University of Jamestown Institutional Review Board: Policies and Procedures

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INTRODUCTION

These policies and procedures is for the researcher who involves human subjects in research. It is not meant to address every possible question related to research with human subjects. These policies and procedures will be revised periodically in order to address emerging issues. Each research project is unique, therefore, for specific direction regarding a concern not found in this guidebook, contact the Institutional Review Board Chair at (701) 356-2136 ext. 5903 or email at sara.voorhees@uj.edu.

ETHICAL PRINCIPLES

The University is guided by ethical principles regarding all research involving humans as subjects. These principles have been set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, "Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research". These principles include respect for persons (autonomy), beneficence (including minimization of risks and maximization of benefits), and justice (fair procedures and outcomes in the selection of research subjects). The Belmont report can be accessed at the following site: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm.

UNIVERSITY POLICY

University of Jamestown, recognizing its responsibility to provide measures to reasonably protect individuals involved as subjects of research conducted under the auspices of the University, requires that the Institutional Review Board (IRB) will review all research projects involving human subjects conducted under the auspices of the University, as set forth in the "Applicability" section on page 4. This review will be completed prior to the initiation of the research.

University policy entrusts the investigator with primary responsibility for the protection of individuals participating as human subjects. The University assumes its responsibility for meeting the conditions for the protection of human subjects as required by the National Research Act, Public Law 93-348 and implemented by the Department of Health and Human Services (Title 45 Part 46 of the Code of Federal Regulations, Protection of Human Subjects, as amended) and by other Federal agencies with appropriate jurisdiction. In assuming its responsibility, the University intends to encourage the conduct of research, which will benefit the human condition and, at the same time, protect the rights and welfare of human subjects participating in the research, the investigators doing the research, and the University. University faculty, staff, and students conducting human subject research under this policy are responsible for compliance with all federal regulations.

Executive functions to be performed by the University include the development of policy; the continuing education of personnel with respect to policy; the modification of this policy to maintain its conformity with laws and regulations and ethical guidelines; and providing appropriate

administrative support and legal assistance for the Institutional Review Board. The Institutional Official responsible for carrying out or delegating these functions is the Vice President for Academic Affairs.

This policy is applicable to all research involving human subjects which is conducted under the auspices of the University, as set forth in the "Applicability" section below.

APPLICABILITY

The Institutional Review Board is responsible for the review and approval, or modifications for approval, or disapproval of all research subject to this policy. In applying for approval of their project, investigators' written protocols must be presented to the Institutional Review Board; the Institutional Review Board will supply the format for the protocols.

This policy applies to all activities which, in whole or in part, involves research with human subjects if:

- The research is sponsored by University of Jamestown, or
- The research is conducted by or under the direction of faculty, staff, or students of University of Jamestown in connection with their institutional responsibilities, or
- The research is conducted using any property or facility of the University, or
- The University of Jamestown researcher is engaged in collaborative research with another institution or institutional representative; or
- The research involves the use of University of Jamestown's nonpublic information to identify or contact human research subjects or prospective subjects.

Graduate and undergraduate student research projects, which meet the definition of research and are intended for dissemination beyond the classroom, are covered by this policy. Student projects designed to provide research training which are not intended for dissemination beyond the classroom are not treated as research projects under this policy (student training projects).

If there is any uncertainty as to whether this policy applies to a particular research project, contact the Institutional Review Board Chair at (701) 356-2136 ext. 5903 or email at sara.voorhees@uj.edu.

DEFINITIONS

RESEARCH - A systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes, for example, some demonstration and service programs may include research activities.

HUMAN SUBJECT – Living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

INTERVENTION – Physical procedures (for example, venipuncture) by which data are gathered and manipulations or the subject or the subject's environment that are performed for research purposes.

INTERACTION – Communication or interpersonal contact between investigator and subject.

PRIVATE INFORMATION – 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 has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

MINIMAL RISK – 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.

