UNIVERSITY POLICY

ACADEMIC AND FACULTY POLICIES

Number: 104
Subject: Human Subjects Application Policy
Covered Individuals: UIU Employees, Students and external researchers
Covered Campus Locations: Fayette Campus and Centers
Date of Origin: December 3, 2015
Effective Date of Last Revision: March 29, 2017

PURPOSE

Consistent with guidelines set forth by the U.S. Department of Health and Human Services, Upper Iowa University has adopted the following policies for research using human subjects. UIU intends to protect human subjects participating in research by setting specific policies to establish a review and approval process for research involving human subjects.
This policy applies to ALL research activities involving human subjects conducted by students, faculty, employees, or those outside of the university requesting to do research using UIU students, faculty, or staff as human subjects.
UIU requires all faculty, staff and students to abide by this policy; lack of compliance may result in disciplinary action.
Those outside of UIU must submit verification of approval by the human subjects review board of their institution. Lack of such verification, will result in denial of the request.
Once approved, needs to be available to all (both internal & external to UIU) seeking to do research using UIU students, faculty or staff. Be available online through uiu.edu

DEFINITIONS:

A. **Policy**. A formal statement of principles on which action(s) for a specific issue are based.
B. **Procedure**. A series of actions conducted in a certain order or manner; operational method by which policy is put into practice.
C. **Research**. A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
D. **Human Subject**. A living individual about whom an investigator conducting research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information. Intervention includes both physical procedures and manipulation of the subject's environment that are performed for research purposes. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which the individual can reasonably expect will not be made public.
E. **Exempt Research**. Research involving the collection or study of existing data,

documents, records, pathological specimens, or diagnostic specimens are publicly available. Such research does not need to be submitted for review.

F. **Human Subjects Committee (HSC)**. A university committee formed to review applications for research using human subjects.

G. **Minimal Risk**. Minimal risk means that the probability and magnitude of harm or discomfort anticipated to the research participant 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.

H. **Deception Studies**. It is best to avoid using deception in research if possible. If it is necessary to include deception in a research design, a rationale for using deception must be included in the research proposal. Deception studies must also include a debriefing plan.

I. **Debriefing Plan.** A debriefing plan specifies how subjects will be informed about the nature, results, and conclusions of the research. This offers the ability of the researcher to take reasonable steps to correct any misconceptions that participants may have. A debriefing plan is needed for **all** studies, but is particularly important if deception has been used once the data have been collected. Researchers should provide a prompt opportunity for participants to obtain appropriate information about the nature of the research. Thus, debriefing should commence upon conclusion of procedures that participant is part of and should include an explanation of the study including researchers' hypothesis and rationale for conducting the investigation. Researcher should encourage and be ready to answer any questions the participants might have. When researchers become aware that research procedures have harmed a participant, they should take reasonable steps to minimize the harm. Participants should leave testing in the same mental state as they arrived.

POLICY

J. UIU Human Subjects Committee (HSC) will maintain written policies and procedures to ensure effective human research protection.

K. These policies and procedures are applicable to all research investigators conducting human subjects research with the endorsement of UIU HSC.

L. The use of word *must* or *will* in HSC policies and procedures means that something is required under federal, state, institutional, or other applicable regulations. The use of the word *should* in HSC policies and procedures means that something is recommended or suggested, but not required.

M. Due to the diverse and complex nature of human research, these policies and procedures cannot address all possible scenarios or issues. When concerns arise not covered by these policies and procedures, they will be addressed through dialog with appropriate personnel. It is further recognized that there will be case-specific departures from these policies and procedures.

RULES, PROCEDURES, GUIDELINES, FORMS, AND OTHER RELATED RESOURCES

II. Procedure.

A. Application and Submission of Proposed Research. Students, faculty or employees who conduct research involving human subjects must submit applications for review as

specified in this policy. Failure to follow approval procedures prior to collecting data can result in a forfeiture of data or other penalties, to be determined by the Human Subjects Committee, in conjunction with supervising faculty, if the researcher is a student doing research under faculty supervision.

