Intro to the ADHS Human Subjects Review Board (HSRB)

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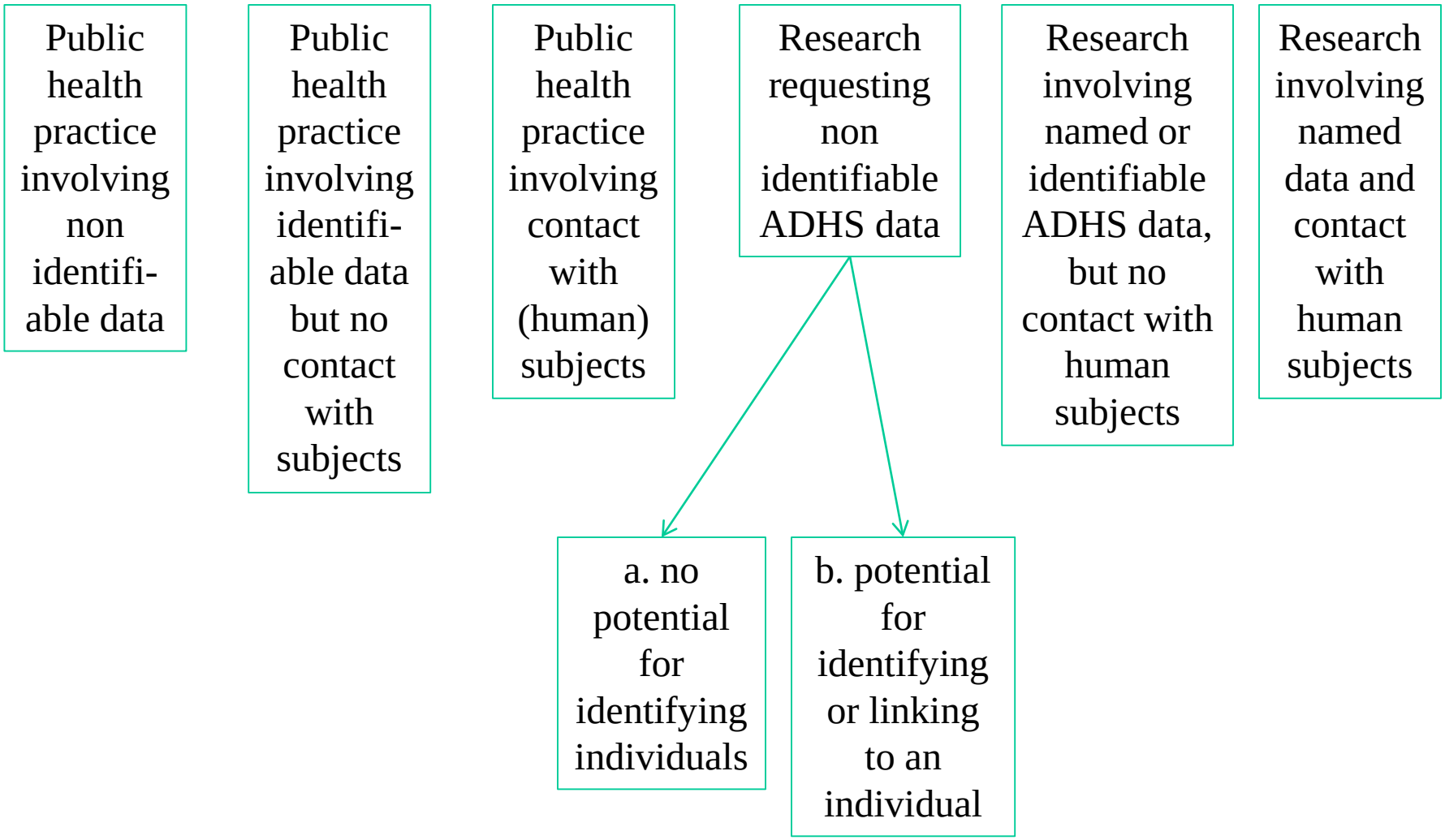
HSRB (the ADHS' IRB)

What we review:

- Research involving human subjects that is conducted, funded, or sponsored by ADHS
- Requests for personally identifiable* data (record level data) or Limited Data Sets from parties external to ADHS
- Project clearance for publication of manuscripts

**HSRB makes this determination*

Spectrum of HSRB Requests



Is it research?

CDC-SA-2010-02
Date of Issue: 07/29/2010
Proponent: Office of the Associate Director for Science

CDC: **"Distinguishing Public Health Research and Public Health Non Research"** Policy

This policy supersedes the Guidelines for Defining Public Health Research and Public Health Non-research, revised October 1999.