REQUIRED EDUCATION ON HUMAN SUBJECTS RESEARCH ETHICS

All researchers who interact with human subjects to collect data must complete a required educational program on ethics and procedures for the use of human subjects in research before the Institutional Review Board may approve a proposal. This includes the principal investigator, co-principal investigators, and other key personnel who are responsible for the design and/or conduct of the study. The requirement applies to subcontractors, consultants, individual fellowship applicants, study coordinators, and persons who conduct invasive procedures, or conduct health or opinion surveys or interviews. Graduate and undergraduate students that are collecting data from human subjects including providing explanations or answering questions about the research or data gathering instruments are required to complete the training program. Individuals providing technical services only such as setting up a room, handing out and collecting survey instruments without providing explanations or answering questions about the research or data-gathering instruments, typing data into a data base, transcribing audiotapes, or reviewing videotapes to code behavior, are not covered by this requirement; however, they should receive instruction on maintaining privacy and confidentiality of data.

The training requirement is satisfied by completing the National Institutes of Health (NIH) online training: http://phrp.nihtraining.com/users/login.php. Registration is free and open to anyone. The course requires approximately 1-1 1/2 hrs, but may be completed in multiple sessions. Please note, NIH does not automatically send the IRB certificate of completion, so please attach a copy of the certificate to your IRB application.

INSTITUTIONAL REVIEW BOARD

The Institutional Review Board (IRB) for University of Jamestown has the responsibility to oversee procedures for carrying out the University's commitment to protect human subjects in research. The IRB shall review and is authorized to approve, require modifications (to secure approval), or disapprove all research activities using human subjects covered by this policy. Research involving human subjects that will be conducted with external or internal grant funding shall be submitted directly to the IRB for review.

SUBMITTING A PROTOCOL FOR REVIEW

Researchers who propose to conduct a new research project involving human subjects shall prepare and submit via the MyUJ IRB portal:

- The IRB Application form with all appropriate signatures
- A detailed research plan which is a brief summary of research, the methodology, risks to participants, and benefits
- All Informed Consent/Assent forms
- All privacy Authorizations/Consent forms
- Outline or script to be provided prior to participant's agreement to participate (oral solicitation form)
- Outline or script to be used during the study
- A complete statement of the research methods, including copies of the instrument(s) being used to collect data
- Signed letter of permission from an institutional representative, if research is to be conducted in an institution such as a school, hospital, etc., when applicable
- Debriefing form that will be provided upon participant's completion of the research or, when a form is not used, a detailed description of the debriefing procedure that will be employed by the researcher during debriefing
- Certificate of completion for training on protecting the rights and welfare of research participants for all principle investigators and research team members conducting human subjects research.

The initial submission will be reviewed by the IRB chair at University of Jamestown to assure that all necessary documents have been uploaded to the IRB Portal.

Submissions must be approved by the IRB prior to any subject recruitment or other contact with subjects. Researchers must complete the required education program on research ethics for human subjects research prior to approval of a submission.

The IRB cannot and will not review protocols for projects that are already completed. If a project is already underway, research will be immediately suspended until the protocol is reviewed.

Objective of Review

The objective of IRB review is to ensure that the rights and welfare of the subjects are adequately protected and that all activities involving human subjects are in compliance with University policies and Federal regulations to assure that:

- Selection of research subjects is equitable
- Informed consent is obtained and documented where appropriate
- Risks to subjects are minimized
- Risks are reasonable in relation to anticipated benefits to subjects and others
- Privacy and confidentiality are protected
- Data handling and safety monitoring provisions are adequate
- Vulnerable subjects are provided special safeguards against undue influence or coercion to participate in the research.

If you discover after the initiation of your research that your project should have had prior review, contact the IRB Chair at (701) 356-2136 ext. 5903 or email at sara.voorhees@uj.edu.

Types of Review

There are three major types of IRB protocol review depending on the level of risk to the subject:

- Exempt Protocol Review
- Expedited Protocol Review
- Full Committee Protocol Review.

