

Information Regarding Requirement for Institutional Review Board Approval

All UND research involving human participants and conducted by university personnel or students must be reviewed following UND IRB procedures, and must be approved prior to the initiation of research activity and contact with potential human participants. There are no exceptions to this policy. If you are going to complete research with human subjects and collect the data at another institution (hospital, clinic, etc.), you may also be required to obtain approval from the institution's review board.

OBTAINING REQUIRED IRB APPROVAL:

Step 1. Overview of Requirements: The Office of Research and Program Development website <http://www.und.nodak.edu/dept/orpd/regucomm/irb/Default.htm> will provide you with an overview for preparing and submitting an IRB proposal and a link to the Researcher's Handbook. A careful review of this information will simplify the approval process.

Step 2. Complete Required Human Subject Education:

a. Why is training necessary? As a result of recent suspensions of research organizations because of noncompliance with regulations governing human subjects research, the Department of Health and Human Services (DHHS) has emphasized the need for those individuals involved in this kind of research to understand their obligations under the regulations. Recent regulations have specified that an educational program must be provided for investigators by institutions operating under the federal regulations governing human subjects research.

b. Who has to take the training? Principal Investigators and those individuals in contact with subjects and/or data and identifiers (key personnel) will need to complete the training.

c. When do I need to complete this training? *All investigators and key personnel* submitting proposals or Research Project Review and Progress Reports will be required to complete the training before approval of their proposal is granted by the IRB. The Principal Investigator should ensure that *all key personnel* have completed the training prior to submitting their Research Project Review and Progress Report or proposal. Approval will be suspended until all key personnel have completed training.

d. How do I complete this training? The training is done by completing the IRB On-Line Educational Modules at <http://www.citiprogram.org/>. Individuals may register on the website to complete the required modules. The required modules are listed. For most research projects students will want to complete the *medical* modules, however some students may have to complete the social-behavioral module depending on the research topic. Researchers will be asked to complete additional modules if they are using vulnerable populations as subjects such as prisoners, international, workers as research, conflicts of interest, pregnant women or genetic research. It will take approximately 24 hours to receive your password and log in. Each Module will take 10 to 30 minutes. The total required time is estimated to be two to three hours. The course does not have to be completed in one sitting and can be completed in any order. The passing score required is 80% (required modules only). If you fail the training or want to improve your score you may retake any or all of the modules. This process may take a couple of days. If you have forgotten your password or ID please call (701) 777-4279.

Step 3. Complete HIPPA Training: The School of Medicine and Health Sciences requires that each enrolled student must complete HIPPA Training. An online program is available for your use to

access this training on the UNDSOM&HS HIPAA training site at <http://cf.med.und.nodak.edu/hipaa/>. You may need to submit a "Student HIPAA Form" or verification of the completion of HIPAA training with your IRB Proposal. (Check with the IRB where you submit your proposal.) If you are planning on using medical records in your research, please refer to the Researcher's Handbook section entitled **Use of Medical Records in Research**. You will also be required to fill out the HIPAA Application Form.

Step 4. Determine the approvals needed for your project:

a. Research completed by UND students: If you are collecting data at UND or another location/facility that does not have an IRB, you will submit your proposal to the UND IRB. The forms you will use will be on the UND IRB web page (<http://www.und.edu/dept/orpd/regucomm/irb/Default.htm>). Refer to the Researcher's Handbook (UND IRB web page) to determine the type of approval needed and which forms to use.

b. Research completed by UND students at another site with an Institutional Review Board: If you are collecting subject data at a site (hospital, clinic, etc.) that has an IRB, you may be required to obtain approval from the facility IRB. In this situation, you have two options to consider.

(1) IRB Authorization Agreement. You may complete an "IRB Authorization Agreement" which will allow UND IRB to rely on another IRB outside of a UND for the review of a project. The form is documentation of who has responsibility for the project review and approval and must be signed by both authorized agents of both IRBs (see sample form attached). You would then submit this signed and a copy of your approved IRB proposal to the UND IRB office.

(2) Submission to More than One IRB: If you are not able to obtain a signed IRB Authorization Agreement, you will submit your proposal to both the institution's and UND's IRB. Generally, you will submit the proposal to the institution where you will be collecting the data initially. However, you should check with the IRB coordinator at both facilities for directions regarding the procedure to follow.

Step 5. Prepare the IRB Proposal: Follow the Researcher's Handbook when developing the text for your IRB proposal. The IRB Forms can be downloaded from the ORPD website at <http://www.und.nodak.edu/dept/orpd/regucomm/irb/IRB%20forms.htm> Use the IRB Checklist form to verify that you have completed the proposal appropriately. If you are planning on using the Internet to obtain data, you will also need to review section entitled **Internet Research** and comply with the criteria that applies to your research project. Include the following with your proposal when you submit it to the IRB for review:

- a. Consent Form
- b. Letter of Willingness to Cooperate from cooperating institution(s) or individual(s)
- c. A copy of instrument(s) such as surveys, etc. and or interview questions (if applicable)
- d. Release of Student Educational Forms for each student researcher
- e. HIPPA Student Form (if applicable)

SAMPLE: IRB AUTHORIZATION AGREEMENT

Sample text for an Institution with a Federal wide Assurance (FWA) to rely on an IRB outside their institution (institutions may use this sample as a guide to develop their own agreement).

