Saint Joseph's College of Maine

Institutional Review Board (IRB)

GUIDELINES FOR SUBMISSION of Human Subjects Research Proposals for IRB Review

Instructions:

1. Learn about the IRB process: Read this document.
   - Complete the online training for investigators provided by the U.S. Department of Health and Human Services: https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-training/human-research-protection-foundational-training/index.html
     - At the website, you will take the following:
       - Lesson 1: When HHS Regulations Apply
       - Lesson 2: What is Human Subjects Research
       - Lesson 3: What are IRBs
     - The training is free to you and can take up to three hours.
     - Be sure to print your Certificate of Completion for each lesson – you will need to submit this Certificate to the IRB. If you have existing training certificates, please submit a copy of those.
2. Determine whether your project meets the definition of "Human Subjects Research."
   - Read the definition of "Human Subjects Research" given on page 5 of this document.
   - If necessary, consult with knowledgeable faculty, IRB members, the resources listed on page 4 of this document, or your research advisor to help you make this determination.
   - If your project does not meet the definition of human subjects research, it does not need to be reviewed by the IRB.
   - If your project does meet the definition of human subjects research, it must be reviewed by the IRB. Please continue reading the instructions.
3. Determine which type of IRB review is required for your research project:
   - Read the descriptions of the three types of IRB review (Exempt, Expedited, and Regular), beginning on page 7 of this document.
   - If necessary, consult with knowledgeable faculty, IRB members, the resources listed on page 4 of this document, or your research advisor to help you make this determination.
4. Complete the IRB Human Subjects Research Proposal Form.
   - The IRB Human Subjects Research Proposal Form should be used for ALL proposals, regardless of whether the investigator is requesting an exempt review, an expedited review, or a regular review.
5. The IRB Human Subjects Research Proposal Form is located at: https://my.sjcme.edu/resources/administrative/institutional-review-board/
6. Submit your completed IRB Human Subjects Research Proposal Form and all accompanying documents to:
   - For on-campus students:
     - Dr. Josh Schoenfeld, jschoenfeld@sjcme.edu
   - For online students:
     - Dr. Dale Brooker, dbrooker@sjcme.edu

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IRB Responsibilities

General responsibility of the IRB:

> The Institutional Review Board (IRB) is designated by Saint Joseph's College of Maine to review, to approve the initiation of, and to conduct periodic review of research involving human subjects or materials obtained from human subjects. Federal law and College policy mandate prior written and dated IRB approval of all such research regardless of the funding source.

Specific responsibilities of the IRB include:

1. *Following specific Federal Regulations* applying to the conduct of human subjects research at Saint Joseph's College of Maine;

2. *Developing and implementing institutionally-appropriate procedures* for ensuring the protection of human subjects;

3. *Educating the Saint Joseph's College of Maine community* about the ethical and legal obligations associated with human subjects research;

4. *Reviewing research proposals* to ensure that research will be carried out in a manner which safeguards the rights and well-being of human subjects;

5. *Promoting professional development in research ethics* for Saint Joseph's College of Maine faculty in support of their instructional, research, and administrative work.

Resources

Information:

- A comprehensive “IRB Guidebook” is provided by the Office for Human Research Protections (OHRP), which is a part of the United States Department of Health and Human Services (DHHS):

  http://www.hhs.gov/ohrp/irb/irb_guidebook.htm

  (The OHRP homepage is also a useful resource.)

- The Office of Human Subjects Research (OHSR), a part of the National Institutes of Health (NIH), which is part of the United States Department of Health and Human Services (DHHS), also provides useful information:

  https://www.hhs.gov/ohrp/index.html

Important Definitions

- "Human Subjects Research" (According to Federal Regulations, 45 CFR 46):

  "*Human subject* means a living individual 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."

  "Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

- "Minimal Risk" (According to Federal Regulations, 45 CFR 46):

  "*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."

- "Informed Consent":

  Generally, all research participants must provide voluntary informed consent to participate in research. The three fundamental aspects of informed consent are:

  (a) *Voluntariness*: Individuals' decisions about participation in research should not be influenced by anyone involved in conducting the research

  (b) *Comprehension*: Individuals must have the mental or decisional capacity to understand the information presented to them in order to make an informed decision about participation in research.

  (c) *Disclosure*: Researchers must disclose the following, in such a way that it provides a reasonable person the information she or he would need in order to make an informed decision:

  - The purpose of the study
  - Any reasonably foreseeable risks to the individual
  - Potential benefits to the individual or others
  - Alternatives to the research protocol
  - The extent of confidentiality protections for the individual
  - Compensation in case of injury due to the protocol
  - Contact information for questions regarding the study, participants' rights, and in case of injury
  - The conditions of participation, including right to refuse or withdraw without penalty.

Written documentation of informed consent:

In most research, the investigator must obtain written documentation of each participant's informed consent. A sample Informed Consent Form is shown on page 12 of this document. Of course, this sample form should be modified for any specific research project.