See this link to the 14-page document:

http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf

Submitting an application to HSRB

http://www.azdhs.gov/director/administrative-counsel-rules/index.php#privacy-human-subjects

Submissions to the HSRB must include:

- Submission application signed by the principal investigator
- Confidentiality statement signed by the principal investigator and all researchers handling confidential data in the project
- Security considerations checklist
- Copy of protocol for research project/study
- Copy of local IRB approval
- CVs for principal investigator and co-investigator(s) (if applicable)
- Copies of Consent Forms, Assent Forms (if applicable)
- Survey(s) Questionnaires (if the project will be utilizing these forms in their research project/study)
- An original and three copies of the research project/study must be submitted to the HSRB

Send all Submissions to:

Human Subjects Review Board
Arizona Department of Health Services
150 N 18th Ave; Suite 200; Phoenix, AZ 85007

HSRB_Protocols@azdhs.gov

Questions: call 602-542-6330 (Miriam Johnson)

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.

Informed consent checklist

- ***Informed consent must include the following:***
  - *Written in layman's language understandable to the people being asked to participate.*
  - *A statement that the study involves research.*
  - *An explanation of the purposes of the research.*
  - *The expected duration of the subject's participation.*
  - *A description of the procedures to be followed.*
  - *Identification of any procedures which are experimental.*
  - *A description of any reasonably foreseeable risks or discomforts. If there are none, this should be stated.*
  - *A description of any benefits to the subject or to others that may reasonably be expected from the research. If there are none, this should be stated.*
  - *A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.*
  - *An explanation of whom to contact for answers to pertinent questions about the research and the research subjects' rights, and whom to contact in the event of research-related injury to the subject.*
  - *A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.*

- ***Possibly applicable***
  - *A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.*

- ***Additional elements, as appropriate:***
  - *A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.*
  - *Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.*
  - *Any additional costs to the subject that may result from participation in the research.*
  - *The consequences of the subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.*
  - *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
  - *The approximate number of study participants.*

- The IRB may waive some or all elements of informed consent if (a) the research involves no more than minimal risk to the subjects; (b) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (c) the research could not practicably be carried out without the waiver or alteration; and (d) whenever appropriate, the subjects will be provided with additional pertinent information after participation

Criteria for IRB approval of research
(all of the requirements must be satisfied)

1) Risks to subjects are minimized
2) Risks to subjects are reasonable in relation to anticipated benefits or knowledge to be gained
3) Selection of subjects is equitable
4) Informed consent will be sought, if appropriate
5) Informed consent will be appropriately documented
6) Data are monitored to ensure safety of subjects
7) Privacy is protected; data confidentiality is maintained
8) Rights and welfare of vulnerable populations are protected

From: 45CRF46 §46.111

Annual report of your HSRB-approved project

http://www.azdhs.gov/documents/director/administrative-counsel-rules/hsrb-annual-report.pdf

Request for HSRB "Clearance" of non research

- **What is the nature of this request? (check all applicable)**
  - **__ Project clearance for publication of manuscript**
  - **__ Program Evaluation**
  - **__ Needs Assessment**
  - **__ Other:**

- Contact *HSRB_Protocols@azdhs.gov* and ask for the 'non-research pilot form'

- Tip: If you are designing a project that "uses" or "takes advantage" of your subjects to generate findings that do not provide a benefit to your subjects then you are likely conducting "research." Also, specify whether you are using an 'experimental approach' or 'standard practice.' If we determine you are proposing research, you'll need to submit an application for HSRB to either approve or to exempt your project.

- Alternatively, if you are proposing a project designed to generate information used to measure or improve services to the subjects of your project, you probably are conducting "non-research".

Current HSRB issues

- ‘Public record’ requests
- Public use dataset (HIPAA compliant)
- Use caution in requesting record-level data
  - limited data sets that might allow re-identification (***potentially*** personally identifiable)
  - Personally identifiable data sets

ADHS-NAU MOU for Data Sharing -- Intent of MOU --

- Largely assigns the oversight burden to the academic institution
- Creates a joint Data Use Steering Committee
- Expedites projects
  - Defines early-on whether:
    - data are available,
    - data owner rejects the project,
    - the IRBs agree it is can be exempted from IRB review, or decides which IRB will conduct primary review

ADHS-NAU MOU (2)

- Use of Honest Broker relieves ADHS programs from having to generate minimum needed datasets
  - DON'T ASK FOR THE ENTIRE DATASET
  - Ask only for what you need
- Yet to negotiate: responsibility and expectations of the academic HB
    - e.g., Frequency of reports, destruction of datasets

ADHS HSRB

- Website:

https://www.azdhs.gov/director/administrative-counsel-rules/counsel/index.php#hsrb

- Contact:

HSRB_protocols@azdhs.gov