

Human Subjects Manual
For
Investigators

Idaho State University
Human Subjects Committee
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INTRODUCTION

The Idaho State University Human Subjects Committee Investigator's Manual for the Protection of Human Subjects is the reference guide detailing the policies, procedures and regulations governing research with human subjects and the requirements for submitting proposed research for review by the Idaho State University (ISU) Human Subjects Committee (HSC).

This manual presents information about research using human subjects. Because of the evolving field of protection for humans as subjects, parts of this manual are subject to change. The Idaho State University's HSC staff will update the manual when appropriate.

The review of research at ISU is conducted in accordance with the federal regulations as published by the Office of Human Subject Research (OHSR) of the Department of Health and Human Services (DHHS), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA). These federal regulations stipulate that ISU will protect the rights and welfare of human subjects involved in research through a review process detailed in (45 CFR 46). The HSC has sole authority at ISU for the approval of research with human subjects. HSC review applies to research conducted by faculty, students, staff, or agents of the university, on the ISU campus or utilizing facilities or resources of ISU, as well as research conducted elsewhere by ISU personnel in connection with their institutional responsibilities. The review requirements apply to all research conducted under the auspices of ISU, regardless of the funding source or university support. The HSC has the authority to suspend or revoke its approval of on-going research [45 CFR 46]. Failure to comply with HSC requirements is considered serious misconduct and may be subject to sanctions, including possible termination of approved research.

The review of applications to involve human subjects in research consists of a process of negotiation between the investigator and the HSC. The process of negotiation begins with the submission of the application to the Committee. The HSC creates a dialogue with investigators regarding the risks and benefits posed to potential subjects participating in the research, the nature of the consent process, and the document that represents the legal written part of the consent process, the *informed consent form*. The dialogue between the HSC and investigators will most often take the form of correspondence resulting from the Committee review of the study. Receiving correspondence from the HSC is typical and should not be viewed as a negative comment about the content of the research, nor is it necessarily a disapproval of the study.

DEFINITION OF RESEARCH

Virtually all research with human subjects is governed by federal regulations patterned on those of the Department of Health and Human Services (<http://www.hhs.gov/ohrp/>), found in Title 45 Code of Federal Regulations, Part 46 [45 CFR 46].

Research is defined in [45 CFR 46] as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

Human subjects are defined by the regulations as “living individuals about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.” The HSC at ISU is required by federal regulations to review all university affiliated human subjects research, regardless of funding, to ensure the rights, welfare, and protection of all subjects.

THE FOUNDATION OF 45 CFR 46: THE BELMONT REPORT

In 1974, the passage of the National Research Act established the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. The Commission published the Belmont Report (www.isu.edu/research/docs/hsc_forms/belmontreport.pdf) which conveys the basic ethical principles that guide the conduct of research with human subjects.

The ethical principles of respect, beneficence, and justice are set forth in the Belmont Report guide the HSC. The Commission also published a report on Institutional Review Boards and a series of reports on research involving human fetuses, children, prisoners, and mentally impaired individuals (“those institutionalized as mentally infirm”). The three principles are explored below:

- **Respect.** By honoring the privacy of individuals and maintaining their confidentiality, out of respect for potential research participants, investigators are required to obtain voluntary written informed consent. The consent forms contain specific assurances of the voluntary nature of their participation in terms that are easy to understand, assure subjects that they are not under pressure to participate in the proposed research and adequate information about the study that will assist them in intelligently deciding whether to participate in the research. In addition, respect means honoring the privacy of individuals and maintaining their confidentiality. Respect for minors and mentally disabled persons require taking extra precautions to protect those individuals who are adolescent or debilitated. This requires the possibility of excluding them from participation in certain types of research depending on the risks and benefits of the research to the participants.
- **Beneficence.** The principle of beneficence requires that researchers maximize the potential benefits to the subjects and minimize the potential risks of harm. Direct benefits to subjects or indirect benefits in the form of generalized knowledge gained from the research should always outweigh the risks. In addition, if there are any risks resulting from participation in the research then there must be benefits, either to the subject or to humanity or society in general, which outweigh those risks.
- **Justice.** The principle of justice means that the selection of subjects is fair and that the risks and benefits of research are distributed impartially to all. Investigators should take precautions not to systematically select subjects simply because of the subject’s easy availability, their compromised position, or because of social, racial, sexual, economic, or cultural biases institutionalized in society. Investigators should base subject inclusion criteria on those factors that most effectively and soundly address the research problem.

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REVIEW PROCESS

Applications submitted undergo one of three review levels:

- Certificate of Exemptions
- Expedited Review
- Full Committee Review

CERTIFICATE OF EXEMPTIONS

Research activities in which the only involvement of human subjects will be in one or more of the specified categories may qualify for a Certificate of Exemption from the HSC.

In order to fulfill federal requirements for the proper review of research, investigators cannot “self-exempt” from HSC review. Determination of exempt status is determined by the Chair of the HSC in consultation with the full Committee. Investigators are urged to consult with the Chair of the HSC before applying for exemption from Committee review. Explanations of the exempt categories are found in the following sections. Claims for exempt status must be submitted on the Certificate of Exemption Form (HS-7) found at (http://www.isu.edu/research/hsc_forms.shtml).

A Certificate of Exemption does not necessarily exempt investigators from the requirement for obtaining informed consent from subjects. Most research requires the use of an informed consent procedure. For studies where there are no subject identifiers, i.e., anonymous data is collected; an information sheet or cover sheet is usually required. (See 3, Informed Consent Requirements, for more information.)

The categories of research activities eligible for exemption certification are:

1. Normal Educational Practices and Settings

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special educational instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management techniques. Educational research proposals are exempt providing all of the following are met:

- The study procedures do not entail a significant deviation in time or effort from those educational practices already existent in the study site
- The study procedures do not involve an increase in the level of risk or discomfort beyond normal, routine educational practices
- The study procedures do not involve sensitive topics, such as sexual behavior of individual subjects. A sensitive survey is one which deals with socially questionable or highly personal issues or alcohol and/or drug abuse
- Provisions are made to ensure the existence of a non-coercive environment for all students, including those who choose not to participate
- The school or other agency grants written approval for the research to be conducted.

2. Anonymous educational tests, Surveys, Interviews, or Observations

Research involving the use of educational tests (cognitive, diagnostic aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless information obtained is recorded in such a manner that human subjects can be identified, directly or indirectly, through identifiers linked to the subjects; and any disclosure of the

human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. The HSC is required to review copies of the informed consent form and proposed questionnaire or survey instrument(s) prior to approval and implementation.

Educational tests that are exempt from HSC review are tests of:

- Knowledge
- Mastery
- Skills

Investigators should note that a survey is anonymous when there is no possible way to identify the participants from the data collected. Data is not anonymous if anyone or any procedure such as accessing a computer database will identify the subject. In most instances, the omission of names or other specific identifiers, such as social security numbers, is insufficient to qualify a study as anonymous. Sometimes an investigator may preserve a subject's anonymity while retaining data on individual characteristics such as age, gender, ethnic origin, occupation, or diagnosis. Anonymity is possible only when studying large samples or populations. When the number of potential participants is small or the research setting is identified, anonymity can be threatened or compromised even when the names are removed from the data.

Observational research involving sensitive aspects of subjects' behavior, or in settings where subjects have a reasonable expectation of privacy, is not exempt. Research using survey or interview procedures do not qualify for a Certificate of Exemption if minors are involved as subjects. In addition, observation of minors is not exempt from Committee review if the researcher participates in or influences the observed activities.

Similarly, sensitive survey research is seldom exempt from HSC review (see below for exceptions). A sensitive survey includes questions about illegal activities, or highly personal aspects of the subject's behavior, life experiences, or attitudes. Examples include chemical or substance abuse, sexual activity or attitudes, sexual abuse, criminal behavior, sensitive demographic data, detailed health history, etc. The potential for provoking a negative emotional reaction from subjects is a principal determining factor in sensitive survey research. Questionnaires or surveys covering sensitive topics may qualify for a Certificate of Exemption if they fulfill the following:

- Anonymity of the subject is guaranteed
- Potential subjects are fully informed of the sensitive nature of the topics prior to their participation
- The study does not exceed minimal risk. (See Chapter 6, Risk/Benefit Assessment, for a discussion of the terms "risk", "benefit", and "minimal risk.") Additional consideration for exemption includes whether there is a risk associated with a possible breach of confidentiality (i.e., accidental disclosure of drug use to law enforcement personnel). In surveys with potential psychological risk, review of exemption includes risks associated with surveys about sensitive topics as well as those resulting from a breach of confidentiality. When confidentiality is an issue, the presence or absence of subject identifiers may be a decisive factor.

3. Identifiable Subjects in Special Circumstances

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph two (2) of this section, if the human subjects are elected

or appointed public officials or candidates for public office or federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information be maintained throughout the research and thereafter. Copies of the informed consent form and questionnaire or survey instrument(s) to be used must be forwarded to the HSC for review.

4. Collection or Study of exiting data or documents

There are three different types of items that are considered in this section: existing data, existing documents, and existing human biologic specimens to be used for non-genetic research. Federal regulations stipulate that “research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects” may qualify as exempt from HSC review.

