

A request for review of a research proposal or for data for statistical or research purposes shall be submitted to the HSRB in written form. The written proposal shall include the following:

1. A detailed description of the nature of the research to be conducted and the methodology and procedures which the research will utilize. Incomplete requests will be returned for further documentation.
2. A statement of the goals which the research will seek to accomplish.
3. A description of safeguards utilized during the research which are designed to safeguard the rights and welfare of human subjects involved in the research.
4. A description of the records and documentation which will be maintained by the research investigator and the location of such records and how confidentiality and privacy will be maintained.
5. A list of each research investigator along with a description of the investigator's experience and expertise in the area of research proposed to be conducted.
6. A description of how the research investigator intends to monitor results and to report findings.
7. An assurance by the research investigator that the research will be conducted in accordance with applicable law and regulations and Board requirements, and that all material modifications in the research or problems which may develop thereafter in the research shall be immediately submitted to the Board for review and action.
8. A description of how the research investigator will obtain informed consent of the human subjects in accordance with applicable law and rules, along with the written disclosure form by which informed consent will be obtained.
9. Any other information about the proposed research which will facilitate the HSRB's review of the research.
10. All documents other than the protocol should be pertinent and as brief as possible without reducing the clarity of the project's description because the committee's time is limited.
11. A description of how data, especially those items with personal identifiers, will be disposed of or destroyed.

B. Subjects NOT within the Board's Purview.

The HSRB is not responsible for the scientific merit of the proposed research except that poorly prepared research proposals or inappropriate scientific merit in themselves may be considered an unwarranted risk for a

human subject or inappropriate for disclosure of confidential records. In general, the methods, techniques and goals of the research and its approval are the express responsibility of the investigator(s), and the Assistant Director of the Division or Executive Officer of the Institution submitting the request.

1. The HSRB's action cannot be construed as approving, granting or providing funds for the research.
2. Approval by the HSRB does not obligate the ADHS or its subordinate organizational units to necessarily collect, compile, or provide the data requested, but only that the requestor appears capable of managing the data in a confidential manner so as to protect the human subject and the individual's privacy and not cause the ADHS undue criticism.
3. Any release of confidential information should clearly have benefits and scientific merit that outweighs the contemplated invasion of privacy or confidentiality.

2. Confidentiality

The HSRB shall require documentation (a confidentiality statement) of the intent and ability of the researcher to maintain the provided or collected data so as not to violate the privacy of the human subjects, pursuant to A.A. C. R9-19-410.

General conditions for release of information from vital records research, statistical and other uses:

A. Data from vital records, including copies of part of all of such records, may be released to government agencies, hospitals, foundations, schools, social agencies and similar organizations or individuals for statistical or research purposes. All such requests shall clearly identify the requesting agency or individual, state the number of copies needed, explain the objective of the study and contain a statement over the applicant's signature expressing familiarity with the confidentiality aspects of the records and his willingness to abide by the restrictions.

B. In no case shall the researcher either in the published results of his study or in communication with others:
    1. Identify any individual on a certificate by name or address.
    2. Contact persons named on a certificate without prior permission from the State Registrar.
    3. Deliver the information to other persons not connected with the study.

4. Use the information in any way so as to violate the privacy of any individual named on a certificate or cause embarrassment to him or his family.

C. Violations will bar the applicant from obtaining further assistance from the Department of Health Services, relating to research of vital records, and will make him liable to such other legal action as may be applicable.

3. Informed Consent.

The HSRB shall require documentation of informed consent by research subjects and shall require that information given to research subjects as a part of informed consent is in accordance with applicable law and specifically in compliance with 45 CFR 46.116 and 46.117, or any other regulations adopted by the Secretary. The HSRB may require additional information be given to research subjects if, in the Board's judgment, the information would meaningfully add to the protection of the rights and welfare of subjects. Research approved by the HSRB pursuant hereto may be subject, in the discretion of the Board, to further appropriate review and approval or disapproval

4. Notification of Board Actions.

The Chairperson of the HSRB will notify the requestor in writing of the HSRB decision to approve, request further clarification, or disapprove the proposed research or data use within five working days of the HSRB meeting. If the HSRB requires clarification or disapproves the proposal or request, it shall include in the written notification a statement of the reasons for its decision and shall give the requestor an opportunity to clarify, revise or otherwise respond in writing. The HSRB may either reaffirm or revise its decision following submission of additional clarifying information.