Other necessary IRB reviews include:

- Modifications of Approved Protocols
- Continuing Project Review
- Final Report
- Reporting Adverse Events and Unanticipated Problems

The researcher may request a particular type of review but the IRB makes the ultimate determination regarding the type of review the protocol will receive.

Exempt Protocol Review

Research activities, in which the involvement of human subjects is entirely confined to specific categories described in the Federal regulations, may be exempt from full committee review but must be submitted to the IRB to determine whether the project qualifies for exempt status review. Categories of activities, which may be considered for exempt review, are listed below.

Research activities in which the only involvement of human subjects, in one or more of the following categories, qualify for review under the exempt category:

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 (b) 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.

3) 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 category 2 of this section, if (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4) 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.

5) Research and demonstration projects which are conducted by or subject to the approval of Federal Department or Agency heads, and 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.

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

It should be noted that Category 2 does not apply to research with subjects under the age of 18 except for the specific type of research that is observation of public behavior where the investigator

does not participate in the activities being observed. Also note, a study will not be reviewed as an exempt review study where the researcher is using as subjects students from a class he or she is teaching.

The exempt review process involves a pre-review of submitted materials. The pre-reviewer, if needed, will communicate with the researcher regarding the status of the application, additional information which might be needed, and the likelihood that the protocol can be determined exempt.

EXPEDITED PROTOCOL REVIEW

Research activities involving no more than minimal risk to human subjects and in which the only involvement of human subjects will be in one or more of the following categories may be reviewed through the expedited review procedure. The Expedited Review category does not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization. The categories in this list apply regardless of the age of subjects, except as noted:

1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met: (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (NOTE: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review); (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) 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: (a) from healthy, nonpregnant 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; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be 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 kg in an 8-week period and collection may not occur more frequently than 2 times per week.

3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival 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; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely 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: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) 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 or will be collected solely for nonresearch purposes (such as medical treatment of diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. See previous section listing categories, which qualify for exempt review. This listing refers only to research that is not exempt.)

6) Collection of data from voice, video, digital, or image recordings made 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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. See previous section listing categories, which qualify for exempt review. This listing refers only to research that is not exempt.)

8) Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) 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 two (2) through eight (8)

do not apply but the IRB has determined and documented at a convened meeting that the research involved no greater than minimal risk and no additional risks have been identified.

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 procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

Full Committee Protocol Review

Research activities that do not qualify for exemption or expedited review must be reviewed by the full IRB at a convened meeting. The board meets as dictated by need. The board will review the protocol in accordance with federal regulations, state and local laws, and institutional policies. Investigator(s) will be encouraged to attend the IRB meeting, if possible, to present their project and respond to any reviewers' questions and concerns on the spot, thereby saving time in the review process. At the conclusion of the meeting, the board may approve the protocol as submitted, require minor changes in the protocol as a condition for approval, defer for insufficient information, or disapprove the project. Investigator(s) will be notified of the IRB's decision in writing within ten days from the date of meeting.

Modifications of Approved Protocols

Any changes in an approved protocol, but not limited to, including changes in the subject population, study location, procedures, or project personnel must be reviewed and approved by the IRB prior to initiating changes. Investigators must submit a request for modifications to the IRB for review through the IRB Portal on MyUJ.

Continuing Project Review

All research involving human subjects must be re-reviewed periodically, at least once every twelve months, or more frequently as specified in the original approval notification. This applies to studies for which data are continuing to be collected, analyzed, or for which research data are being maintained with personal identifiers that can be linked to individual subject responses. The Continuing Project Review must be substantive and meaningful. For review of continuing projects, investigators shall submit a completed IRB Continuing Review form to the IRB through IRB Portal on MyUJ.

Final Report

Once a research project is complete, the Final Report form must be submitted to the IRB through IRB Portal on MyUJ. The IRB Final Report form must include a summary of the research such as an abstract along with answers to all other pertinent questions found on the form. Report

any unanticipated problems during the research on this form. If your project was determined to be exempt by the IRB, you do not need to submit an IRB Final Report form.