For example, research using medical records would be exempt from HSC review under the federal regulations if the records:

- Existed prior to the initiation of the research project
- The investigator records the information in such a way that subjects cannot be identified directly or through the identifiers

Archived pathology or diagnostic specimens that are considered residual biological material and are destined to be destroyed can be used in research and are considered exempt from HSC review if there are no patient identifiers linked to the specimen and if the data is not intended to be used in the diagnosis or treatment of a patient. If either of these conditions applies, consent of the research subject is required and the study is not exempt from HSC review. (See the previous section of this chapter The HSC Review Process, Exempt from HSC Review for more information.)

If the data/specimens are collected after the submission of the HSC application, the data is not pre-existing or archived. When the data/specimen is not archived or if the information is recorded with direct or indirect identifying links to subjects, the protocol requires HSC review and may require written informed consent.

Research which includes review of private records involving access to and/or recording of identifiable information is *not exempt* from HSC review and *requires prior written consent* of the subjects.

Records considered private based on federal and state statutes, including medical records, insurance records, and educational records, require written release by the individual subject or by the custodian of the record and prospective HSC full review to be used in research.

Specimens received as extra material or extra specimens requested from a physician conducting a clinical procedure are not pre-existing or archived and thus require written informed consent from the subject and review by the HSC. If there is a link to the patient’s identity and a possibility that the patient may be contacted in the future, an informed consent document is required. Furthermore, informed consent is required if there is a link to the patient’s identity and a possibility that the research may result in commercial or economic value.

This section does not apply to human biological specimens collected or used for genetic research. There are additional ethical concerns for genetic research that may apply for other types or research with biological specimens. Contact the HSC for additional information.

Many agencies and/or departments routinely collect data or information as part of an on-going quality control or quality assurance process. In most situations, the collection of such information does not constitute research and is, therefore, not reviewable by the HSC. In

addition, educational agencies may collect information related to student progress or to assess the effectiveness of new programs or projects. As with quality control or quality assurance information, the data collected by educational agencies is usually not reviewed by the HSC. The HSC becomes involved when researchers wish to access this information for research purposes. Research involving existing data and/or documents is typically exempt under “Exempt Category 4” as long the following conditions pertain:

- The data and/or documents must exist prior to the conceptualization of the research project. This is what was earlier referred to as archived or “on-the-shelf” data and/or documents.
- The data and/or documents are publicly available, which means that anyone off the street may have access to the data and/or documents. Data and/or documents whose access is restricted to select groups are not publicly available.
- The information from the data and/or documents must be recorded in such a manner that subjects cannot be identified directly, or through identifiers linked to the subjects.
- The custodian of the data and/or documents provides written consent for the use of the data and/or documents. Further, the custodian of the data and/or documents certifies that they are publicly available.

5. Public Benefit or Service Programs

Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine;

- Public benefit or service programs
- Procedures for obtaining benefits or services under those programs
- Possible changes in or alternatives to those programs or procedures
- Possible changes in methods or levels of payment for benefits or services under those programs

This category may also be applied to service/program evaluations of state, city or county programs providing;

- The program being studies delivers public benefits or services
- There is specific statutory authority over the program
- There is no statutory requirement that the program evaluation plan be reviewed by an IRB
- There is no significant invasion of the privacy of the participant

6. Taste and Food Evaluation and Acceptance Studies

Taste and food quality evaluation and consumer acceptance studies if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency or the Food Safety and Inspection Services of the U.S. Department of Agriculture.

These exempt categories **do not** apply to research involving:

- Prisoners, fetuses, pregnant women or human in vitro fertilization
- The review of medical records if the information is recorded in such a way that subjects may be identified

- Survey or interview techniques which include minors as subjects
- Research involving the observation of the public behavior of minors
- Techniques which expose the subject to discomfort or harassment beyond levels in daily encountered life
- The deception of research subjects

EXPEDITED REVIEW

Research activities that can be considered for *Expedited Review* present no more than minimal risk to human subjects, and involve only procedures listed in one or more of the following categories may be reviewed by the HSC through the expedited review procedures authorized by [45 CFR 46.110] and [21 CFR 56.110]. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedures when specific circumstances of the proposed research involve no more than minimal risk to human subjects. Though the federal regulations state that the categories in this list apply, regardless of the age of the subject, the “vulnerable population” stipulation still applies. The *expedited review* procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. Investigators are reminded that the standard requirements for informed consent apply regardless of the type of review utilized by the HSC. Expedited review procedures do not release the investigator from the obligation of obtaining informed consent from human subjects enrolled in the research.

Additional categories eligible for expedited review in accordance with [45 CFR 46. 100] and [21 CFR 56.110] are:

1. Clinical studies of drugs and medical devices only when conditions are met:
 - Research on drugs for which an investigational new drug application [21 CFR Part 312] is not required. (Research on marketed drugs that significantly increases the risks associated with the use of the drug is not eligible for expedited review.)
 - Or**
 - Research on medical devices for which an investigational device exemption application [21 CFR Part 812] is not required or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows:
 - From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period, and collection may not occur more frequently than 2 times per week
 - From other adults considering the age, weight, and health of the subjects, the collection procedure, the amount of blood collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kilogram in an 8 week period, and collection may not occur more than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means:
 - Hair and nail clippings in a non-disfiguring manner

- Deciduous teeth at the time of exfoliation or if routine patient care indicates a need for extraction
 - Permanent teeth if routine patient care indicates a need for extraction
 - Excreta and external secretions (including sweat)
 - Non cannulated saliva collected either in a non stimulated fashion or stimulated by chewing gum base or wax or by applying a diluted citric solution to the tongue
 - Placenta removed at delivery
 - Amniotic fluid obtained at the time of rupture of the membrane prior to or during delivery
 - Supra- and sub gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
 - Mucosal and skin cells collected by buccal swab, skin swab, or mouth washings
 - Sputum collected after saline mist nebulization
4. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples of non-invasive procedures that may qualify for expedited review are;
- Physical sensors that are applied either to the surface of the body or at a distance and do not involve the input of significant amounts of energy into the subject or an invasion of the subject's privacy
 - Weighing or testing sensory acuity
 - Magnetic resonance imaging
 - Electrocardiograph, ultrasound, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, diagnostic infrared imaging, doppler blood flow, and echo-cardiography
 - Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records or specimens) that have been collected solely for non-research purposes (such as medical treatment and/or diagnosis). (Note: Some research in this category may be exempt from HSC regulations for the protection of human subjects [45 CFR 46.101(b)(4)]. This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital or image recordings for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (*Some research in this category may be exempt from HSC regulations for the protection of human subjects [45 CFR 46.101(b)(2) and (b)(3)]. This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the HSC as follows:
 - Where the research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, and the research remains active only for long-term follow-up of subjects
 - Where no subjects have been enrolled and no additional risks have been identified
 - Where the remaining research activities are limited to data analysis
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories (2) through (8) do not apply but the HSC has determined and documented at a convened full Committee meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Usually research involving “vulnerable populations” does not qualify for expedited review. The full Committee must review research involving “vulnerable populations.”

Expedited reviews are reviewed by an individual Committee member. All studies received by the HSC are evaluated for possible expedited review. Reviewers conducting an expedited review may exercise all of the authority of the HSC, except they may not disapprove a study. When a reviewer cannot approve the research under expedited review, the study is remanded to the full Committee for review at its next scheduled meeting.

Minor modifications to approved protocols submitted between scheduled continuing reviews, which only involve minor changes in protocols or minor changes in consent forms, also may qualify for expedited review. Only changes that do not increase the risk to research subjects may receive an expedited review. Modifications to approved protocols that may affect the risk to subjects are forwarded to the full Committee for review.

Investigators will receive written notification of HSC action resulting from an expedited review. Notification may include approval of the protocol as is or a request for minor modifications in the protocol. Requests for major modifications will result in the protocol being remanded to the full Committee for review.

FULL COMMITTEE REVIEW

Full Committee review usually takes a minimum of 14 days from the date of submission. If no additional information or modifications are required, the HSC will approve a study within this period.

The HSC performs a detailed examination of the protocol, informed consent form, and all supporting documentation, including any questionnaires or survey instruments. Consideration, discussion, and a vote regarding the proposed research must occur during a properly convened meeting of the HSC. Letters, sent to investigators following the HSC meeting, will include the results of the Committee decision, justify any conditions required for approval, may request additional information, and will indicate the next step in the review process.

The HSC may come to one of four determinations regarding an application:

1. Approve without questions or requests for modifications.
2. Approve with requests for clarification and/or minor modifications. An investigator’s response to the HSC request may be approved by the Chair of the HSC without additional review from the full Committee.
3. Request major modifications. The HSC has substantive concerns or significant requests for clarification. Responses to the HSC request in this category must be returned to the full Committee for deliberation and review.
4. Disapprove or remanded.

Investigators have the right to discuss HSC requests for revisions and decisions with the Chair. The HSC, however, retains the final authority for approval of proposed research with human subjects.

Investigators can contact the secretary of the HSC to determine the meeting schedule of the Committee or consult the website www.isu.edu/research/hsc_meet.shtml.