5. Suspension or Termination of Approval

The HSRB shall have authority to suspend or terminate approval of research not being conducted in accordance with HSRB requirements, has violated the confidentiality requirements, or that has been associated with unexpected serious harm to subjects. Any suspension or termination or approval shall include a statement of the reasons for the HSRB's action and shall be promptly reported to the investigator and the Director, ADHS.

6. Right of Appeal

Any person may petition the Director of the Department for a hearing in accordance with the rules of practice to appeal a rejection, suspension or termination of approval or access to confidential vital records (A.R.S. Title 36, Chapter 3, 36-345, and Title 39, Chapter 1, 39-121.02).

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7. Expedited Review of Projects

The Chairperson shall be authorized to review and approve emergency projects requiring the collection of data, biological specimens including blood by finger stick or phlebotomy and other minimal risk procedures in the routine response to emergencies and epidemics where time is of the essence. The HSRB will review the proposal and the Chairperson=s decision and provide in the minutes a comment of concurrence or objection. In reviewing projects pursuant to expedited review, the members may exercise all their powers which they, as members, are authorized to exercise except that the project shall not be disapproved. This section applies only to ADHS organizations in the routine performance of their mandated duties and responsibilities.

8. Statement of Ethical Principles

In reviewing the biomedical and behavioral research involving human subjects, the HSRB shall consider and apply the ethical principles set forth in this article X. In general, the ethical principles of the HSRB shall encompass the ethical convictions that individuals be treated as autonomous agents and that individuals with diminished autonomy be entitled to protection. Respect for the autonomy of individuals will require that human subjects involved in research be given the opportunity to choose what shall or shall not happen to them through informed consent. In considering whether a research subject has given informed consent, the HSRB shall consider whether sufficient information has been provided to the human subject. The information shall generally include: the research procedure, the purpose, risk, and anticipated benefit of the research, a statement offering the subject the opportunity to ask questions and to withdraw from the research, and any other information that reasonable persons would wish to know in order to make a decision regarding their care and well-being. With respect to the selection of human subjects for participation in research, the HSRB shall consider whether the research investigator has exhibited fairness in the selection. For selection of subjects, a distinction should be drawn between classes of subjects that ought, and ought not, to participate in a particular kind of research, based upon the ability of members of that class to bear the burden which may be present in the research activity.

9. Criteria for HSRB Approval of Research

To approve research, the HSRB shall determine that all of the following requirements are satisfied:

A. Risks to subjects are minimized (1) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risks, and (2) whenever appropriate, by using procedures already being performed on the persons for diagnostic or treatment purposes.

B. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. Social, psychological and physical risks and benefits will be considered. In evaluating risks and benefits, the HSRB shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The HSRB shall not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public safety) as among those research risks that fall within the purview of its responsibility.

C. The ability and methods by which data confidentiality and personal privacy will be maintained are clearly specified.

D. Informed consent is sought from each prospective subject to the subject's legally authorized representative in accordance with, and to the extent required by, regulations adopted by the Secretary.

E. Informed consent is appropriately documented in accordance with regulations adopted by the Secretary.

F. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure safety of subjects.

G. Adequate procedures exist for continuing review by the HSRB.

H. Appropriate additional safeguards shall be required by the HSRB in research activities involving subjects likely to be vulnerable to coercion or undue influence, such as subjects with great or severe physical or mental illness, or persons who are economically or educationally disadvantaged.

12. Continuing Review of ADHS Research

The HSRB may conduct continuing review of research approved pursuant hereto, at intervals appropriate to the degree of risk. In approving research activity, the HSRB shall determine a method of verification of research approved by the HSRB.

13. Amendment of Procedure

These organizational procedures shall not be amended without approval of the Director, ADHS and a majority of the members.

Print Form

NEW PROJECT/STUDY SUBMISSIONS TO THE HUMAN SUBJECTS REVIEW BOARD (HSRB)

Human Subjects Review Board - Purpose: The HSRB is formed pursuant to the provisions of Section 474 of the National Research Act (Public Law 93-348) and Regulations (45 CFR 46.101. et seq.), to review biomedical and behavioral research involving human subjects that is conducted, funded, or sponsored by the Arizona Department of Health Services (ADHS), or uses data collected or maintained by ADHS in order to protect the rights of the human subjects of such research.

