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.

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Signature of Submitter Date of Submission