Reporting Adverse Events and Unanticipated Problems

The investigator for a research protocol must immediately report an Adverse Event or Unanticipated Problem to the IRB Chair at (701) 356-2136 ext. 5903 or email at sara.voorhees@uj.edu and then promptly submit the completed IRB Adverse Event/ Unanticipated Problem Reporting form through IRB Portal on MyUJ within five working days. Policy information regarding adverse events and unanticipated problems may be found on University of Jamestown's IRB website, and the form may be found at the IRB Portal on MyUJ.

Deadlines for the Review Process

The different types of reviews will each take a different amount of time. It is important to understand that the times listed are from submission to initial feedback or approval. If questions or issues arise about the study the approval may be delayed or denied. The following are guidelines for minimal time required for an IRB review to occur:

1) Exempt Review should be submitted a minimum of 15 working days prior to the planned commencement date of the proposed study.

2) Expedited Review should be submitted a minimum of 30 working days prior to the planned commencement date of the proposed study.

3) Full Board Review should be submitted a minimum of 45 working days prior to the planned commencement date of the proposed study.

Studies submitted during the Summer Semester may encounter additional delays due to the availability of committee members during this time. It is highly recommended that Expedited and Full Review requests be done during the Fall and Spring semester.

Conflict of Interest

Conflict of interest occurs when a researcher has some financial stake in a research project through, but not limited to, being compensated for carrying out the research, having a financial interest in a company or agency sponsor, or benefiting in some way from the research. In such instances, it is the responsibility of the researcher to fully disclose to the IRB any real or potential conflict of interest.

Informed Consent

Informed consent is required for all research projects unless waived by the IRB. An informed consent should adhere to the following principles:

1) Write the form in clear and simple language. For example, the name of the study does not need to be exactly the same as the official name of your project. Rather it should be short and easy to remember for your participants.

2) Inform the participant about the nature and purpose of the study in a brief and non-technical way.

3) Inform participants of significant factors that may be expected to influence their willingness to participate (such as risks, mental or physical discomfort, adverse effects, significant time commitment, or limitations on confidentiality).

4) Explain carefully any discomforts and risks. Both immediate and long-term hazards must be identified. Any treatments, procedures, or drugs that are clearly experimental in nature must be identified as such.

5) Identify benefits the person might expect as a result of participating.

6) Make a statement about confidentiality of data.

7) Inform participants that they are free to participate or to decline to participate or to withdraw from the research and explain any foreseeable consequences of declining or withdrawing.

8) Offer to answer questions about procedures at any time desired by the participant.

Please refer to the Required Elements for Informed Consent document at the IRB Portal Resources page for additional information.

In order to not ask participants to complete a consent form prior to their participation in your research you must request a waiver from the IRB and provide the following:

1) Explain in detail why a written consent form will not be used.

2) Specifically explain why the waiver will not adversely affect the rights and welfare of participants.

3) Explain why the research could not practically be carried out without the waiver.

4) Explain how voluntary participation will be obtained.

5) Include any related material, such as a copy of a public notice, script, etc., that you will use to inform participants of all the elements that are required in a written consent.

RESEARCH SUBJECTS UNDER AGE 18

Permission from parent(s) or legal guardian(s) is required for children under age 18. College students who are under age 18 must have parental or guardian permission to participate as research subjects. In addition to parental or guardian permission, children should also be asked for their assent to participate in the research project in language appropriate to the subject's age and maturity. Surveys, interview procedures, or participant observations are not eligible for exempt status when persons under age 18 are involved as subjects. The following guidelines apply to all research conducted that includes subjects under age 18:

1) Parent or guardian permission: Investigators must make adequate provisions for soliciting the written permission of each child's parent or guardian for their participation in research, unless the IRB has waived the requirement.
    a. Research involving no more than minimal risk: The permission of only one parent or guardian is required for research that involves no more than minimal risk.
    b. Research involving more than minimal risk, and no direct benefit to subjects: The permission of both parents (or guardians) is required for research that involves more than minimal risk, and no potential for direct benefit to subjects. Exceptions include situations where one parent or guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
    c. Permission process and documentation: Obtaining permission of a parent or guardian is equivalent to the process of informed consent. The language used in Parent/Guardian permission forms should reflect that permission is being sought for their child to participate in research.