Nature of Research Requests to be Reviewed: All ADHS biomedical or behavioral studies, or investigations that seek to use data maintained by ADHS shall be considered under the purview of the HSRB. This includes all projects developed by ADHS personnel and all requests for data from outside persons, but does not necessarily include projects submitted for funding under state or federal programs, unless specifically required by the funding organization and accepted by the HSRB.

CONTENT OF SUBMISSIONS:

A request for review of a new research protocol involving human subjects or request for ADHS-maintained data shall be submitted to the HSRB in written form. The written submission must have the pages numbered and include the following:

1. A detailed description of the nature of the research to be conducted and the methodology and procedures which the research will utilize. Incomplete requests will be returned for further documentation. The HSRB requires an Executive Summary be prepared and submitted.
2. A statement of the goals which the research seeks to accomplish.
3. A description of mechanisms to be utilized during the research which are designed to safeguard the rights and welfare of human subjects involved in the research, including mechanisms to safeguard individually-identifiable data.
4. If applicable, a description of the ADHS-maintained data to which the researcher is seeking access, the name of the Program maintaining the data, and the frequency with which data is to be disclosed.
5. A list of each research investigator involved in the protocol, along with a description of the investigator's role in the protocol and the investigator's experience and expertise in the area of research proposed to be conducted.
6. A description of how the research investigator intends to monitor results and to report findings.
7. An assurance by the research investigator that the research will be conducted in accordance with applicable law and regulations and HSRB requirements, and that all material modifications in the research or any problems which may develop thereafter in the research shall be immediately submitted to the HSRB for review and action.
8. A description of how the research investigator will obtain informed consent of the human subjects in accordance with applicable law and rules, along with the written disclosure form by which informed consent will be obtained.
9. Any other information about the proposed research which will facilitate the HSRB's review of the research. All documents other than the protocol should be pertinent and as brief as possible, without reducing the clarity of the project's description, because the HSRB's time is limited.
10. Copies of any previous Institutional Review Board approval.
11. A completed Confidentiality Statement, signed by all named investigators; a completed Security Considerations Form; and, if applicable a signed Waiver of HIPAA Authorization.

CONFIDENTIALITY:

The HSRB requires documentation (Confidentiality Statement) of the intent and ability of the researcher to ensure that the data provided by ADHS or collected as part of the protocol is maintained so as to preserve the privacy of the human subjects.

Any release of confidential information by ADHS must clearly have benefits and scientific merit that outweigh the contemplated invasion of privacy or confidentiality. After the HSRB approves a submission, any requests for ADHS-maintained data must be signed by the individual who signed the Confidentiality Statement.

SUBJECTS NOT WITHIN THE HSRB'S PURVIEW:

The HSRB is not responsible for the scientific merit of the proposed research except that poorly prepared research protocols or inappropriate scientific studies in themselves may be considered an unwarranted risk for a human subject or inappropriate for disclosure of confidential records. In general, the merit of the methods, techniques, and goals of the research, as well as any required institutional approval, are the express responsibility of the investigator(s) and the appropriate administrator of the institution of the investigator submitting the request.

The HSRB's action cannot be construed as approving, granting, or providing funds for the research, nor guaranteeing that the requested data will be made available. These decisions are the responsibility of the offices having either the data or the funds.

SUBMISSION FORM AND COVER SHEET FOR
A HUMAN SUBJECTS PROTOCOL OR REQUEST FOR ADHS INFORMATION
REQUEST FOR REVIEW BY THE HUMAN SUBJECTS REVIEW BOARD

PRINCIPAL INVESTIGATOR INFORMATION

Submitter(s) Name:	Date:
Organization:	Type of Organization:
Address:	
Telephone Number:	Fax Number:
Email Address:	

PROJECT/STUDY NAME

PURPOSE OR OBJECTIVE

Time Period of Project/Study: _____

Check the box if seeking access to: Birth records ☐ (and/or) Death records ☐

TYPE OF SUBMISSION

☐ New Submission

☐ Five-Year Renewal/ Renewal Beyond Five Years HSRB Number, if known _____

☐ Protocol Modification HSRB Number, if known _____

☐ Continuing Review Report HSRB Number, if known _____

☐ Other:

ACKNOWLEDGMENT

The signer acknowledges that the submission to the HSRB for the project/study must contain the required elements in order to be reviewed by the HSRB, and will **provide an original and 3 copies** of said project/study, completed Security Considerations Form, and signed Confidentiality Statement to the HSRB for review, as well as one copy of the Waiver of HIPAA Authorization, if applicable.

