

## **CLARKSON UNIVERSITY GUIDELINES FOR WRITING IRB RESEARCH PROTOCOLS**

The following guidelines are based on the NIH guidelines available from <http://ohsr.od.nih.gov/info/sheet5.html>, accessed 12/13/05. Text used with NIH permission.

### **1. OVERVIEW**

The design, conduct and monitoring of a research activity involving human subjects is the responsibility of the Principal Investigator (PI) who provides a complete written description of the proposed research (a "research protocol") to the Clarkson University Institutional Review Board (IRB).

The Clarkson Federal Wide Assurance (FWA) describes the Clarkson policies and procedures related to research involving human subjects. In keeping with its FWA, no activity involving human subjects or involving Clarkson may begin until it has been reviewed and approved by the IRB. This information sheet provides guidelines for writing research protocols which contain all the necessary information for IRB review.

### **2. RESEARCH PROTOCOLS AND CRITERIA FOR IRB APPROVAL OF RESEARCH**

The primary responsibility of the IRB is to safeguard the rights and welfare of human research subjects. Therefore, a PI must provide enough information for the IRB to determine that human subjects will be adequately protected and that the research will be conducted in full compliance with the regulations. In order to approve a research activity involving human subjects, an IRB must assure that all of the following requirements are satisfied:

- (a) Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk. Foreseeable risks, discomforts, inconveniences, and harms may be physical, psychological, social or economic. Whenever possible, medical research should employ procedures already being performed on subjects for diagnostic or treatment purposes, to minimize unnecessary procedures.
- (b) Risks to subjects are reasonable in relation to (1) anticipated benefits, if any, to subjects, and (2) the importance of the knowledge that may reasonably be expected to result.
- (c) The selection of subjects is equitable. In making this assessment, the IRB must take into account the purposes of the research and the setting in which the research will be conducted. It must be particularly attentive to the special problems which may arise in research involving vulnerable populations, such as children, pregnant women, prisoners, mentally disabled persons, or economically or educationally disadvantaged persons. If any of the subjects are likely to be vulnerable to undue influence or coercion, the IRB may require additional safeguards to protect such subjects. Note that students and patients who might not normally be considered vulnerable are particularly vulnerable when research is being conducted by faculty or health care providers who may make decisions that affect these individuals; special safeguards need to be taken in these situations.

(d) Informed consent will be sought from each prospective subject, or the subject's legally authorized representative, generally by means of a written consent document that the IRB has carefully reviewed to assure that it contains the required elements of informed consent and that it is understandable to a lay person.

(e) The research plan makes adequate provisions for ensuring the safety of subjects.

(f) There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data both during and after data collection.

### **3. CITI Human Subjects Research Online Training**

**Before working on your protocol**, please complete the online CITI Human Subjects Research training modules. The training covers concepts and laws that will help you better understand what issues to cover in your protocol. There are instructions for the training on the IRB website in the right-hand column. Select the module most appropriate to your research. Most researchers (including faculty, grad students, and staff) will need to take the Biomedical Research, Social & Behavioral, or Data or Specimens Only (data or specimens provided by a third party such as a tissue bank) modules. Undergraduate students working on class projects or as supervised research assistants should take the Students – Class Projects module.

Researchers or assistants with access to HIPAA-protected data will additionally need to take the appropriate CITI HIPS module. Choose from clinicians, investigators, students and instructors.

### **4. SPECIFIC PROTOCOL CONTENT**

In order to avoid the submission of incomplete protocols which may lead to delay in the IRB review and approval process, all new protocols should include the following documents and headed sections. The Informed Consent form (IC) may need to include additional information beyond the standard template provided.

#### **Documents that must be submitted**

1. A completed Clarkson IRB Cover Sheet and Research Summary, signed by the PI(s), Department Chair, and Faculty Advisor (in the case of student research). Because the IRB often requests modifications, you should wait until the final, revised version before obtaining Department Chair signatures. Advisors should sign initial and final version of student research.
2. Clarkson IRB Proposal form, or document containing the same information in the same order. Proposals should be submitted electronically, and attachments or appendices to the IRB form should be included in the same file as the primary proposal. Do not attach and reference a grant proposal; include appropriate content within the IRB proposal or as appendices. If the research is being conducted primarily at another institution, the IRB form from that institution will be acceptable if it contains the same elements as required in the Clarkson form.