2) Child assent: Investigators must make adequate provisions for soliciting assent (agreement) of children to participate in research, where the children have sufficient capacity to make this decision. Under certain circumstances, this requirement may be waived by the IRB.

3) Waiver or alteration of child/youth assent. The IRB may waive the requirement to obtain child assent, under any one of the following condition.
    a. Capability of children is limited that they cannot reasonably be consulted: Institutional policy has considered children under 7 years of age, in general, to have limited capacity for understanding. Therefore, it is generally not necessary to seek their assent for research participation; only parent or guardian permission is required.

4) Additional IRB determinations for approval of research involving children: In order to approve research involving children in a school setting, the researcher must obtain consent from the involved teachers and superintendents.

RESPONSIBILITIES OF RESEARCHERS FOR THE CONDUCT OF RESEARCH

Researchers acknowledge and accept their ethical and legal responsibilities for protecting the rights and welfare of human research subjects for complying with all applicable provisions of the University policy.

It is the responsibility of the researchers to obtain approval for proposed human subjects research prior to recruiting subjects or collecting data from subjects. This applies to preliminary and pilot studies, which are developing or testing instruments and procedures, as well as the full study.

Researchers will explain to subjects, prior to their decision about whether or not to participate, the objectives of the research, the procedures to be followed and the potential risks and benefits. Researchers shall not use individuals as subjects unless satisfied that they, and/or others legally responsible for their well-being, fully understand the consequence of participation and freely consent to participate in the research. The IRB may waive these requirements only when persuaded that the research cannot otherwise be done, that its potential value outweighs the indignity to the subject, and that the subject runs no further risk or harm in participating.

Researchers will seek consent from subjects to participate only under circumstances that provide the prospective subject sufficient opportunity to consider and decide freely whether or not to participate. Subjects shall be given a copy of the informed consent materials to keep.

Researchers will make clear to subjects that they are free to withdraw from active participation in the research at any time. Subjects who indicate a desire to withdraw shall be allowed to do so promptly and without penalty or loss of benefits to which the subject is otherwise entitled. Any payment to subjects must be reasonable and prorated with partial payment in the event subjects discontinue participation during the course of the study.

Researchers will respect the privacy of subjects. They shall protect confidential information given them, advising subjects in advance of any limits upon the researchers' ability to ensure that the information will remain confidential.

Researchers will obtain approval from the IRB prior to making any changes in the research procedures.

Researchers will promptly report to the IRB any adverse events or unanticipated problems involving risks to the subjects or to others.

STUDENT RESEARCHERS

Student Research Projects whose goal is to add to generalizable knowledge through dissemination of results in publications (including Senior Honors theses, Master's theses, Doctoral dissertations, or program capstone/special projects) or presentations beyond the classroom are covered by this policy on human subjects research. Faculty members who assign or supervise research conducted by students are responsible for ensuring that the proposed research is reviewed

and conducted in accordance with University policy and IRB policy and the student is qualified to safeguard adequately the well-being of the subjects.

Class Projects designed to provide hands-on experience or research training to students are not treated as formal research projects in this policy and do not require IRB review. Projects in this category are expected to be confined to the specific class and end at the termination of that class. They are not intended to be research projects used in other classes or published or presented beyond the classroom. Faculty members who assign research-learning experiences are responsible for assuring that participants used in such projects are treated ethically. Faculty members must provide information to students on University policies and guidelines on human subjects research and develop class procedures in a manner that protects participants' privacy, dignity, and welfare. If there are questions, contact the IRB Chair at (701) 356-2136 ext. 5903 or email at sara.voorhees@uj.edu.