_____

Signature of Submitter Date of Submission

Print Form

HSRB Number Assigned by ADHS: _____

CONFIDENTIALITY STATEMENT
(To be signed and returned with your submission to the HSRB)

Name of Project: _____

We/I, _____, the Principal Investigator, and _____, the undersigned researchers for the above-referenced project, agree to abide by Arizona Revised Statutes to protect the confidentiality of the data provided and the privacy of the human subjects under this study. These statutes and rules prohibit the following:

1. Disclosure in published results of the study or in communication with others of the name, address, or any other personally identifiable information of any individual identified on a vital record or other record provided by the Department;
2. Contact with any individuals named on a vital record or other record provided by the Department without prior permission from the State Registrar;
3. Delivery of confidential information to other persons not identified specifically in the submission to the HSRB as being connected with the study; and
4. Use of vital record information or other records provided by the Department in any way that may violate the privacy of any individual named on a vital record or other record provided by the Department or cause embarrassment to the registrant or the registrant's family.

After the HSRB approves a submission, any requests for ADHS-maintained data must be signed by an individual who signed the Confidentiality Statement.

ACKNOWLEDGEMENT:

We/I understand the above requirements and agree to maintain the confidentiality of the vital records, records which have been provided by the Department, or other data related to the above project by appropriately protecting all electronic and paper data during the conduct of the project, as described in the submission.

We/I agree to destroy all personally identifiable information provided by ADHS or derived from information provided by ADHS upon completion of the study, as described in the submission. We/I further agree to submit to ADHS through the Human Subjects Review Board (HSRB), immediately upon the conclusion of the project and the destruction of records, a written statement setting forth the specific date and the method of destruction used to destroy the vital records or other ADHS-provided records (Certificate of Destruction Form).

We/I understand that for a project using personally identifiable information, a request must be submitted to the HSRB for another review at least 30 days before: a change in the protocol for the project is implemented, the data is modified in any way, or the expiration of the HSRB's approval period. If the personally identifiable information provided by ADHS is to be kept for more than 5 years from the date of the HSRB's approval, the project must be re-submitted to the HSRB for another review/approval.

We understand that ADHS and/or the program providing the confidential information retain the right to review any report prior to dissemination to ensure that confidentiality has been protected.

Violators may be subject to other legal actions.

_____
Typed Name of Principal Investigator — Title/Position of the Principal Investigator

_____
Signature — Date

Typed Name of Researcher	Title	Signature	Date
Typed Name of Researcher	Title	Signature	Date
Typed Name of Researcher	Title	Signature	Date
Typed Name of Researcher	Title	Signature	Date

Print Form

ARIZONA DEPARTMENT OF HEALTH SERVICES

Human Subjects Review Board

SECURITY CONSIDERATIONS FOR INVESTIGATORS

In Arizona and nationwide, there is a growing concern about identity theft and other fraudulent use of birth and death records or other individually identifiable information. There can be great temptations for unscrupulous persons (e.g., professional thieves or computer hackers) to obtain and use individually identifiable information unlawfully.

As part of the Arizona Department of Health Services (ADHS) heightened security awareness for research use of Arizona's vital records, registries and other confidential information, the ADHS requires you to address security considerations in your research protocol or request for ADHS-maintained data. **The following checklist may assist you to satisfy this requirement.**

ACCESS CONTROLS

☐ Yes ☐ No Have you identified all individuals who will be granted direct access to the information requested and their role in the study?

☐ Yes ☐ No Have these individuals signed the HSRB confidentiality agreement?

☐ Yes ☐ No Have you provided documentation of who is authorized to directly access confidential study data?