IRB Authorization Agreement

Name of Institution or Organization Providing IRB Review (Institution A):

IRB Registration #: _____ Federal wide Assurance (FWA) #, if any: _____

Name of Institution Relying on the Designated IRB (Institution B):

OHRP Federal wide Assurance (FWA) #: _____

The Officials signing below agree that (name of Institution B) may rely on the designated IRB for review and continuing oversight of its human subject research described below: (*check one*)

This agreement applies to all human subject research covered by Institution B’s FWA.

This agreement is limited to the following specific protocol(s):

Name of Research Project:

Name of Principal Investigator:

Sponsor or Funding Agency: _____ Award Number, if any: _____

Other (*describe*):

The review and continuing oversight performed by the designated IRB will meet the human subjects protection requirements of Institution B’s OHRP-approved FWA. The IRB at Institution A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB’s determinations and with the terms of its OHRP-approved Assurance. This document must be kept on file at both institutions and provided to OHRP upon request.

Signature of Signatory Official (Institution A): _____ Date: _____

Print Full Name: _____ Institutional Title: _____

Signature of Signatory Official (Institution B): _____ Date: _____

Print Full Name: _____ Institutional Title: _____

Form is available at: <http://ohrp.osophs.dhhs.gov/humansubjects/assurance/iprotsup.rtf>

Obtain the correct forms (see Researcher's handbook for information about forms) from the UND IRB Web Site (<http://www.und.edu/dept/orpd/>)

USE OF MEDICAL RECORDS IN RESEARCH

The privacy rule establishes conditions under which protected health information may be used or disclosed by covered entities (hospitals, clinics, schools, etc.) for research purposes. The information below will assist researchers in complying with the regulations and expediting the approval of the research proposal by the IRB. If research falls under the HIPAA regulations, the research records must be kept for a minimum of six years, not the usual three years. The regulations define three conditions that allow researchers access to medical records.

1. De-Identification of Health Information

The privacy rule allows the release of health information if a list of 18 identifiers is stripped from the records. The identifiers that must be removed include: name, street address, mailing address, city, county, telephone and fax numbers, social security number, birth date, date of death, age (if over 90), chart number, admission and discharge dates, five digit zip code (allows for the initial three digits of the zip code to be used if the information could not be used in a combination with other information to identify someone), license number, vehicle identifiers, URLs, IP, and email addresses, and full face photos. The de-identified information may be coded by the hospital or institution to allow for re-identification at a later date.

2. Use of Medical Information with Subject Authorization

A hospital or institution may release information if authorization is granted by the subject. The authorization must contain the following information: 1) a specific description of the purpose of the authorization and the information to be used or disclosed; 2) Who is authorized to disclose the information; 3) Who is authorized to receive the information; 4) An expiration date for the authorization or a statement such as, "end of research study", "none" or similar language; 5) A statement that the individual has a right to revoke the authorization; 6) A statement that the entity disclosing the information may have conditions to the disclosure of information; and 7) A statement that the information disclosed is no longer protected by the privacy rule and may be re-disclosed. The authorization must be written in plain language. The authorization may be included within a consent form to participate in the same research study. It is required that the authorization be signed and dated. A signed copy of the authorization must be given to the subject. (See Sample Form attached)

3. Use of Medical Information without Subject Authorization

There are four options stated in the regulations to gain access to medical records without written authorization from the subject. The researcher will be required to state specifically in the protocol what information will be taken from the medical records, and provide a reason why that specific information is necessary to the research. Only the minimum amount of information necessary to conduct the research may be disclosed.

a. IRB Approved Waiver of Authorization The waiver must include the following information:

(1) The date the IRB approved the waiver and a statement identifying the IRB

(2) A statement that the IRB approved the waiver based on the following criteria:

(a) The use or disclosure of the information involves no more than minimal risk to the privacy of the individuals, based on the presence of the following elements: an adequate plan has been stated to protect the identifiers from improper use and disclosure; an adequate plan

has been stated to destroy the identifiers; adequate written assurances that the protected information will not be reused or disclosed other than what is required by law

(b) The research could not practicably be conducted without the waiver

(c) The research could not practicably be conducted without access to and use of the health information

(3) A brief description of the health information determined is necessary by the IRB (e.g. labs, family history)

(4) A statement that the waiver has been reviewed and approved under either normal or expedited review procedures; and

(5) the signature of the Chair or other member designated by the Chair, of the IRB

b. Preparation of a Research Proposal. A researcher may be granted access to records if the researcher agrees in writing or orally that the use or disclosure of the health information is solely to prepare a research protocol or for similar purposes preparatory to research; that the researcher will not remove any health information from the covered entity (e.g. hospital, clinic); that access is necessary for the purpose of research.