Application materials are available online at www.isu.edu/research/hsc_forms.shtml. Any questions regarding HSC review or the content of this manual should be directed to the secretary or the chair of the HSC.

The HSC secretary can be contacted:

Human Subjects Committee
Mail Stop 8130
Telephone 282-2179

The **Certificate of Exemption Request Form (HS-7)** consists of the following sections:

1. Cover Page and Investigator's Assurances
2. Exemption Category claimed
3. Protocol Questions (answer the questions appropriate for your research).
4. The Informed Consent Form (HS-2a or 2b) and/or Assent Form for children.
5. Other Considerations
 - 1) Off campus Research or Recruitment requires a letter of approval from the non-ISU facility or agency. Do not wait for approval of non-ISU sites before submitting the proposal to the HSC. If the HSC approves the project prior to obtaining the letter of approval or non-ISU IRB approval, the HSC approval notice will carry the following addition: "This Approval Notice is issued for administrative purposes only. No subjects may be contacted, recruited, or enrolled for the study. All related HSC approved consent forms will be held on file with the HSC until the approval notice from the IRB of [name of the facility] is received by the ISU HSC." If the non-ISU site has an IRB, approval must come from this entity. If no IRB exists approval must come from the administrative official of that organization
 - 2) The HSC is required to review any advertisements, flyers, internet postings (with the internet address), etc., for subject recruiting, correspondence with subjects or with other cooperating individuals, such as referring physicians or facilities. In addition, the Committee reviews all press releases intended to facilitate recruitment of subjects. For medical and pharmaceutical studies, contact documents should not make any claims, either explicitly or implicitly that the research is superior to any current practice. Limit advertisements to:
 - i. Name, address, contact information of investigators and research facility
 - ii. Condition under study and/or purpose of research
 - iii. General eligibility criteria for participation
 - iv. Participants' benefits, if any
 - v. Time or other commitments required of the subjects
 - vi. Location of research and persons or office to contact for further information
 - 3) The HSC is required to review all research instruments, such as surveys, questionnaires, etc. Include the instruments, if available, with your initial application. Investigators may submit draft versions of study instruments for the

HSC to review. The HSC is also required to review any modifications to research instruments. Submit an addendum to the Committee when requesting changes to previously approved instruments.

6. A grant proposal (when applicable).

Certificates of Exemption have a three-year expiration date and are not required to submit six-month progress reports or final report. However, they are required to submit a renewal if the study continues longer than three years. The HSC will send a letter one month prior to the three-year expiration date reminding the investigator to submit the Certificate of Exemption (HS-7) to renew the certificate. The investigator needs to keep a copy of the renewal of the Certificate of Exemption for her/his records. **It is the investigator's responsibility to notify the HSC of any changes and to apply for a renewal of the proposal, etc.**

The **HSC Full or expedited Review Form (HS-1)** consists of seven sections:

- I. Cover Page and Investigator Assurances
- II. Funding and Disclosure
- III. Summary Information (Lay Language Summary)
 - 1) Background
 - 2) Procedures
- IV. Protocol Summary
 - 1) Purpose
 - 2) Background
 - 3) Literature Review
 - 4) Characteristics of Subject Population
 - 5) Subject Identification and Recruitment
 - 6) Methods and Procedures
 - 7) Questionnaires or surveys
 - 8) Data Collection, confidentiality, and Data Disposition
 - 9) Risk/Benefit Assessment
 - 10) Financial Considerations
 - 11) Consenting Information
 - 12) References
- V. The Informed Consent Form (HS-2a or 2b) and/or Assent Form for children.
- VI. Other Considerations
 - 1) Pilot studies and feasibility studies, even if they include only one subject, require the same consideration by the HSC as a project of 100 or more participants. Investigators interested in conducting feasibility or pilot studies should consider contacting the HSC prior to submitting an application. The HSC can advise the investigator on how to appropriately address issues related to the risks and benefits of participation.
 - 2) Off campus Research or Recruitment requires a letter of approval from the non-ISU facility or agency. Do not wait for approval of non-ISU sites before submitting the proposal to the HSC. If the HSC approves the project prior to obtaining the letter of approval or non-ISU IRB approval, the HSC approval notice will carry the following addition: "This Approval Notice is issued for administrative purposes only. No subjects may be contacted, recruited, or enrolled for the study. All related HSC approved consent forms will be held on file with the HSC until the approval notice from the IRB of [name of the facility] is received by the ISU HSC." If the non-ISU site has an IRB, approval must come

from this entity. If no IRB exists approval must come from the administrative official of that organization

- 3) Review and approval from other ISU committees must be submitted to the HSC with the application. Ultimately, the final authority for participation of human subjects in research falls on the HSC, although other institutional committees also share the responsibility for following guidelines.
- 4) The HSC is required to review any advertisements, flyers, Internet postings (with the Internet address), etc., for subject recruiting, correspondence with subjects or with other cooperating individuals, such as referring physicians or facilities. In addition, the Committee reviews all press releases intended to facilitate recruitment of subjects. For medical and pharmaceutical studies, contact documents should not make any claims, either explicitly or implicitly that the research is superior to any current practice. Limit advertisements to:
 - i. Name, address, contact information of investigators and research facility
 - ii. Condition under study and/or purpose of research
 - iii. General eligibility criteria for participation
 - iv. Participants' benefits, if any
 - v. Time or other commitments required of the subjects
 - vi. Location of research and persons or office to contact for further information
- 5) The HSC is required to review all research instruments, such as surveys, questionnaires, etc. Include the instruments, if available, with your initial application. Investigators may submit draft versions of study instruments for the HSC to review. The HSC is also required to review any modifications to research instruments. Submit an addendum to the Committee when requesting changes to previously approved instruments.
- 6) The HSC is required to examine the Investigator's Drug Brochure and/or device manual in order to adequately assess the risk/benefit ratio for subjects participating in the research. In addition, complete Section IV, of the Full or Expedited Review Form (HS-1), Investigational Drug Information Record, for research conducted with non-Food and Drug Administration (FDA) approved drugs or drugs used for indications other than those approved by the FDA.

VII. A grant proposal (when applicable).

MODIFYING AN APPROVED RESEARCH PROTOCOL

All modifications to currently approved research are required to have HSC review and approval prior to implementation. Minor changes that do not increase the risk to research subjects may receive an expedited review. Modifications to approved protocols that may increase the risk to subjects are forwarded to the full Committee for review, even if they were originally reviewed and approved through the expedited process. (See Chapter 2, The HSC Review Process, for information regarding expedited review.) Include the Full or Expedited Review Form (HS-1), a cover letter explaining the requested modifications, and any modified items such as consent forms, protocols, investigator brochures, study instruments, recruitment tools, etc., with the application.

The HSC may only approve modifications submitted during a current approval year to the end of that period. For example, if the new, renewal, or continuing approval is issued on January 1, 2006, it will have an expiration date of December 31, 2006. If an addendum is approved during

that time, the approval still lasts until December 31, 2006. Incorporate all modifications and addendums into the renewal protocol, and when applicable, the informed consent forms for HSC consideration during the annual renewal.

Changing Investigators. When changing investigators, include the Full or Expedited Review Form (HS-1), a letter from the principal investigator indicating the change in responsibility and a letter from the new investigator accepting responsibility for the research (or his/her role in the research). Changes in investigators may qualify for expedited review of the proposal.

REVIEW FOR RENEWAL

The federal regulations do not allow an HSC to approve a study for more than one year except for exemptions. For multi-year research, **the principal investigator is responsible for submitting a renewal application prior to the expiration date of the current HSC approval.** If the approval expires prior to submission of the renewal application, the investigator is required to suspend subject contact and data collection until the continuation is approved by the HSC. For therapeutic studies where subject safety is a concern, the FDA allows some flexibility for the continued treatment of currently enrolled subjects. However, no new subjects may be contacted, recruited, or enrolled in the study until the investigator obtains current HSC approval.

The renewal application should incorporate all of the addenda and modifications submitted to and approved by the HSC during the previous approved period. Include a cover letter indicating the modifications to the study during the previous approved period. If it was approved for Expedited Review, Full Review, or Certificate of Exemption, it should be renewed as such.

Renewal review and approval is necessary if the recruitment of subjects stops but the previously enrolled subjects continue to participate in the research or the study is in the process of data analysis at ISU.

PROGRESS AND FINAL REPORT

Federal regulations, especially those governing research monitored by the FDA, require researchers to submit periodic reports to the HSC. The first periodic review is due six months following the date of the original approval by the HSC, and every six months after each renewal until the Final Report is submitted. The **principal investigator has the responsibility for submitting the progress report.** Failure to submit a Progress Report in a timely fashion may result in withdrawal of the HSC approval for that project.

COMPLETION/TERMINATION

In order to formally complete a study file, the HSC requires that investigators officially notify the Committee when a study is terminated or completed. Investigators are required to complete a Final Report Form when closing a study. All studies require the completion of this form before the study file can be formally closed.

3

Informed Consent

Informed consent is the hallmark of ethical research; investigators must pay very close attention to this issue. This section describes the elements of informed consent, the procedures for obtaining and maintaining consent, and checklists and sample language. This section begins with the simplest case – signed consent of competent adults to participate in non-medical research – and then addresses more complex situations. Consult the relevant sections of this manual for more detail on determining competence to consent and vulnerable populations.

