NDDoH Institutional Review Board
Information for Researchers

Authority of the IRB

The Office of Human Research Protections (OHRP) of the US Department of Human Services has secured a commitment from this agency that all human research will be subject to the oversight of this agency to ensure the protection of human subjects. OHRP acts to guide and assist this agency to protect the rights of human research subjects. IRB authority extends to all research on living human subjects. Public health practice is not considered research and can be released from oversight; however, many public health projects have characteristics of both. A RESEARCHER MAY NOT DECIDE FOR HIMSELF OR HERSELF IF A PROJECT CAN BE RELEASED FROM IRB OVERSIGHT.

Certain studies may be released from NDDoH IRB oversight and/or from federal oversight. That is, a study may qualify for release from federal oversight yet remain under the oversight of NDDoH IRB at the discretion of the IRB, or may be released from all oversight. 46.101(b) A researcher may apply to the board chair for a release from IRB oversight; however, no researcher may determine for himself or herself that a study can be released. Even though a project may be released from oversight does not mean that the investigator is released from departmental expectations to follow the current standards for human subjects' protections or from standards for high quality science and value to the agency.

Research conducted by another institution which is using NDDoH confidential data is not subject to the NDDoH IRB (as long as no NDDoH employee is a co-researcher[1]), but is subject to the IRB of the other institution. The NDDoH role is limited to data release procedures which may involve securing evidence that the other institution has approved the research before we release confidential data. This is a privacy issue that must go through the privacy officer.

Research funded by NDDoH, but in which NDDoH does not have a participating researcher must still have had IRB review (approval or release), but not necessarily by this agency. This agency covers local public health for IRB.

Studies which may be released from IRB oversight at the determination of the IRB Chair

1. Not research;
2. Not human subjects research;
3. Survey or interview where neither personal identifiers nor numbers which link to personal identifiers are used or where release of results would not place any participant at any risk (civil, criminal, financial, personal);46.101(b)(2) or

[1] There may be some situations in which the determination that NDDoH employee is not a co-researcher is not clear. These should be discussed with the IRB chair or IRB administrator.

4. Research using existing data or records which are public information or which does not contain identifiers or links to identifiers 46.101(b)(4) or
5. Other types of studies not common within this agency may meet OHRP guidelines for release. A researcher may request release based upon review of guidelines from OHRP 46.101 which is available at: http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm. The IRB submission form lists the usual categories for release.
6. Research on certain vulnerable groups may alter these criteria (e.g., children).

Classification of Risk

Studies are categorized into two broad risk categories – minimal risk and greater than minimal risk. "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." 46.111(a)(2) A study which is minimal risk, as many public health studies are, may not receive as much scientific scrutiny as one which is greater than minimal risk; however, no research risk is justifiable for a poorly designed study.

Responsibility of Investigators

Investigators must:

a. Submit to the IRB administrator documentation requesting IRB review.
b. Attest that the investigator has read and understood the requirements and expectations of IRB oversight.
c. Obtain the consent and complete understanding of all research subject participants without pressure or threat to well-being or opportunities of an individual who refuses consent. Consent must conform to federal requirements. For children, this may include assent depending on child's understanding.
d. Protect all personally identifiable health information;
e. Minimize risks to the full extent possible;
f. Provide special protections for vulnerable populations consistent with federal regulations (children, pregnant women, prisoners, persons with disabilities, and those with impaired English language skills);
g. Report all complications of research or changes in protocol to the IRB;
h. Report to the this board all actions taken by another IRB regarding the study in question;
i. Provide to the board for review all of the following documents at least one week in advance of the scheduled board meeting:
    a. Complete protocol describing the study;
    b. All data collection instruments to be used;
    c. All consent forms;
    d. An approved grant application if one exists;
    e. A completed IRB review request form (available from IRB administrator);

f. Any documents used for participant recruitment;
g. Any reviews by other IRBs.

j. Label all documents with date and revision number
k. Ensure that IRB approval is up-to-date given that IRB approval cannot be longer than one year without continuing review, and may be shorter.

Informed Consent

Informed consent shall be obtained from all participants in all investigations unless the board determines that the research meets conditions for waiver and agrees to the waiver. The board may waive the requirement for informed consent (or alter some or all of the required elements of informed consent) if all of the following conditions are met:

1. The researchers involves no more than minimal risk; and
2. The waiver or alteration will not adversely affect the rights and welfare of the research subjects; and
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, research subjects will be provided with additional pertinent information after participation. 46.116(d)(1-4)

The board may waive the requirement for written consent (i.e., a signed consent form from each participant) in any of the following circumstances:

1. Research involves not greater than minimal risk and no procedure is being performed for which consent is normally required outside of research. 46.117 (c)(2)
2. In research in which breach of confidentiality is the primary risk and the only research linking the subject to the research is the consent form. In this case each subject of the research shall be offered the opportunity of signing consent (with the attendant risk of linkage) or of refusing consent. 46.117 (c)(1)

Informed consent shall be in writing, signed by the participant, and a copy shall be given to the participant. 46.116(a) Oral consent which does not involve obtaining the signature of the participant or their legal representative is not acceptable unless the board has determined that the study meets OHRP approved criteria for waiver of written consent as noted above. 46.117(a)(1-2)

The investigator must ensure that the person fully understands the study and the nature of his or her consent and his or her right to withdraw at any time. An interpreter must be used if the research subject lacks English proficiency.