1. **Exempt Research.** Research which is exempt, as defined above, does not need to be submitted for review.
2. **Nonexempt research.** Research which does not meet the criteria for exempt research, as defined above, must follow these procedures. Applications shall be submitted to the Department Head of the department from which the research is proposed, or the School Dean. The Department Head or School Dean shall review the application to determine whether the research qualifies for expedited review or whether it requires full HSC review.

   HSC Review. If the Department Head or School Dean determines that the application requires full review by the HSC, they will submit it to a member of the HSC, who will send it to committee members for full review.

B. Expedited Review. The University Department Head or the School Dean (or representative) may review and approve research in one or more of the following categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   a. research on regular and special education instructional strategies; or
   b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless
   a. information obtained is recorded in such a manner that human subjects can be identified, directly or 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 or
   b. the human subjects are elected or appointed public officials or candidates for public office.
3. Research and demonstration projects which are designed to study, evaluate, or otherwise examine
   a. public benefit or service programs;
   b. procedures for obtaining benefits or services under those programs;
   c. possible changes in or alternatives to those programs or procedures; or
   d. possible changes in methods or levels of payment for benefits or services under those programs.
4. In some cases, such as in certain naturalistic investigations, both informed consent and debriefing may be waived by the Human Subjects Committee.
   a. Examples of naturalistic investigations could include
      (1) A researcher places a piece of obvious trash on walk paths in two areas of a park (several crumpled up wrappers from a nearby fast food restaurant), one that is right after a sign that says "Think Green! Care about keeping Earth beautiful." On the second path there is no such sign. There is also a garbage receptacle within a few feet of the trash on both paths.

(a) In one situation, the researcher sits on a park bench that is in clear view of the particular walkway and simply records how many people picked up the trash. There is no attempt to contact the "participant." In the above scenario, neither informed consent nor debriefing is necessary as these are anonymous passersby with no identifiers and who are protected by the obscurity of the naturalistic setting.

(b) In a second situation, the researcher sits on a park bench that is in clear view of the walkway and records how many people picked up the trash. Additionally, there is another researcher who approaches the participant further down the pathway. He or she proceeds to interview the participant or ask them to fill out a survey. In this second set-up, both informed consent and debriefing would be required. The researcher is attempting to gather intimate details from the participant. In this case, participants would no longer be protected by the obscurity of the naturalistic setting. The participants in this case, need to be assured of confidentiality and anonymity and must be fully debriefed to safeguard that they leave the investigation in the same psychological state as they entered it.

(c) In a third situation, the researcher approaches a participant and asks them a question, such as "Where is nearest trash can?" or "Can you show me how to sort my trash for recycling?" The researcher records observations about the participant's response, but no personal details or identifying characteristics are recorded. In this situation, the researcher is directly interacting with the participants and manipulating the environment, though minimally. As the study involves participant interaction, it is not strictly naturalistic and requires HSC review. However, upon review, the HSC may consider the safety of the participants and constraints of acquiring unbiased study results and decide whether informed consent and/or debriefing may be waived on a study-by-study basis.

(2) Once approved as expedited research, the Department Head or School Dean who approved the research will place the approved proposal in the Human Subjects Research Folder for approved research on the G Drive, and the researcher (or supervising faculty member, when applicable) will be notified.

C. Human Subjects Committee Review.

1. A HSC review is required for the following research:
   a. Research involving minors (except where standardized or education tests **only** are being administered);
   b. More than minimal risk, as defined above, to the human subjects is involved;
   c. Subjects are mentally and/or physically challenged;
   d. Prisoners are used as subjects;

e. Deception studies, as defined above, are proposed (a debriefing plan will be required with any deception study);
f. Research is of a controversial nature;
g. Research is conducted in a public setting, but involves contact with human subjects (approaching people asking directions etc.);
h. Proposed interview and/or survey research;
i. Public observation studies;
j. Any research application passed to the HSC from the School Dean;
k. Any research request involving the use of UIU students and/or staff as research subjects, even if the research has been approved by another institution sponsoring the research. In this case, the Provost will also review the proposal. Prior to review by the UIU HSC and the Provost, research approval documentation from the institution sponsoring the research must be forwarded to the HSC.
l. Once approved after full review, the member of the HSC who received the initial research proposal will place the approved proposal in the Human Subjects Research – Approved folder on the G Drive.