Although a good consent form is essential, remember that this must be combined with an appropriate process of consent. This includes recruitment procedures, opportunities to ask questions, time to consult with others, efforts to inform participants of new developments, and the freedom to withdraw from the study. It is difficult to be confident that volunteers truly understand the nature of their participation in research when they are confronted with a lot of complicated details in a brief and isolated session. Investigators and subjects should work as partners in a healthy process of an equal exchange of. As a result, subjects will have an improved understanding of the risks and anticipated of participation. An on-going consent process will facilitate an exchange of information between subjects and investigators in a scientific environment of increasing complexity. Providing subjects with a continuing consent process will ensure that subjects are completely informed about their participation in the research.

Writing a Good Consent Form

The consent form needs to give potential research subjects sufficient written information to decide whether to participate in a research study. A proper consent form protects both participants and researchers. Sample forms and instructions can be found at http://www.isu.edu/research/hsc_forms.shtml.

Here are some general tips for writing consent forms:

- Document Title: “Consent to Participate in Research”
- The title of your research project should be in clear lay language. Don’t just use the title of your grant proposal, dissertation, etc.
- Consent forms should be written at an 8th-grade level or below. Most word processing software includes tools for determining a document’s reading level. Avoid technical terms, jargon, acronyms, and abbreviations; make the document as simple, clear, and readable as possible without sacrificing accuracy or completeness.
- Use section headings to make clear the document’s organization. Don’t worry if some sections are just a few sentences long. It’s better to err on the side of having too many sections rather than too few.

Consent Form Checklist

Your consent form should include the following components. Use this checklist to ensure that you have included them all.

- Title of the research project *in clear lay language*
- Researcher’s name and affiliation
 - E.g., “You are invited to participate in a research project conducted by Dr. Jane Doe, a faculty member in the Psychology Department of Idaho State University”

- Purpose of the research *in clear lay language*
- Voluntariness! Make clear that participation is entirely voluntary; people are free to refuse to participate or to change their minds and withdraw once they've begun participation
 - E.g., "Your participation is completely voluntary. Your decision to participate will not change your medical care/course grade/etc. in any way"
- Summary of inclusion and exclusion criteria *in clear lay language*
- Step-by-step description of what will happen to participants
 - Explain when and where events will take place
 - Include reasonable estimates of how long each step will take
 - Use diagrams or other aids to understanding where appropriate
 - Make clear any procedural differences for those in different groups (e.g., experimental vs. control)
 - If participants will be randomly assigned to groups, make this clear
 - If participants will be "blinded" (i.e., will not know whether they are in experimental or control groups), make this clear
- List potential risks or discomforts
 - Describe both the likelihood and the seriousness of each risk
 - Include risks of breach of confidentiality
 - Explain what will be done to minimize these risks
 - If the researcher has no funds for compensating those who may be harmed as a result of participation in the research, then say so
 - *Exculpatory language is NOT PERMITTED.* Participants must not be asked to waive any rights, agree not to sue researchers, etc. Remind them that they are entitled to pursue compensation through the courts.
- List potential benefits to individual participants, to society, etc.
 - *Please* don't invent spurious benefits (e.g., "Participants will benefit by knowing they are helping to bring about a better future for everyone"). If participants will not directly benefit from participation, say so.
 - Don't simply assume that the experimental procedures will work – in many cases this is precisely what the experiment is intended to determine
- If participants will be paid or receive other compensation (e.g., receive merchandise or services, be entered into a drawing for a gift card), explain the details
 - Explain what participants will receive if they withdraw before completion. Pro-rated payments are recommended.
 - If participants will incur expenses for which they will be compensated (e.g., travel costs, parking fees), provide details. Explain any requirements for reimbursement (e.g., "You must submit your original receipts in order to receive reimbursement")

- Explain any anticipated delays in payment or reimbursement (e.g., “It may take 6 weeks for you to receive your check”)
- Don’t make payments so large that they constitute an undue influence
- Explain what steps will be taken to protect participants’ privacy or confidentiality
 - There may be limits to the confidentiality of this information. Note any reporting obligations (e.g., for child or elder abuse), as well as the authority of any applicable sponsors, federal agencies, the IRB or others to examine research records
 - If the research project has a Certificate of Confidentiality from a federal agency, explain this in the consent form
- Contact Information for the Principal Investigator and other key personnel
- Signature line for participants indicating that they have read the document, offered opportunities to ask questions and consider their choice, and agree to participate
 - It is rarely necessary to have a witness sign the consent form; it’s best to leave this out
 - Signed consent is not always required; see the “Waiver of Documentation of Consent” section below for details

Photo, Video, & Audio

If your research involves making photos, videos, or audio recordings of subjects, this needs to be explained clearly in the consent form. Make clear how these will be used. (Who will see them, and under what circumstances? Will they ever be used in presentations, publications, teaching, etc.? How will they be stored and protected, and for how long?)

If participants will be identified or identifiable in these records, it is highly recommended that they be allowed to review them before they are seen or heard by anyone else and empowered to have them edited or deleted in whole or in part. Explain this in the consent form.

Waiver of Documentation of Consent

Under certain conditions, the HSC may waive the requirement that subjects sign the consent form. A waiver of documentation of informed consent, however, *does not constitute a waiver of informed consent*. It is only the signature requirement that is waived; *the rest of the consent process must still take place*. In cases where documentation is waived, the HSC may require the investigator to provide subjects with a written statement regarding the research. The HSC is required to review and approve the written statement prior to its distribution to the subjects.

The HSC may waive the requirement to obtain a signed consent form for some or all of the subjects enrolled in the study if one of the following conditions exists:

- The consent document is the only record linking the subject and the research, where the principle risk would be potentially harmful resulting from a breach of confidentiality. The HSC will request that the investigator ask subjects whether they want documentation linking them to the research and the subjects’ wishes prevail.
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. Since this condition is subject to misinterpretation, it is rarely approved as a sole justification for a waiver of documentation of informed consent.

- For projects of minimal risk involving the use of questionnaires, the required elements of informed consent may be included in an introductory letter attached to the instrument, which included a statement that completion and return of the questionnaire constitute consent to participate.

Waiving or Altering the Consent Process

The HSC may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to document informed consent, provided one of the following sets of conditions exists and is documented:

- The research or demonstration project is conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
 - Programs under the Social Security Act, or other public benefit or service programs
 - Procedures for obtaining benefits under those programs
 - Possible changes in or alternative programs or procedures

Or

- Possible changes in methods or levels of payment for benefits or services under those programs

And

- The research could not practicably be carried out without the waiver or alteration

- The HSC may also grant a waiver if the research meets all of the following conditions:
 - The research involves no more than minimal risk to the subjects
 - The waiver or alteration will not adversely affect the rights and welfare of the subjects
 - The research could not practicably be carried out without the waiver or alteration and whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Research Involving Decisionally Impaired Subjects

Researchers must proceed with great caution when their projects involve people with an impaired ability to understand and evaluate the various aspects of their participation. These are vulnerable individuals, and great care must be taken to avoid exploiting them or exposing them to harm. The recruiting and consent process must include some means of determining whether potential participants are capable of providing valid consent.

In some cases, the HSC may stipulate that an independent third party be present during the consent process to ensure that potential subjects’ rights and interests are protected.

Anyone who is lacking decision-making capacity may not be involved in research presenting more than minimal risk without the written consent of an agent designated by a health care power or attorney, or some other legally authorized representative. Protocols submitted to the HSC should describe how capacity to consent will be determined, by whom it will be done, and what procedures will be in place to assure that legally effective informed consent is provided for all individuals found to lack decision-making capacity.

Individuals with severe cognitive or psychiatric disorders may or may not have the capacity to consent to participate in research. If the disorder has affected their reasoning, they may not be able to process information about the research, or they may be subject to actual or perceived

duress (coercion). This is particularly true of those who are institutionalized. Therefore, the first rule is to recruit subjects from non-institutionalized populations, to the fullest extent possible, even though it may be more convenient to work with patients confined to an institution or residents of a nursing home.

Deception or Withholding Information

There are times, especially in behavioral research, when investigators plan to withhold information about the real purpose of the study or purposely give subjects false information about some aspect of the research. As a result, the subject cannot be fully informed. The use of deception or incomplete disclosure imposes special responsibilities on the investigator.

Studies involving deception or withholding information *must involve no more than minimal risk*. In addition, the waiver of the elements of consent must not adversely affect the rights and welfare of subjects, and must be essential to the ability to carry out the research.

Debriefing Script: When research involves deception or withholding information, participants are typically debriefed afterwards. This debriefing explains the true nature of the research, filling in gaps or correcting misunderstandings. The HSC, in collaboration with the investigator, will determine whether subjects should be debriefed either after unwittingly participating in the research or after knowingly participating in research that involved deception. *Prepare a debriefing script and include it in your submission to the HSC.* Also explain when and where the debriefing will take place, and who will conduct it.

The debriefing must *offer participants the opportunity to have their data discarded* if they so choose.