3. If the research is being conducted in collaboration with another institution that requires IRB or similar review, you must submit evidence that the proposal (the same version as approved by Clarkson) has been approved by that other institution. This is likely if the research is being conducted at or in collaboration with faculty or staff from another university, research or medical institution. The IRB recognizes that review by another institution may occur before, during or after review by Clarkson's IRB; proof of approval from the other institution may be submitted any time prior to initiating the research. Clarkson's IRB will not provide full approval until this evidence has been submitted.
4. Each investigator listed on the proposal must have Human Subjects Research Certification (appropriate CITI training as described above) documented on file at the University of Clarkson (SRS). If it has not been submitted previously, it must be submitted with the proposal. Any research assistants who will be obtaining informed consent must also have such certification documented.

## Headed Sections

Title Page – Demographic-type information about researchers and the proposal.

Cover Sheet – Signatures should be obtained for the final, approved version of the proposal (not the initially submitted version), and this page should be sent to SRS. By signing this page, the PI agrees to Clarkson's regulations regarding human subjects research.

- 1) Research Summary - In 400 words or fewer, summarize the objectives, study population, design, outcome parameters, and potential risks to subjects.
- 2) Introduction - Describe the background relevant to the design and conduct of the study. The Introduction should justify the research objectives and methods that are to follow.
- 3) Objectives and Hypotheses – Provide a concise statement of the study objectives and hypotheses to be tested.

## Human Subjects Protection

### 4) Participants

- a) Number of subjects, age range and gender
- b) Recruitment population: other descriptive characteristics (e.g., students in a certain class, patients with a specific diagnosis, etc.)
  - i) Inclusion criteria and rationale for subject selection: The protocol must include a rationale for research subject selection based on a review of gender/ethnic/race/age or other categories appropriate for what is being studied; If vulnerable populations are to be included, provide a justification for why this is appropriate or necessary.
  - ii) Exclusion criteria, including justification for exclusions and the method by which exclusion will be determined.
- c) Describe recruitment procedures; attach advertisement posters, announcements, or verbal solicitation;

- i) When vulnerable populations will be involved, include a description of how these vulnerable populations will be protected. Vulnerable populations include children, cognitively impaired individuals, prisoners or other institutionalized individuals, or pregnant women. However, students or patients who may be or believe they are beholden to the researcher for academic requirements or health care may also be vulnerable. Discuss what, if any, procedures or practices will be used in the protocol to minimize their susceptibility to coercion, undue influences and unnecessary risks (physical, psychological, etc.) as research subjects. When a proposal plans to include vulnerable populations, the IRB may have an advocate for that population present during the review process; this advocate may be an IRB member with appropriate training or may be a consultant invited to provide input on just this proposal.
- ii) "However, when investigators are in a position to penalize or reward potential subjects, including students, colleagues, or staff, there is a significant potential for coercion or undue inducement. Accordingly, the IRB should carefully scrutinize protocols in which researchers intend to recruit individuals for whom the researcher has the authority to influence grades, ranking, or other evaluations and promotions. When students are recruited into protocols as part of course requirements, the IRB should consider mandating that the course instructor provide at least one other alternative, comparable in required effort and commitment of time, that would satisfy the course requirements and protect the students' right to refuse participation in a protocol."<sup>1</sup>
- iii)
- d) Describe any incentives or compensation provided to encourage participation. If subjects are to be paid, specify the amount and conditions of compensation. Incentives in the form of course credit are also considered compensation.
- e) For studies involving assignment to groups, describe this process.