Characteristics of the informed consent document are as follows:

1. Simple language explaining
    i. That consent is consent to participate in research;
    ii. The purpose of the research;
    iii. Duration of participation;

iv. Procedures to be followed; and
v. Identification of experimental procedures. 46.116(a)

2. Description of reasonably foreseeable risks or discomfort to the participant;
3. Potential benefits, to participant or to others, which may be expected from the research;
4. Any alternative procedures or treatments available to the participant;
5. Description of confidential information which will be recorded and maintained regarding the subject;
6. If greater than minimal risk
   i. Availability of compensation if injury occurs, and
   ii. The nature of available treatments for any injury that occurs;
   iii. Contact persons for
      1. Reporting injury arising from the research, and
      2. Obtaining answers about research and participant rights;
7. Statement that
   i. Participation is voluntary; and
   ii. Refusal to participate or termination of participation will not result in penalty or loss of benefit (except that which might have arisen as a direct consequence of treatment offered through participation), and
   iii. Participation may be terminated at any time;

When appropriate the consent shall also contain the following:

1. Possible occurrence of unforeseen risks which could potentially harm the participant (and fetus or embryo if participant is pregnant);
2. Circumstances which may result in the investigator terminating the research;
3. Any additional costs that may result from participation;
4. Potential consequences of participant's early withdrawal from the research, and how such termination will be conducted to minimize any risk to the participant;
5. Statement of the impact of new information or findings which could affect the participants willingness to participate;
6. The approximate number of persons to be enrolled in the study. 46.116(b)

Exculpatory Language in Consents

Consents may not include any statement which attempts to absolve the researcher of liability.

Protection of Information under the Law

Unless a Certificate of Confidentiality has been obtained from NIH, consents should say the confidential information will be protected "to the extent allowable by law" since the researcher does not have the power to protect the information from a court of law. In certain instances (e.g., research involving drug abuse or other highly sensitive information), a Certificate of Confidentiality may be

requested from the National Institutes of Health which would protect the information from all disclosure. Certificates are infrequently granted.

Research Involving Children

For research enrolling children as research participants, additional requirements must be met as follows:

1. Researchers must clearly state to the board the extent to which children will be involved in the study, and specifically obtain consent from the board for research which will involve children as participants.
2. The board will require review of research (normally not required for adults), which involves survey, interview or observation, although release may still be given based on other criteria.
3. Any child who is capable of understanding the nature of the research in which they are being asked to participate must agree to participate (i.e., provide assent). The child's assent to participate shall be witnessed by the person granting permission (e.g., parent or guardian). In obtaining permission from the parent or guardian, the researcher must make sure that the person granting permission is also documenting that either
    i. The child can give and has given assent, or
    ii. The child cannot reasonably provide such assent.

Factors to be weighed in considering a child's capability to provide assent include the age, maturity, and psychological state of the child. [46.408(a)] In the research protocol, the researcher must state the procedure to be used for determining a child's capability of providing assent. When assent is waived because a child is incapable of providing it, the researcher must record how that determination was made in sufficient detail that the board could concur with the decision if reviewed.

Research Involving Prisoners

Unique protections are required for review of research involving prisoners. The researcher should review the federal requirements and discuss them with the board chair or administrator. Note that these requirements take affect even if an enrolled research participant who was not a prisoner at the time of enrollment, becomes a prisoner while participating in the research.

Continuing Review

Research approved by the board must be reviewed no less often than annually. If the board requires continuing review sooner, the researcher will be notified at the time of review. The researcher is responsible for making sure continuing review is scheduled with the board. If it has been more than a year since the last approval, the research is no longer approved and must stop until approval is obtained.. OHRP prohibits the use of any data collected by a study which no longer has IRB approval. It must be discarded.

Presentation of information for continuing review should include the following:

1. A brief review of the research, its purpose, and methods, and a full description of procedures or data collection which pose risk to the participants, whether risk to health or confidentiality;

2. A review of study progress including number of subjects enrolled;
3. Adverse or unanticipated events which have occurred which may reflect on the risk to participants, and any reasons for any person's withdrawing from the study;
4. Review of complaints received about the study;
5. Proposed modifications to the protocol;
6. Any new results from this study or other studies which may reflect upon the risk to the participants;
7. Review of the current informed consent document which is in use.

Appeal

A researcher who is unhappy with the decision of the board may request from the chair or administrator information regarding how to request an appeal and re-hearing by the board.