PROFESSORS/INSTRUCTORS/GRADUATE STUDENTS USING SUBJECTS FROM THEIR CLASSES

The use of one's own students as research subjects is generally discouraged due to the inherent risk of coercion. It is recognized that situations exist when it is necessary to use one's class for research that cannot be conducted in any other manner. Therefore, given the commonality of using students as research subjects and the possibility of using one's own classroom students in studies, the IRB requires that certain conditions be met by the researcher(s) in such instances.

First, any study involving the researcher's own students will be reviewed as an expedited study. Such research is not anonymous and involves minimal risk to the subject given the possibility of perceived coercion to participate on the part of the student. Additionally, such studies will require an informed consent document that each research participant from the class(es) will be asked to sign prior to the initiation of the research.

In addition to the standard language included in the IRB exemplars, the informed consent document in such instances must also include two more elements. First, there must be a statement that a student's grade or grades will not be impacted by the student's decision to participate or not to participate. Second, students must be fully informed that the Researcher/Instructor will not examine any data until the semester's grades for the class or classes have been submitted to the Office of the Registrar.

Depending on the type of study, Researchers/Instructors may or may not be permitted to administer, collect, or in any way gather data themselves from their students. If a study takes place during the course of a term with a class or classes, and the data being gathered is part of a pre-existing and planned part of the course, an instructor may be allowed to engage in the act of data collection with his/her own class. However, if a study is cross-sectional in nature (one shot case studies, one time surveys, one time experiments), Researchers/Instructors will be required to arrange for another person to observe, administer, or carry out the experiment or study.

ARCHIVAL DATA

Archival data is that data that exists prior to the development of the research project. Some archival data is anonymous while some is not. For instance, data sets from the Inter-University Consortium for Political and Social Research (ICPSR) are typically anonymous whereby given individual cases or subjects cannot be identified. However, some archival data is not anonymous. For instance, medical records or educational records used for a research study may allow a researcher to identify individual subjects. In the latter case, or non-anonymous archival data, the researcher is responsible for obtaining the proper institutional/agency permissions, consent from subjects, and creating a data set from the records so the subjects become anonymous. Thus, in some cases the use of archival data may qualify a study for exempt review while in other cases it might be expedited review.

INCENTIVES AND PAYING RESEARCH SUBJECTS

The IRB may approve research projects involving chance such as raffles or drawings for prizes as long as the procedures are equitable and fair.

Incentives (such as gift cards) must be equal and provided to all subjects. Incentives may not be given if the subjects perceive the incentive as reward for the quality of performance.

Subjects may be paid for inconvenience, time spent, and as reimbursement for expenses. However, payments should not be so large as to induce prospective subjects to consent to participate in the research against their better judgment.

DEBRIEFING STATEMENTS

Debriefing statements are used in two types of research contexts. The first is when deception is a part of the research design. The second is research where departmental subject pools are used to recruit research participants.

As a general rule, the use of deception in research is not encouraged. When information is withheld, the subject cannot make an informed decision regarding his or her participation in the research. It is recognized, however, that there are certain types of research that cannot be carried out effectively if all of the parameters of the research are presented to the subject. In such a case, a justification for the withholding of information from the subject must be presented in the protocol. The informed consent document must explain that there is information pertaining to the research that cannot be disclosed prior to the initiation of the study but will be provided following the completion of the subject's participation. Following participation, the researcher must explain the research study to the subject. The explanation must describe the purpose of the study as well as the information that could not be given to the subject at the beginning of the research and why. In addition, the subject should be given a written Debriefing Statement that fully describes the purpose of the study, gives an explanation of the information not provided in the consent form and why it could not be provided. The subject should be given the opportunity to withdraw from the research and have his or her data destroyed.

The second context where a Debriefing Statement is required is in the case of research conducted using a departmental subject pool. One justification for the existence of the subject pools is that they provide students with an educational experience related to research. One purpose served by the Debriefing Statement is to educate the student by providing an explanation of the research methods employed and how they relate to the purpose of the research. The Debriefing Statement is a written statement given to the subject that, in addition to the previously described points, supplies the contact information for the researcher in the event the subject has additional questions.