Biomedical Research

The following changes or additions to the standard consent form are required:

- Identify the source of funding for the research
- If information will be gathered from the patient's medical record, provide details
- Explain which procedures are part of standard care and which are experimental
- Explain the clinical or treatment alternatives to participation in the research
- Make very clear whether participants should expect to be benefited by participation
 - Participants in medical research often assume that experimental procedures are as effective as or better than standard treatments. If this is not the case – and it generally is not! – then make this very clear
- Make clear that refusal to participate or withdrawal from participation will not affect the relationship with any clinicians, medical providers, or institutions
- **Consequences of Withdrawal:** When appropriate, the consent form should state the consequences of a subject's decision to withdraw from the research. If applicable, the consent form should also state any anticipated circumstances under which the subject's participation may be terminated by the investigator or sponsor without regard to the subject's wishes.
 - **Sample language:** *The investigator may withdraw you from this research activity (without your consent) if certain circumstances arise. For example, you may be withdrawn from this study if the investigator feels your continued participation places you at unnecessary risk of harm or you become ineligible because (list reasons). (If appropriate, describe the anticipated circumstances*

under which the subject's participation may be terminated by the investigator without regard to the subject's consent.)

- Describe which costs (if any) participants will be responsible for covering (e.g., medications, physician services, imaging, hospitalization, lab work); provide reasonable, good-faith estimates of these costs
 - Explain that insurance companies are very unlikely to cover any costs for experimental procedures
- Emergency care or compensation for injury: This section is required for any research whose risks are greater than “minimal risk” (i.e., risks greater than participants would encounter in daily life or in the course of an ordinary medical examination or psychological assessment).
- If the research may result in commercial products, processes, cell lines, etc., then explain whether participants will receive any share of the profits. If participants will not benefit from such commercialization, make this clear.

Other Parts of the Consent Process

Allow Time to Consider Participation

All efforts should be made to offer potential subjects sufficient time to consider the information contained in the consent form. The subject should be given the opportunity to take the consent form home and sign the form on a return visit, or the subject may be left alone to consult about enrollment with family or friends. If the individual decides to participate, he or she would sign the consent form.

Keep Participants Informed

Research is an on-going process that involves the constant re-evaluation of current information and procedures. Therefore, investigators are ethically obligated to keep subjects apprised of all issues related to their participation in the study. For example, new information may become available regarding the risks or benefits of the study procedures; researchers should keep abreast of the relevant literature, and pass important findings along to participants. This should be done in writing, accompanied by appropriate verbal summaries and explanations. In some cases, new findings or information may require that participants be asked to sign a revised consent form and reminded that their participation is voluntary and need not continue. Likewise, adverse events may occur during a research activity that would directly affect whether prospective or enrolled subjects would wish to continue in a particular research activity. Subjects must also receive the new information as a part of the continuing consent process. *New information, revised consent forms, etc. must be approved by the HSC before presenting them to participants.*

Information also may arise regarding the study, which should be shared with previously enrolled subjects after the completion of a study, a specific treatment, or procedure. For example, dysfunctional families may participate in qualitative research examining parenting techniques. Following data analysis, the investigator finds that a specific technique is superior to the other study arms of the project. As a health care and educational institution, ISU investigators are morally obligated to provide this valuable new information to research participants.

4

RISK/BENEFIT ASSESSMENT

Investigators submitting research proposals for HSC review should understand that the Committee is responsible for assessing the risks versus anticipated benefits of research as one of its primary functions. In addition, once risks and benefits have been assessed, the HSC is responsible for ensuring that the risks of study participation are minimized to the greatest extent possible, while the benefits of study participation are maximized.

The following definitions of risk, minimal risk, and benefit, which are used to assess risks and benefits as they pertain to research conducted at ISU, are defined by the DHHS as follows:

Risk: The probability of harm (physical, psychological, social, or economic) occurring because of participation in a research study. Both the probability and the magnitude of possible harm may vary from minimal to significant. The federal regulations only define “minimal risk.”

Minimal Risk: A risk is considered to be minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

Benefit: A valued or desired outcome; an advantage

Although these terms may appear straightforward, evaluations of risk and benefit are made more complex both by the subtle distinctions between therapeutic and research activities, and by evaluations of actual risks in the lives of normal and vulnerable classes of subjects (i.e., prisoners, children, cognitively impaired individuals, etc.)

HUMAN SUBJECTS COMMITTEE CONSIDERATIONS

There are a number of steps discussed by the DHHS that the HSC must follow when assessing risks and anticipated benefits. The HSC is required to:

- Identify the risks associated with the research, as distinguished from the risks of therapies the subjects would receive even if not participating in the research
- Determine that the risks will be minimized to the fullest extent possible

- Identify the probable benefits to be derived from the research
- Determine that the risks are reasonable in relation to the benefits to subjects, if any, and the importance of the knowledge to be gained
- Assure that potential subjects will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits
- Determine intervals for periodic review, and, where appropriate, determine that adequate provisions are in place for monitoring the data collected and, if the subjects are likely to be members of vulnerable populations, determine that appropriate additional safeguards are in place to protect the rights and welfare of these subjects.

Because the HSC is required to follow the above listed procedures, investigators should address these considerations in their protocol and consent form.

IDENTIFICATION AND ASSESSMENT OF RISKS

When considering risks, the HSC considers only those risks associated with the research, i.e., physical, psychological, social, legal, emotional. Investigators should be aware that risks would include immediate risks of study participation, risks of randomization (especially to placebo groups in medical and pharmaceutical research), risks of breach of confidentiality, and risks of long term effects.

For biomedical research (primarily medical and pharmaceutical research) the HSC is required to determine and differentiate between the risks associated with the research and the risks associated with standard diagnostic or therapeutic interventions or therapies subjects would undergo regardless of participation in research. Since the HSC does not establish or determine what constitutes “standard of care”, it is important for investigators to clearly distinguish procedures which are “standard of care” from those which are conducted solely for research purposes in the protocol and the informed consent form.

Physical Risks. Some research presents risk of physical injury to subjects. Although most of these risks are temporary, some adverse effects of study participation (especially those which result from medical procedures, drug research or device research) may result in permanent injury to subjects. For all research with the potential to do physical harm investigators are encouraged to think through all risk possibilities, however rare they may seem, so that they can be resolved quickly and effectively minimize harm to subjects.

Psychological Risks. Some research has the potential to cause undesired changes in thought processes and emotion including episodes of depression, confusion, and hallucination resulting from drugs, feelings of stress, guilt, and loss of self-esteem. As is the case with physical risks, these effects are usually temporary. For all research with the potential to cause psychological harm investigators are encouraged to think through all risk possibilities, however rare, so that a course of action can be planned to quickly and effectively minimize the distress to subjects.

Social and Economic Risks. Some research proposals involve the handling of sensitive information which may result in injury to subjects through a breach of confidentiality. These breaches may result in embarrassment within a subject’s business or social group, loss of employment, or criminal prosecution. The HSC is especially concerned about information regarding drug and alcohol use, mental illness, sexual behavior, and illegal activities. For these situations investigators should clearly detail strong precautions to ensure that the research does not cause social or economic risks to the subjects.

Research may also pose direct economic risk to study subjects. Procedures billed to insurance companies may require a significant co-payment on behalf of subjects, insurance companies may refuse to pay for “investigational” therapies, subjects may be responsible for transportation costs, and subjects may lose wages during research participation. Investigators should attempt to

minimize economic costs to subjects. If the research may involve additional actual costs to individuals, the anticipated costs should be described to subjects during the consent process.

Minimal Risk. Much of the HSC review process is governed by the concept of “minimal risk.” Assignment of research for expedited review, approval of waiver of consent, and the conduct of research involving vulnerable research populations may be dependent upon whether the research places subjects at minimal risk or greater than minimal risk (significant risk). Investigators should note that studies proposing procedures which pose less risk than standard procedures may not necessarily be determined to be of minimal risk to subjects. Investigators should pay particular attention to the term minimal risk as it is applied throughout this manual. (When the risks are unknown, they are considered greater than minimal risk.)

Benefits. The benefits of research fall into two categories: benefits to individuals and benefits to society.

Research frequently provides subjects with treatment, diagnosis or examination for an illness or abnormal condition. In these cases, the research involves evaluations that may benefit the subjects by improving their condition or providing better understanding of their disorder. Investigators should clearly detail those potential benefits for the HSC in the protocol and subjects in the consent form, while not over stating these benefits. The investigator should also attempt to maximize benefits to the greatest extent possible for potential subjects.

When research does not provide direct benefit to potential subjects, this should be stated in the protocol and in the informed consent form. Although research may not always provide a benefit to society, researchers are encouraged to design research projects so that information, in the form of generalizable knowledge, can contribute to societal benefit whenever possible. Investigators should clearly detail these potential benefits for the HSC in the application and for subjects in the informed consent form, while not overstating these benefits. Research, when not providing benefits to individuals, is required to provide a reasonable likelihood to result in benefits for society.