c. Research on Health Information of Decedents. A researcher may be granted access to records if the researcher agrees in writing or orally that the use of the information is solely for research on the health information of decedents; that the health information is necessary for the research; and that documentation of the death of the individuals about whom information is being sought it provided to the hospital or institution.

d. Limited Data Sets with a Data Use Agreement. A data use agreement can be entered into by the researcher and the hospital or institution, or with UND and the hospital or institution. A limited data set can be disclosed for research. A limited data set can not include the following: name, street address, telephone and fax numbers, e-mail address, social security number, chart number, finger and voice prints, certificate/license number, vehicle identifiers and serial numbers, URLs and IP addresses, and full face photos. A limited data set can include admission and discharge dates, date of death, age, and five-digit zip codes. A date of birth may be disclosed if it is needed for the purpose of the research. If not, the age of the individual can be expressed in years or in months, days, or hours as appropriate. Only the minimum amount of information necessary to conduct the research may be disclosed. The data use agreement must: establish the permitted uses and disclosures of the limited data set by the researcher; limit who can use or receive the data; and require the researcher to agree to the following: not to use or disclose the information other than as permitted by the data use agreement; use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the agreement; report to the hospital any use or disclosure of the information not provided for by the data use agreement of which the researcher becomes aware; ensure that any agents, including a subcontractor, to whom the recipient provides the limited data set agrees to the same restrictions and conditions that apply to the researcher with respect to the limited data set; and not to identify the information or contact the individual.

INTERNET RESEARCH

Guidelines for Conducting Web-Based Survey Research (this material was originally presented on the University of New Hampshire website)

1. General: In addition to the information requested in the Human Subjects Review Form or Exempt Certification Form, researchers must address the following:

- a. State how subjects will be recruited.** (See Schmidt ([Appendix E](#)) for more information on publicizing a Web survey).
- b. State that the survey is part of a research project.** Researchers need to explicitly state this information in both the survey's introductory page/screen and in the informed consent information. Researchers may want to add a hyperlink to their institution on the introductory page/screen to demonstrate their affiliation.
- c. State contact information.** This can be accomplished by placing email links to the researcher(s) throughout the screens containing the introduction, consent, and/or debriefing information. As email links may cause problems with confidentiality, a telephone number for the researcher should also be provided.
- d. Provide feedback (debriefing) to participants at the end of the survey.** An example of a debriefing sheet is available on the UND ORPD-IRB web site Appendix A.

2. Informed Consent: As it is not practical in most Web-based surveys to get a consent form signed by participants, researchers need to request from the IRB a waiver of the requirement for obtaining a signed consent form from each participant. The IRB has the authority to waive this requirement, but in order to do so, it must ensure that the study meets the requirements as stated in 45 CFR 46, Section 117 (refer to UND ORPD-IRB web site Appendix C).

Informed consent can be readily obtained prior to responding to the actual survey by having the first page as an information sheet and consent form rather than the actual survey. The screen displaying the informed consent information can be designed so that the participant is required to take an action to signify their acknowledgment of the consent information. Many surveys are designed so that participants are confronted with an on-screen button that says "I consent/agree to participate" to click on if they accept the terms of the consent information. Participants then proceed to the actual survey. Alternatively, researchers can place a link after the consent information to take participants to the survey. Ideally, once participants have read and acknowledged the consent information, they can request a copy of, or print, the consent document.

Another method of obtaining informed consent in Web-based surveys is to have participants read the consent document and indicate whether or not they agree to participate by supplying and submitting a valid email address. Upon receipt, participants are sent a confirmation of their consent to participate via email and provided with the survey's Web address. If researchers retain the email addresses (they should notify potential participants they are doing this, and the purpose for doing so), they need to log them separately from the participants' survey responses to ensure confidentiality and privacy (Schmidt, 1997).

Informed consent must contain all elements required by federal regulations. Examples of a Web-based consent form and a debriefing information sheet in Appendix A on the UND-IRB web page.

**SAMPLE FORM: AUTHORIZATION FORM FOR DISCLOSURE OF HEALTH
INFORMATION FOR RESEARCH PURPOSES**

I voluntarily give permission for the use or disclosure of my health information as stated below for the research study titled, (Research title).

The following people may provide my health information:

The following people may receive my health information:

This information is being disclosed for the following purposes: (Include study title)

I may withdraw my permission at any time by writing to (insert PI name and address). If I withdraw my permission, any information already disclosed cannot be taken back. Once information about me is disclosed as this form states, the person receiving the information may disclose the information and it may no longer be protected by federal privacy laws.

I may refuse to sign this form. If I choose not to sign this form, I may not be able to participate in this research study. My decision not to sign this form will not affect my relationship with my doctors, hospital, or insurance.

This permission will expire when the research ends (give a date or state "the authorization will have no expiration date").

If I have any questions about this form or the research, I can call (PI name and phone number and second contact and phone number) or the Office of Research and Program Development at the University of North Dakota at (701) 777-4279.

I will be given a signed copy of this form.

Signature and date line for subject or subject's legal representative

Printed name of subject or legal representative