5) Informed Consent/Assent

- a) The proposal should describe the details of the Informed Consent (IC) process and the IC document must be attached to the proposal. IRB approval requires a readable, grammatical IC document that is consistent with the rest of the proposal.
  - i) Requirements for Informed Consent:
    - (1) Describe the consent procedures to be followed, including the circumstances in which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent.
    - (2) The IC document should follow the template; additional elements, listed on the IC document template, should be used if appropriate or deleted if not.
    - (3) The IC document must be consistent with the proposal in describing procedures, duration of subject involvement, risks and benefits.
    - (4) The IC document should be written in the second person, in language understandable to someone who has not completed high school (i.e., 8<sup>th</sup> grade education). If non-English speaking participants are involved, IC document must

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<sup>1</sup> NY State Dept. of Health. Safeguarding Healthy Research Subjects: Protecting Volunteers from Harm. Available at <http://www.health.state.ny.us/nysdoh/provider/volunteer/subjectidx.htm>.

be provided in an appropriate language and a person speaking that language must be available to answer questions subjects may have.

- (5) The investigators listed for the proposal are the only people automatically authorized to obtain IC. If any research assistants will be participating in the IC process, these people must be listed as authorized individuals on the IC document. Any person authorized to obtain IC must also have Human Subjects Research Certification (CITI training) documented on file at the University of Utah. Investigators are responsible for ensuring that people obtaining IC (and interacting with human subjects, in general) are properly trained to do so. The person obtaining IC should sign the IC document.
  - (6) A witness is also required if the research constitutes more than minimal risk or if vulnerable populations, such as patients, are involved.
  - (7) Additional IC guidelines can be found at <http://www.nihtraining.com/ohsrsite/info/sheet6.html>
- ii) When deception is necessary for implementation of the study, the IC document should state that “Not all information about this study can be revealed at this time.” See information on Deception, below. Deception must adhere to the ethical guidelines put forth by the American Psychological Association ([http://www.apa.org/ethics/code2002.html#8\\_07](http://www.apa.org/ethics/code2002.html#8_07)).
  - iii) There are a variety of optional elements that should be included in the IC document when appropriate. Some of these are listed on the IC document template; all optional items must be inserted into the IC document above the subject’s signature. More information about these items is available at <http://www.nihtraining.com/ohsrsite/info/sheet6.html>
  - iv) HIPAA Authorization. When using subjects who are patients, HIPAA (Health Insurance Portability and Accountability Act of 1996) researchers must adhere to HIPAA rules regarding patients’ Protected Health Information (PHI). Clarkson is considered a ‘Covered Entity’ as a result of Student Health Services. The elements of Authorization may be incorporated into the IC document or provided as a separate document. More information about HIPAA can be found at <http://privacyruleandresearch.nih.gov/authorization.asp>. Health care practitioners are knowledgeable about HIPAA privacy regulations, and can often provide guidance regarding regulations; researchers are encouraged to have someone knowledgeable about health care on the research team when patients are involved.
    - (1) HIPAA Authorization includes: a) A description of what PHI is to be used, b) Names of those authorized to make the requested use or disclosure, c) Names of those to whom information will be given, d) Description of the purpose of the use, e) Authorization expiration date; ('end of study' or 'none' are acceptable), f) Signature of the individual and date of signature, g) Right to revoke authorization and instructions on how to do so (previously obtained information remains in possession of researchers), h) How revocation will impact treatment or benefits, i) Statement of risk that PHI may be disclosed by the recipient of the information.
- b) Informed consent requires that the individual be competent to make a decision about participation in the research. Research studying individuals with cognitive impairments need to document that these individuals are competent to provide informed consent. Cognitively impaired individuals should be tested for competence by an appropriately

trained individual. If the research involves any more than minimal risk, the person assessing competence should be independent of the research project; this is to avoid conflict of interest in having the investigators make the determination regarding competence. The testing procedure and criteria should be described in the proposal.

- c) When children, cognitively impaired individuals, or others not legally competent to provide Informed Consent participate in the research, include an Informed Assent procedure. Assent may include a simplified document that the individuals read or have read to them. These individuals should sign the Informed Assent if they are capable of signing; if not, the parent or legal guardian may sign for them if the verbal or non-verbal assent of the individual has been witnessed. The Informed Assent should include: an explanation of the purpose of the protocol; what is required of the participant; what they will experience while participating in the protocol; an explanation of risks, discomforts or inconveniences; and a description of potential benefits. When involving subjects unable to provide Informed Consent, remember to phrase the IC document in terms of giving permission for another person to participate in the research (e.g., "Your child will be asked to...")
- d) When the research involves inclusion or exclusion criteria verified by the subjects, the subject should attest to these criteria in the IC document. If you plan to exclude minors, the IC document should include the statement "By signing below, you attest that you are 18 years old or over."