5

SELECTION AND RECRUITMENT OF SUBJECTS

SELECTION OF SUBJECTS

In order to allow for the fair and equitable distribution of the burden of research and to ensure that certain populations, such as prisoners or patients in mental institutions, were not recruited solely because of their easy availability, the National Commission for the Protection of Human Subjects recommended a hierarchy of preference in the selection of subjects for research: adults before children; competent individuals before incompetent individuals; non-institutionalized individuals before institutionalized individuals. To adequately assess the risks and benefits of participation in research, the HSC requires accurate information regarding the number of subjects to be recruited and tested. In order to ensure that the burdens of research are evenly distributed, the HSC is required to consider more than the risks associated with the research procedures. The HSC will also consider the impact that participation poses on the daily life of the potential subject.

RECRUITMENT OF SUBJECTS

Recruitment is the dialogue that takes place between an investigator and a potential subject prior to the initiation of the consent process. Investigators who are responsible for both the primary care of a patient/client and wish to consider enrolling the patient/client in a research project should carefully differentiate for the patient/client the alternatives and options of participation in the research without undue prejudice or pressure.

Respect for potential subjects begins with recruitment procedures that ensure the voluntary participation of the subject. Investigators proposing to recruit their students or patients as research subjects should justify in the protocol the necessity for the inclusion of the dependent subject. In addition, the HSC will closely scrutinize the precautions in place to prevent the appearance of coercion in the recruitment of subjects.

Investigators build a strong foundation for ethical research by ensuring and preserving the privacy and confidentiality of potential research subjects. In order to avoid a breach of the potential subject's privacy, investigators should not ask institutions, or their employees to directly identify potential subjects for a research study. Instead, an investigator should ask the institution director or an employee to first approach potential subjects (or their parent/guardian,

as appropriate) and inform them of the research. A potential subject's privacy and confidentiality may be compromised simply by being identified as a potential participant in a study or by identifying a patient/client's disorder to an investigator for the purposes of recruitment into research without the patient's consent.

Frequently, in order to protect the privacy of the potential subject and decrease any appearance of coercion, the HSC will request the use of a flyer or a contact letter posted in the waiting room or lobby of the facility to inform potential subjects about the research. The flyers, letters or post-cards would include a description of the study and a telephone number for potential subjects to call if they are interested.

Recruitment Tools. A recruitment tool informs potential subjects of a research activity and provides them with an opportunity to contact the researcher. Recruitment tools may include, but is not limited to, post-cards, flyers, advertisements, press releases, brochures, and postings on the Internet. All recruitment materials are required to have HSC review and approval prior to implementation. Investigators are encouraged to use the following guidelines when developing recruitment tools:

- Information should not be misleading to subjects, especially when the study involves vulnerable populations
- Include the name, affiliation, and address of the investigator
- The purpose of the research
- The eligibility criteria for participation
- An honest and direct description of the risks and benefits of the study
- Whom to contact for further information

No claim should be made as to the superiority, safety, or effectiveness of drugs or devices used in research

PAYMENT FOR PARTICIPATION IN RESEARCH

The nature, amount, and method of payment or other compensation should not constitute undue inducement to participate (i.e., the payment should not serve as sufficient inducement for the subject to volunteer). Investigators should consider reimbursement for the inconvenience posed to subjects or other costs to subjects resulting from participation in the research, such as parking fees, travel, lost time from work, baby-sitters, etc. The HSC must review any cash or alternative form of payments to potential participants.

Special precautions should be taken when payment is offered to a third party for the participation of someone else (other than the person who receives the payment) in the research. The HSC is concerned that such payments may constitute undue coercion from the third party to the actual research participant. For example, a parent may be offered remuneration for volunteering their child to participate in a research project. In these cases, precautions should be taken to clearly separate the payment to the third party from the consent/assent process with the actual research participant. Final approval for participation rests solely with the research participant and their consent/assent takes precedence over that of the person to whom payment is offered. Investigators should be aware that they might be making payments to a third party when the actual research subject declines participation.

Since subjects reserve the right to withdraw their participation from the research without prejudice, payment to subjects should be pro-rated, i.e., partial participation in a research activity would obligate partial payment. The HSC will review both the amount of the payment, to whom it is offered, and the proposed method of disbursement to ensure that payment for participation does not constitute coercion or undue influence.

Incentives to Physicians for Subject Enrollment. Payments and incentives to physicians for recruiting subjects could put inappropriate pressure on them to enroll participants. The IRB needs to review all cash incentives to physicians. This includes more money if their patients are enrolled, less money if they are only referred, and other types of payments other than money offered to promote their study.

6

RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS

Investigators should be aware of certain, specific responsibilities that are undertaken when conducting research. Although most investigators are familiar with some of the paperwork requirements associated with research, there are many reporting requirements which are often overlooked by investigators until problems are encountered with respect to a certain research activity. In today's litigious environment, it is important for investigators to prepare and maintain clear documentation of research activities in an attempt to minimize or alleviate unnecessary confusion which may arise during the performance of research and during the course of routine audits carried out by the HSC, the FDA or other sponsoring or regulatory bodies.

APPLICATIONS AND DEFINITIONS

Investigators are required to obtain a prospective ISU HSC review and approval if any of the following criteria exist:

- When research with human subjects is conducted by or under the direction of an employee, student or agent of ISU in connection with his or her institutional responsibilities
- When the conduct or recruitment of the research involves institutional resources (property), facilities or funding, including extramural funds administered by ISU
- When the research involves the use of ISU's non-public information to identify or contact human research subjects or prospective subjects
- Investigators who transfer research to ISU from their previous institution are required to submit the project to the HSC for review and approval in order to continue the study.

STUDENT RESEARCH

All ISU research which includes the participation of human volunteers is subject to federal regulations. The HSC is charged with the responsibility to protect the rights and welfare of all research subjects, not just those subjects who participate in federally funded projects. The HSC at ISU is committed to reviewing all research

- Involving human subjects
- Using records gathered on human subjects

- Involving human tissue. All research will receive HSC review and approval prior to the initiation of the research.

Student initiated research involving human subjects, whether dissertation, thesis or other research projects, should be supervised by a faculty advisor and submitted to the HSC for review. HSC review and final approval should take place during the proposal stage of the dissertation or thesis. By signing on as a sponsor of a student project, faculty advisors take the responsibility for ensuring that all research procedures comply with federal and university policies pertaining to the protection of human subjects.

Classroom Research. Some projects assigned to students in a class may have a research component or constitute training in research methodology. If such projects are intended to contribute to generalizable knowledge (e.g., through publication), they are subject to the regulations and are required to undergo HSC review and approval. Classroom projects that are exclusively for instructional purposes need not undergo review by the HSC. However, instructors and students are encouraged to follow federal and university policy when designing and conducting class projects with human volunteers.

RESEARCH FILES

Principal investigators are required to maintain a research file. The requirements for a research file include, but are not limited to, all correspondence with the HSC and the sponsor (as applicable), and documentation of subject eligibility as well as a copy of the signed informed consent form obtained from all subjects participating in and/or who have participated in the protocol regardless of whether or not the subjects completed the study. The protocol files should also contain any data derived from the study. The file will act as the investigator's documentation regarding proper performance of the study. This information will be reviewed by the HSC, federal or local authorities, sponsors, and other authorized individuals to ensure proper performance of the study. These rules also apply to all student researchers. Faculty advisors are required to maintain research files for student research completed under their direction.

For medically invasive research involving patients as research subjects, the investigator should ensure that a copy of the HSC approved consent form, signed by the subject or his/her legal representative, and is inserted into each subject's medical record. The investigator is responsible for ensuring that a copy of the consent form is provided to each subject enrolled in the study.

RECORD RETENTION AND CONFIDENTIALITY OF DATA

Record Retention. Requirements for record retention vary with the type of research conducted, provisions of the investigator's funding source, and the requirements of the investigator's professional association. The HSC highly recommends that investigators clearly understand the retention requirements of their sponsor and of their professional organization. Research records should be retained for at least three years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of the HSC, department, or agency supporting the research. The conditions for maintaining confidentiality of the subjects and the research records are required for the life of the data. These rules apply equally to research conducted by students and faculty.

Protocols conducted according to FDA guidelines must be maintained in accordance with current FDA regulations. Current FDA policy states that investigators are required to maintain records for the longest of either:

- A period of at least two years following the date on which the results of the clinical investigation are submitted to the FDA in support of an application for a research Investigational New Drug (INDs) number or Investigational Device Exemption or marketing permit;

Or

- A period of at least two years following the date on which an application for research or marketing permit (in support of which the results of the clinical investigation were submitted to the FDA) is approved by the FDA

Or

- Two years after the investigation is discontinued and the FDA is notified of that fact

OHRP (formerly OPRR) guidelines for federally funded research stipulate that records pertaining to the research are required to be retained for three years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of the department or agency supporting or conducting the research at reasonable times and in a reasonable manner [45 CFR 46.115(b)]. The HSC encourages investigators to maintain research records for longer periods, if practicable.

Confidentiality. Investigators are required to maintain and protect the privacy and confidentiality of all personally identifiable information of all human subjects participating in research, except as required by law or released with the written permission of the subject. Subjects, including children, have the right to protection against invasion of their privacy, to expect that their personal dignity will be maintained, and that the confidentiality of private information will be preserved. The more sensitive the research matters are, the greater the care required in obtaining, handling, and storing the data.