D. The Human Subjects Committee (HSC) consists of five members:
1. Four faculty members, including one representative from each academic school. Representation must include at least one faculty member whose primary responsibilities are to teach for the Extended University, and at least one faculty member whose primary responsibilities are to teach at the Fayette campus.
2. Office of Student Development Representative Appointed by the Dean of Student Development.
3. Members of HSC will be appointed by Faculty Senate.

E. HSC Review Procedures and Timeline.
1. Upon receipt of a nonexempt research application, the Department Head or School Dean within five (5) working days, will determine whether the research is expedited or whether the research requires HSC review.
2. An electronic copy of research proposals requiring HSC review will be sent to the Chair of the HSC, who will convene the committee. If an application is determined to require HSC review, the applicant will be notified by the Chair of the HSC and may be required to attend a committee meeting.
3. The HSC may request additional information regarding the research project.
4. The HSC shall, within ten (10) working days of submission to the HSC, decide whether to grant or deny the research application.
5. Appeals of Human Subjects Committee decisions will be sent to the Provost.
6. Any HSC member submitting an application for research using human subjects or supervising the research of a student whose work is submitted will recuse her or himself from the review process.

F. Informed Consent. A subject's informed consent must be obtained prior to commencing the collection of data. Consent must be written. An informed consent solicits intellectual understanding from a person volunteering that the person knows what is about to happen and agrees. Informed consent should provide sufficient information relative to the research so that the participant has the capacity to make an intelligent decision regarding whether to participate in the study or not participate. In some cases, such as in certain naturalistic investigations, both informed consent and debriefing may be waived by the Human Subjects Committee.

1. **Waiver of Rights**. An informed consent form should not require a subject to waive any legal rights the subject may have. The informed consent form should **not** include any language through which the subject is made to waive (i.e., give up), or appear to waive any of his/her legal rights, or to release the institution or its agents from liability for negligence.
2. **Capacity**. Individuals under 18 years of age lack the capacity to give consent to be a research participant. Therefore, for those subjects 18 years of age or older or if there is a question of a person's ability to give consent (regardless of age), appropriate psychological consultation and review should be obtained.
3. **Informed Consent Form**. The form should be written with language which is understandable at a seventh or eighth grade reading level and must include the following:
    a. Researcher's name (title and position), contact information (i.e., phone number, address or e-mail). Include the following if pertinent: Supervising faculty advisor name (title and position) & supervising faculty advisor contact information (i.e., phone number, address, or e-mail).
    b. Purpose of the study and procedures to be followed, including identification of those procedures which are experimental.
    c. Description of the participation required of subjects (i.e., what is involved in participation, for example a survey, a test, an observation).
    d. Nature and amount of risk, or substantial stress or discomfort involved
    e. Benefits to be expected or knowledge hoped to be gained.
    f. Appropriate alternative procedures that might be advantageous to the subject, if any.
    g. Opportunity to ask questions before consenting
    h. Voluntary nature of participation and freedom to withdraw at any time without prejudice
    i. A statement as to how data will be handled and how confidentiality/anonymity will be maintained.
    j. Debriefing plan specifies how subjects will be informed about the nature, results, and conclusions of the research.
    k. Identify the person to call with any questions regarding research design.

    (Additional elements may be required, as appropriate, if activities exceed minimal risk.)
4. Written Consent (signature is required from subject/participant): When the researcher is conducting the research in person, written consent is sought. Subjects must be informed of the same information they would be provided in a written consent form and told that by participating in the project, they are giving their consent.

H. Forms

- Human Subject Application

I. Other related resource materials *[reserved]*

REFERENCES/BENCHMARKING

None

CONTACTS

Acting as the Policy Owner, the Chair of the Human Subjects Committee is responsible for answering questions regarding the application of this policy.

SANCTIONS

None

HISTORY

- March 29, 2017
  - Revised Policy Approved by President's Council
- December 3, 2015
  - Policy was created and approved