#### 6) Study Design and Methods –

- a) *Procedure*: Give detailed procedures for testing or intervention (if appropriate). Separate standard and experimental aspects of the study as much as possible. When the study involves providing a treatment intervention, describe alternatives to this treatment if it exists. Address the experience of investigators if procedures are to be performed for which the investigators have not been specifically credentialed.
- b) *Measurement tools*: Describe questionnaires, outcome measurements or other measurements to be done involving human subjects. Attach copies of these questionnaires or data collection sheets.
- c) *Equipment*: Describe equipment that will interface with subjects for measurements or interventions. Describe potential risks in both the normal operation of this equipment, and under plausible conditions that might alter normal operation. Include safety features and mechanisms for ensuring safety of this equipment (e.g., annual safety inspection or testing).
- d) *Deception*: If deception is to be used, the proposal must justify why deception is necessary to answer the research question. Deception is not permitted if the research could cause real harm (physical, psychological, social or economic) to participants, or if deception is about the confidentiality of data. When deception is used, describe the debriefing process and attach a copy of the debriefing statement.
- e) *Analysis of the Study*: Describe how the outcomes will be statistically analyzed. When possible, delineate methods used to estimate the required number of subjects and describe power calculations if the study involves comparisons.

- 7) Risks and Benefits: In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research)
- a) *Risks*: Describe any potential physical, psychological, social, legal, or other risks, discomforts, inconveniences, and harms that are created by participation in the research. Assess the likelihood and seriousness of any risks. Describe the procedures for protecting against or minimizing any potential risks, such as violations of confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects (e.g., first aid or referral to student counseling). In research involving patients, describe alternative treatments and procedures that might be available to the subjects. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Consequently, all research involves at least minimal risk. Note that if the research design minimizes the possibility of an adverse event, that risk still exists but is managed through the research design. Hence, the proposal should describe all risks and actions taken to minimize them.
  - b) *Adverse events monitoring and reporting*: Describe how subjects will be monitored for adverse events related to the research and what immediate and long term actions will be taken. Also include how data confidentiality and storage will be monitored.
  - c) *Illegal activities*: State whether the research will involve or collect data on illegal activities. Recognize that there are typically restrictions on the extent to which we can safeguard confidentiality. If the risk associated with collecting data regarding illegal activities is great, consider utilizing a Certificate of Confidentiality. A Certificate of Confidentiality can prevent a researcher from being forced to reveal information that could incriminate subjects; however, researchers may still voluntarily or be mandated to release information such as evidence of child abuse or a subject's threatened violence to self or others. The Certificate of Confidentiality should describe conditions under which the information might be revealed.
  - d) *Rating the risk*: rate the risk using the scale provided. The risk assessment should take into account both the seriousness of consequences if an adverse event occurs and the likelihood that such an event will occur. For example, if you ask subjects about illegal behavior or health history such as HIV status, the risk to subjects could be quite substantial if that information were released, but the likelihood might be quite small due to the safeguards to be implemented. Research involving substantial risk must be also approved by the chief academic officer of the University.
  - e) *Anonymity and confidentiality*:
    - i) *Anonymity*: Subjects are anonymous when no information is collected that may be used to identify them at the present or in the future; i.e., there is no link between subjects and data. Describe how data will be anonymized and who will have access to the data before it becomes anonymous (e.g., researchers, research assistants collecting data). Note that information about gender, ethnicity, etc., may compromise anonymity when subjects belong to a group that is uncommon in the sample population. In these cases, answering questions about these characteristics may compromise anonymity; in