Information through which subjects may be identified include their name, student identification numbers, hospital ID numbers, social security numbers, driver's license numbers, home addresses, photographs, videotapes, and the like. Individuals also may be identified by description, for example, as the personnel manager of a particular company, the sixth grade teacher in a certain school, or the pediatric nurse at the local hospital. If information or data to be collected may be traced back to the individual subjects, safeguards should be provided to ensure confidentiality.

Guidelines for Protecting Confidentiality. Investigators are encouraged to adopt the following principles in order to protect the confidentiality of subjects participating in research:

- Limit recording of personal information to that which is essential to the research.
- Store personally identifiable data securely and limit access to the principal investigator or authorized research assistants/associates.
- Code data as early in the research as possible, and plan for the ultimate disposition of the code linking the data to individual subjects.
- Apply for Federal Certificates of Confidentiality (see below) for all situations for which certificates are reasonable and available.
- Do not disclose personally identifiable information to anyone other than the research team without the written consent of the subjects or their legal representatives. (Exceptions may be made in case of an emergency or as required by regulatory agencies.)

Certificates of Confidentiality. Data collection about sensitive issues (such as illegal behavior, alcohol or drug use, or sexual practices or preferences) requires the protection of confidentiality beyond preventing accidental disclosures. Under federal law, researchers can obtain an advance grant of confidentiality, known as a Certificate of Confidentiality, which will provide protection against compulsory disclosure, such as subpoena, for research data.

The investigator should define in the HSC application any conditions under which confidential information might be disclosed and create an informed consent document that accurately reflects those conditions, including any voluntary disclosure by the researcher. The HSC is required to determine whether the risks to subjects are minimized, informed consent is appropriate, and privacy and confidentiality protections are adequate.

The HSC has determined that Idaho State Code for reporting child/elder abuse/neglect is interpreted to include researchers. The Certificates of Confidentiality were developed to encourage participation in research by granting certain protections to a subject divulging possible compromising information. The Certificates, however, do not exempt investigators from performing ethical research nor do they allow investigators to renounce the responsibility to act in the public good. Though Certificates of Confidentiality can be used to defend against compelling a researcher to disclose child/elder abuse/neglect, they do not address the principal ethical issue, i.e., the responsibility of an investigator to act in the public good which logically extends to the protection of victims of abuse/neglect. As a result, the HSC expects investigators to act in an ethical manner and therefore comply with state law by informing subjects in the consent form of the obligation of a researcher to obey state law.

Incomplete disclosure or the use of deception cannot be used as a means to secure the participation of subjects in research. The federal regulations indicate that effective informed consent requires complete disclosure of all information that a subject could use to decide whether to participate in research. In addition, the regulations do not allow a waiver of the conditions of informed consent because conditions are difficult or because the conditions make it difficult to enroll subjects into the research. The HSC is required to consider whether the withheld information would influence the decision of potential subjects to participate in the research. Therefore, investigators are required to include a statement in the consent form that alerts potential subjects of the legal and ethical mandate compelling researchers to report known or suspected child/elder abuse/neglect.

Investigators, who are likely in the course of their research to become aware of a possible danger to an individual, are responsible for creating a mechanism that will both protect the subjects and comply with all incumbent moral and legal responsibilities. The HSC may require a modification of the Certificate of Confidentiality if an investigator may be informed of child/elder abuse/neglect. (See Chapter 4, Informed Consent Requirements: Confidentiality, for more information.)

Investigators should contact the following appropriate agency in order to obtain a Certificate of Confidentiality:

Protection for research on medical disorders or the use and effects of alcohol and other psychoactive drugs may be obtained from:

National Institute of Alcohol Abuse and Alcoholism (NIAAA)
Wilco Building, Suite 412
6000 Executive Boulevard, MSC 7003
Bethesda, MD 20892-7003

Protection for research on drug use or that includes the use of illegal substances can be obtained from the National Institute on Drug Abuse (NIDA):

National Institute on Drug Abuse
10-42 Parklawn Building
5600 Fishers Lane

Rockville, MD 20857

Protection for research on mental illness can be obtained from the National Institute of Mental Health (NIMH):

National Institute of Mental Health
9-C-04 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

For other health research contact:

Office of Health Planning and Evaluation
Public Health Service
737F Humphrey Building
U.S. Department of Health and Human Services
Washington DC, 20201

Certificates of Confidentiality for biomedical, behavior, clinical, or other research that does not fall into these categories are issued by the Assistant Secretary of the Department of Health and Human Services and are available for

- Direct federal activities (i.e., intramural research)
- Federally-funded activities
- Research in the United States that has no federal funding

Certificates are issued only “when the research is of a sensitive nature where the protection is judged necessary to achieve the research objectives.” The Public Health Service policy defines “sensitive” research as involving the collection of information falling into any of the following categories:

- Information relating to sexual attitudes, preferences, or practices
- Information relating to the use of alcohol, drugs, or other addictive products
- Information pertaining to illegal conduct
- Information that if released could reasonably be damaging to an individual’s financial standing, employability, or reputation within the community
- Information that would normally be recorded in a patient’s medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination
- Information pertaining to an individual’s psychological well-being or mental health.

Information in other categories not listed may also be considered sensitive because of specific cultural or other factors, and protection can be granted in such cases upon appropriate justification and explanation.

Additional policy considerations apply to research that involves the collection of data that relates to communicable diseases. The Assistant Secretary of the Department of Health and Human Services has issued a policy granting Certificates of Confidentiality to projects that “intend routinely to determine whether its subjects have communicable diseases and that are required to report them under state law.” Certificates will be issued:

- Where the referring and/or treating physician assures the project director that they have complied with reporting requirements.

Or

- Where there is no referring and/or treating physician, the investigator has reached an agreement with the health department about how they will cooperate with the department to help serve the purposes of the reporting requirements. (Unless the investigator can show why such cooperation is precluded.)

And

- Only where disclosures of identifiable information about subjects comply with regulations on subject protection and are explained clearly to subjects prior to their participation.

7

REPORTING ADVENTS, COMPLICATIONS OR COMPLAINTS

REPORTING ADVERSE EVENTS, COMPLICATIONS OR COMPLAINTS

All investigators conducting research with human subjects are required to report adverse events to the HSC in a timely fashion. For this purpose, adverse events are defined by the Department of Health and Human Services as “an undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention” (e.g., muscle soreness and tenderness following a physical therapy session). In non-medical research, an adverse event can consist of an undesirable and unintended consequence of, or reaction to, procedures. In either case, if new information becomes available, because of an adverse event, the investigator is required to submit the new information for HSC review for the possible inclusion in the consent form or additional deliberation by the HSC.

Situations may arise in which it is difficult to determine what constitutes a “serious” adverse reaction, or an “unexpected” event. Often it is impossible to completely understand the nature of a serious adverse reaction or unexpected event without fully considering other events which may have occurred and been reported to oversight bodies. As a result, investigators are discouraged from making determinations as to whether or not an adverse reaction is serious enough to warrant review by the HSC. Therefore, all adverse reactions and unexpected events should be reported to the HSC for review in accordance with the following procedures:

- All problems related to the safety of subjects; incidents of injury, any incidents or serious problems involving the conduct of the study or subject participation, such as, problems with recruitment and/or the consent process must be reported, in writing, to the HSC within five working days of awareness of the problem.
- The federal regulations require filing an Adverse Event Report with the HSC for each incident (See http://www.isu.edu/research/hsc_forms.shtml, Full and Expedited forms (HS-1), the form for Reporting Adverse Events and/or Incidents at ISU Sites (HS-5) and the form for Reporting Adverse Events and/or Incidents at Non-ISU Sites (HS-6)). The principal investigator is responsible for indicating whether a change in protocol and/or consent form is warranted and whether, in the investigator’s opinion, the adverse event was related to the research activity and why the investigator holds this opinion.

- In addition, the FDA has specific definitions, reporting requirements, and forms for reporting adverse events involving drugs, devices, and biologics (See Chapter 10, FDA Requirements).

Following receipt of an Adverse Event Report, the HSC will review the information to determine whether any further action is required regarding the protocol and/or consent form. The HSC reserves the right to review all additional information regarding a protocol to determine whether the study should continue (as originally approved), be modified, or be discontinued.

Investigators are responsible for reporting two types of adverse events:

- Any subject injuries, adverse events associated with the study procedures and/or problems involving the conduct of the study that may occur during the course of the research project

And

- Any possible breach of human subject protection in other research activities at ISU of which the investigator becomes aware

All fatal or life-threatening events must be reported to the HSC in writing within 48 hours of their discovery. All other problems regarding subject safety are required to be reported in writing to the HSC as soon as possible, but no later than five working days after their discovery. (See http://www.isu.edu/research/hsc_forms.shtml, Full and Expedited forms (HS-1), the form for Reporting Adverse Events and/or Incidents at ISU Sites (HS-5) and the form for Reporting Adverse Events and/or Incidents at Non-ISU Sites (HS-6)).