☐ Yes ☐ No Do those staff members receive privacy/security training, and are they required to sign a confidentiality agreement?

☐ Yes ☐ No Will anyone else have access to the area where ADHS information will be stored (e.g., students, custodians)?

☐ Yes ☐ No Are there any controls in place to prevent unauthorized access to the information?

PHYSICAL SECURITY: For ADHS records maintained in hard copy format, please address the following security issues.

☐ Yes ☐ No Have you established restricted access procedures for record storage areas (e.g., key code devices, locked cabinets, shelving or storage rooms, etc.)?

☐ Yes ☐ No Does your institution use a controlled-access vault or safe for the protection of this type of paper or electronic files?

☐ Yes ☐ No Does your institution have a monitored alarm system or physical security guards to detect unauthorized entry after hours?

☐ Yes ☐ No Does your institution destroy the hard copy records containing individually identified data after data entry is completed? If so, please identify in your protocol/submission the method of destruction to be used (e.g., shredding or incineration). If not, please explain in your protocol/submission the rationale for not destroying them.

☐ Yes ☐ No Does your institution require hard copy records containing confidential information to remain on-site? If not, please describe in your protocol/submission the procedures used to ensure the protection of hard copy records transported and used at off-site locations.

☐ Yes ☐ No Did you describe in your protocol/submission any other physical or electronic security procedures to protect hard-copy records?

ELECTRONIC DATA SECURITY: For ADHS records maintained in electronic format, please address the following security issues.

☐ Yes ☐ No Are workstations on which study personnel can access the records located in a secure area? If not, please explain in your protocol/submission.

☐ Yes ☐ No Are workstations on which study personnel can access the records part of a network? If so, please explain in your protocol/submission the type of computer network (e.g., VPN, LAN, WAN, etc.) that will house the ADHS records, and how you will ensure protection against unauthorized access (e.g., encryption, firewalls, intrusion detection or other security techniques).

☐ Yes ☐ No Is a method of authentication used to access data (e.g., passwords, passwords plus another level of authentication, etc.)?

☐ Yes ☐ No Are there scheduled updates of passwords and a policy against sharing of passwords?

☐ Yes ☐ No Are electronic records containing confidential information taken off-site or accessed from off-site? If so, describe in your protocol/submission the procedures used to ensure the protection of electronic records transported to or used from off-site locations. (Address, as applicable, connectivity or use of a web-based system; use of privacy/security agreements; storage on laptops or devices such as flash drives or PDAs; and storage procedures at the off-site location.)

☐ Yes ☐ No Are electronic records containing individually identified data from coding or data entry destroyed after transfer to statistical analysis programs? If not, please explain in your protocol/submission the rationale for not destroying them.

☐ Yes ☐ No Are other physical or electronic-security procedures used or planned to be used to protect electronic records?

OTHER INFORMATION PROTECTION AND SECURITY MEASURES

Please provide any additional pertinent information to the Human Subjects Review Board on how you will assure the integrity, privacy, and security of information you've requested, if applicable.

Print Form

THIS CERTIFICATE SHOULD NOT BE COMPLETED AND RETURNED UNTIL THE ADHS DOCUMENTS HAVE BEEN DESTROYED

CERTIFICATE OF DESTRUCTION

SUBMIT TO: Human Subjects Review Board, Arizona Department of Health Services
1740 West Adams, Room 203, Phoenix, AZ 85007

HSRB Number Assigned by ADHS:

Name of Study:

Principal Investigator:

Organization:

Address:

Telephone:

Type of Documents:

DESTRUCTION OF DOCUMENTS

Actual Date (not projected):

Actual Time (not projected):

Method Used to Destroy:

I, _____, as Principal Investigator of the above referenced project, certify that the documents described above were destroyed on the date and time indicated by the means of _____.

_____ _____

Signature of Principal Investigator **Date**

1/16/08

Arizona Department of Health Services

PHOENIX OFFICE
150 N. 18th Avenue, Suite 540
Phoenix, AZ 85007-3248
Phone: (602) 364-3150
Map to Phoenix Office:

TUCSON OFFICE
400 W. Congress, Ste. 100/Box 19
Tucson, AZ 85701-1353
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Map to Tucson Office:

Bureau of EMS & Trauma System

Arizona Department of Health Services