- studies where risk is minimized through anonymity, subjects should not be required to answer questions that may compromise their anonymity.
- ii) *Confidentiality*: Confidentiality is often required when anonymity is not practical. Describe how confidentiality will be achieved, who will have access to the data (when researchers or research assistants will have access to data, describe their training with respect to confidentiality), and how the data will be stored. In most cases, the IRB prefers print data to be stored in a locked file cabinet or drawer and digital data on a password-protected computer to which only the researcher and research assistants have access. There are some legal limitations to confidentiality that must be acknowledged on the IC document: researchers must release information in case of a subpoena from law enforcement officials, audit by the IRB, or review by the funding agency.
  - iii) *HIPAA*: Research involving patients typically uses Protected Health Information (PHI); researchers must either obtain patient Authorization (in addition to Informed Consent) or de-identify the PHI. The Privacy Rule requires that *all* 18 pieces of identifying information be removed to de-identify PHI. This requires removal of the following identifiers of the individual and of the individual's relatives, employers, or household members: (1) Names; (2) all geographic subdivisions smaller than a state, except for the initial three digits of the zip code if the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; (3) all elements of dates except year and all ages over 89; (4) telephone numbers; (5) fax numbers; (6) email addresses; (7) social security numbers; (8) medical record numbers; (9) health plan beneficiary numbers; (10) account numbers; (11) certificate or license numbers; (12) vehicle identifiers and license plate numbers; (13) device identifiers and serial numbers; (14) URLs; (15) IP addresses; (16) biometric identifiers; (17) full-face photographs and any comparable images; (18) any other unique, identifying characteristic or code, except as permitted for re-identification in the Privacy Rule. More information is available at [http://privacyruleandresearch.nih.gov/clin\\_research.asp](http://privacyruleandresearch.nih.gov/clin_research.asp) and [http://privacyruleandresearch.nih.gov/pr\\_08.asp#8a](http://privacyruleandresearch.nih.gov/pr_08.asp#8a).
  - f) *Methods for destroying data*: Any private, identifiable data must be destroyed at the end of the study (even if you are no longer working directly with subjects). You must request annual requests for continuation until this data is destroyed. Note that simply deleting files from hard drives is not a secure form of deletion (because the files can be restored fairly easily). A web search of your operating system plus "secure delete" will give you advice on secure deletion methods (e.g., "windows secure delete"). Paper files can be shredded.
  - g) *Benefits to participants*: A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences.
  - h) *Benefits to society*: Briefly describe the value of the research to society.
  - i) *Risk/Benefit Ratio*: Justify why the risks to subjects are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may reasonably be expected to result. It should fall within one of the following categories:

- i) No more than minimal risk with tangible potential benefit to subjects and/or in knowledge gained.
  - ii) More than minimal risk of harming subjects or violating their rights, but justified by the potential benefits.
  - iii) Real possibility of significant injury to subjects or violation of their rights, but justified by the importance of the direct benefits to the subject and the importance of the knowledge to be gained outweigh the risk to the subjects. This type of research must be approved by the chief academic officer of Clarkson.
- 8) Investigational Device Exemption (IDE): For research using a device designed with the intent of ultimately marketing it commercially, PI may need to request an IDE. The IRB can review IDE requests for non-significant risk devices, but the FDA must approve IDE for significant risk devices. See Clarkson's guidelines on IDE and <http://www.fda.gov/cdrh/devadvice/ide/index.shtml> for additional information.
- 9) Conflict of interest statement: Researcher conflict of interest is defined as "*a set of conditions in which an investigator's judgment concerning a primary interest (e.g., subject welfare, integrity of research) could be biased by a secondary interest (e.g., personal or financial gain).*"<sup>2</sup> Report any financial or other conflict of interest for any person involved in implementing this study: commercial sponsors, consulting fees, royalties, patent rights, or honoraria for serving on advisory boards when the combined financial interest is above \$10,000 in income or equity, or 5% company ownership. These financial limits do not apply to government grant funding, even when that funding provides salary for any of the investigators.
- 10) Citations: Include selected references.
- 11) Appendices: Must include the Informed Consent form. The following items should be attached to the proposal if they are part of the study: recruitment notices, questionnaires, data collection sheets, descriptions or pictures of equipment, debriefing statements, assent forms or statements, letters of support from other institutions.

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<sup>2</sup> Bankert EA & Amdur RJ, Institutional Review Board Management and Function, 2<sup>nd</sup> ed. Jones & Bartlett Publishers, Boston. 2006. p 167.