There are situations where a serious or unexpected adverse event requires an immediate change to a protocol in order to relieve an apparent immediate hazard to research subjects. In these situations, the principal investigator may implement a change necessary to protect the welfare of the research subject. Investigators are encouraged to contact the HSC if this type of situation arises prior to implementation of the protocol change. Investigators are required to notify the HSC in writing of the change with 72 hours, and include a written description of the change and events that necessitated immediate implementation

AUDITS

The HSC, the FDA, and the sponsor of a research activity are empowered to conduct periodic random audits of an investigator's protocol records. Investigators are required to keep copies of signed consent forms readily accessible for review. Since members of the HSC are familiar with current regulations, their presence during an audit may help prevent unnecessary confusion during the audit process. Audits may be performed during an on-going research project or following the completion of a research project. Investigators should ensure that all records for completed research projects are maintained for a reasonable amount of time following the completion of the research project. Storage time is often specified by professional organizations. The time that research records are maintained should not be less than that specified by the professional organization. Where no storage time is specified, research records, including all consent forms, should be maintained for no less than three years.

CLOSING STUDIES

Principal investigators have the responsibility of informing the HSC when a study is completed. A study is considered open and active until the investigator has submitted a final report to the HSC. (See the Final Report Form (HS-9)). The HSC secretary will contact investigators at six-month intervals following the initial approval of the research. At these six-month intervals, investigators are to submit either a continuation request or a final report. Investigators will be

notified by the HSC when their continuation or final reports have been approved. Faculty advisors for student research have the obligation to ensure that final reports are filed with the HSC in a timely fashion.

When a principal investigator terminates employment or other association with ISU, they are obligated to submit a termination report to the HSC or formally transfer the protocol to another principal investigator via an amendment, which is reviewed and approved by the HSC and the Department or Division head.

Generally, change of key personnel in federally funded or FDA regulated research requires prior approval of the funding agency and/or FDA.

Final reports are required because of the serious risks to subjects that may arise when research activities are terminated without HSC knowledge. For example, if a study is closed or HSC approval has lapsed, then ethically or medically indicated follow-up procedures might not be available. (See Application Forms (HS-9)).

Research activities may be closed by the HSC without investigator approval if it is determined that the investigator is no longer affiliated with ISU.

Blinded and double blinded research. Researchers need to notify the HSC of when the unblinding process is going to take place. Researchers also need to establish how they will notify the subjects (via telephone, written letter, in person during their next visit). If a letter is used, the HSC needs to review a copy of the letter before it is sent to the subjects. This letter will be placed in the study file after an acknowledge receipt of the information is forwarded to the researcher. If subjects will be notified by telephone or in person at their next visit, the researcher is to document the notification in the patient's study chart. The letter will be reviewed when the study is monitored internally. The unblinding results are not required to be reported to the HSC.

CONFLICTS OF INTEREST

Conflicts of interest refer to situations where one or more researchers have a financial interest in the research that is proposed. Financial interest does not refer to receiving funding for the support of the research project. Rather, a conflict of interest exists when one or more of the principal investigators might profit financially from the research, either directly or indirectly. In the preparation of the protocol, the researchers should carefully consider whether a conflict of interest exists. The HSC requires that conflicts of interest be fully disclosed in the protocol and that they be carefully explained. Researchers should also explain how they would minimize potential conflict of interest. Federal regulations require the reveal of all conflicts of interest to potential research subjects in the subject consent form.

8

SPECIAL CLASSES OF RESEARCH SUBJECTS

There are a number of research populations described in the federal regulations as “vulnerable” or that require additional consideration or protection. “Vulnerable” or “special” classes of subjects include children, prisoners, pregnant women, mentally disabled persons, and the economically and/or educationally disadvantaged [45 CFR 46.111]. In addition, the regulations outline specific provisions for research involving: fetuses, pregnant women, and *in vitro* fertilization [45 CFR 46 Subpart B], prisoners [45 CFR 46 Subpart C], and children [45 CFR 46 Subpart D]. Exemption from Committee review does not apply to research involving vulnerable populations or special classes of subjects. The following is a listing of some “vulnerable” subject populations. Consult with the Human Subjects Chair for special instructions in dealing with these groups.

- Fetuses and human *in vitro* fertilization
- Pregnant Women as Human Research Subjects
- Minorities
- Children
- Terminally Ill Patients
- Prisoners

Consult with the Chair for research concerning Medical Devices

9

REPORTING SUSPECTED CHILD ABUSE AND/OR ELDER ABUSE

Under Idaho law, health practitioners and educators are required to report to appropriate authorities when there is good reason to believe that a child or an elderly or dependent adult has been abused. They are required to also report an injury that indicates possible abuse of an elder or dependent child or if they have personally seen a child or adult with injuries from an apparent assault (See Child Protective Act, Idaho Code 16-1601 *et seq.*; “Adult Abuse, Neglect and Exploitation Act, Idaho Code 39-5301 *et seq.*”) (See Chapter 5, Informed Consent Requirements: Confidentiality, Chapter 8, Responsibilities of Principal Investigators: Confidentiality for more information.)

The state law differentiates between required reporting of physical abuse and the endangering of “emotional well being.” Investigators are reminded that state law periodically changes, and does vary from state to state. Investigators conducting research outside of Idaho should be familiar with the applicable reporting requirements of the state or country where the research is to take place.

CHILD ABUSE

“Any physician, resident on a hospital staff, intern, nurse, coroner, school teacher, day care personnel, social worker, or other person” who has knowledge of or observes a child who has been abused or reasonably suspects has been the victim of child abuse is required to report the known or suspected instance of child abuse to a child protective agency. They must be notified immediately or as soon as possible by telephone and to prepare and send a written report thereof within 24 hours of receiving the information concerning the incident to the proper law enforcement agency or department [Idaho Code 16-1619]. Child abuse reports are confidential.

ELDER ABUSE

“Any physician, nurse, employee of a public or private health facility, or a state licensed or certified residential facility serving vulnerable adults, medical examiner, dentist, ombudsman for the elderly, osteopath, optometrist, chiropractor, podiatrist, social worker, police officer, pharmacist, physical therapist, home care worker or other person” [Idaho Code 39-5303] is required to report known or suspected abuse or neglect to the appropriate law enforcement agency within 4 hours. Reports of abuse, neglect or exploitation are confidential.

State of Idaho Cancer Data Registry (CDRI) In 1969 the Cancer Data Registry of Idaho was established and became population-based in 1971. The Idaho State Legislature has provided guidelines for the establishment, requirements, and funding of the statewide cancer registry. The operations of the registry are mandated by Idaho Code 57-1703 through 57-1701. Funding is appropriated in Idaho Code 57-1701 and 63-25. The goals of the CDRI are to;

- Determine the incidence of cancer in the state of Idaho with respect to geographic, demographic, and social characteristics
- Monitor trends and patterns of cancer incidence over time
- Identify high risk populations
- Provide a database and serve as a resource in conducting epidemiological studies
- Provide data to assist public health officials, hospital administrators, and physicians to effectively plan services, prioritize health resource allocation, and develop and measure prevention and intervention strategies.

The HSC considers the data collected for and reported to the CDRI as secondary data (in most situations) for research purposes. However, researchers wishing to access CDRI data are required to submit a research protocol to the HSC prior to the use of the CDRI information. The completed protocol should include a letter from the CDRI granting permission to access the CDRI database. The research protocol and the letter from the CDRI should specify the records to be accessed and their relationship to the research objectives. Researchers are obligated to inform the CDRI that no data is to be released until the researcher has received approval from the HSC. In addition, researchers are bound by law to respect the confidentiality of data. Researchers accessing the CDRI database are required to sign a pledge of confidentiality and are subject to penalty if they through negligence or willful misconduct disclose confidential data.

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REPORTING NON-COMPLIANCE

The principal investigator is responsible for ensuring that they and any other co-investigators adhere to the principles and practices for the use of human subjects in research as set forth in this manual. In the case of student research, it is the responsibility of the faculty advisor to ensure that the policies and procedures of this manual are followed. Failure to observe these policies and procedures will result in a notification of non-compliance being forwarded to the Vice President for Research. The following is a partial list of situations that will result in a notification of non-compliance:

- Failure to submit the Application to Involve Human Subjects in Research and to receive approval from the HSC for such research
- Failure to obtain signed informed consent from human subjects or their duly authorized representatives, or failure to fully inform subjects of the purposes, risks and benefits of research participation
- Failure to notify the HSC of any adverse events or reactions
- Failure to submit six-month periodic reviews in a timely manner
- Deviating from the approved research protocol without prior notification and approval of the HSC

The Vice President for Research will follow the procedures for Responding to Allegations of Non-compliance. These procedures allow the investigator to respond to the allegations and to present evidence of compliance with all applicable rules and regulations governing the use of human subjects in research. During the time that an investigation of non-compliance is occurring, approval for the continuation of the research being investigated for non-compliance will be suspended. When the Vice President for Research has verified that non-compliance has occurred, the investigator's supervisor (Department chair) and Dean will be notified. In addition, for research supported by external funding, notification will be sent to the sponsoring agency. If the research involves drugs or medical devices, the Food and Drug Administration (FDA) will also be notified, regardless of the funding status.

Primary responsibility for the investigation of allegations of non-compliance rests with the Vice President for Research and not with the HSC. However, the HSC should be notified of any known or suspected issues of non-compliance.