Waiver of written informed consent:

The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent, provided the IRB finds and documents that (45 CRF 46):

1. The research involves *no more that minimal risk* to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practically be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Examples of times when a waiver may be appropriate are when anonymous or secondary data are used.

- Anonymous questionnaires and surveys: Anonymous questionnaires and surveys, where the only link to the subject would be the signed Informed Consent Form, allow for consent to be waived because the subject is better protected without the existence of a signed document. Signed informed consent is required, however, when coding or demographic data preclude anonymity.

- Secondary data: If an investigator receives secondary data about human subjects where no possible personal identifiers are transferred to the researcher, written consent may be waived. The source of the data, however, must be disclosed to the IRB in the application.

Three Types of IRB Review

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There are three types of IRB review:

1. Exempt Review 2. Expedited Review 3. Regular Review

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1. Exempt Review:

- Research that qualifies for exempt status is exempt from the requirements for the protections of human subjects set forth in Title 45, Part 46 of the Federal Code of Regulations, such as the requirement for a written informed consent document and for continuing IRB oversight.

- Federal Regulations mandate that determinations of exemption must be made by the IRB.

- A research project may qualify for exempt status if the project presents *no more than minimal risk* to the subjects AND falls into one of the following categories of research specified by Federal Regulations (45 CFR 46):

  (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) 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: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) 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 paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) 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 department or agency heads, and which are designed to study, evaluate,

or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) 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, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

2. Expedited Review:

- Research that qualifies for expedited review may be reviewed by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB (45 CFR 46).

- A research proposal may qualify for expedited review if the research project is not exempt but presents *no more than minimal risk* to the subjects AND falls into one of the following categories of research specified by Federal Regulations (45 CFR 46). These categories 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 research proposal is eligible for expedited review when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

  (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, (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.

  (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.)

(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 or diagnosis).

(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.

(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 involves no greater than minimal risk and no additional risks have been identified.

3. Regular Review:

- Research that requires regular review is typically reviewed by the full IRB.

- Research proposals that do not meet the criteria for exempt review or expedited review must be submitted for regular review.

- A research proposal must undergo regular review if the research project presents the possibility of *more than minimal risk* to at least one participant, no matter how unlikely the realization of that risk may seem.

Frequently Asked Questions

- *What is the Institutional Review Board (IRB) and why is it needed?*
  As mandated by Federal Regulations, Saint Joseph's College of Maine has an Institutional Review Board which reviews research proposals involving human subjects. The purpose of the review is to insure that participants' rights are protected and that the research meets ethical standards.

- *Who is on the IRB?*
  The IRB consists primarily of faculty members.

- *What research projects must be approved by the IRB?*
  Any research project which collects data from human subjects must be reviewed by the IRB. Research is defined as a systematic investigation which is intended to contribute to generalizable knowledge.

- *Does all research with human subjects require an IRB review?*
  A project that does not meet the definition of research does not require IRB review. Determinations of whether particular projects meet the definition of research must be made by persons who are knowledgeable about the Federal Guidelines governing IRB processes. When in doubt, the researcher should consult with the IRB.

- *What ethical issues does the IRB consider?*
  Three human rights must be safeguarded by researchers: freedom from harm, privacy, and voluntary participation. Ethical considerations include:
    - Risks to participants are minimized
    - Risks are reasonable in relation to anticipated benefits
    - Selection of subjects is equitable
    - Informed consent is obtained from each participant
    - Informed consent is appropriately documented
    - Data collection is monitored to ensure participant safety
    - Privacy and confidentiality of participants is protected
    - Additional safeguards are included for vulnerable populations (i.e., children, prisoners, etc.).

- *What is informed consent?*
  Informed consent refers to the voluntary choice of an individual to participate in research based on an accurate and complete understanding of its purposes, procedures, risks, benefits, alternatives, and any other factors that may affect a person's decision to participate.

- *Where can I obtain IRB forms and instructions?*
  https://my.sjcme.edu/resources/administrative/institutional-review-board/

- *How long does it take the IRB to review a proposal?*
  Please allow two weeks for the IRB to review your proposal. A proposal may be submitted any time during the school year.

- *Does the IRB need to review revisions to previously approved research projects?*
  Yes, any substantive revision to a research project previously approved by the IRB must be reviewed by the IRB.

- *What if I have a question not addressed by these FAQ's?*
  Please contact Josh Schoenfeld, the IRB chair or Dale Brooker, IRB member.

Sample Informed Consent Form

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PARTICIPANT'S INFORMED CONSENT FORM

TITLE of the RESEARCH PROJECT

I AM BEING ASKED TO READ THE FOLLOWING MATERIAL TO ENSURE THAT I AM INFORMED OF THE NATURE OF THIS RESEARCH PROJECT AND OF HOW I WILL PARTICIPATE IN IT, IF I CONSENT TO DO SO. SIGNING THIS FORM WILL INDICATE THAT I HAVE BEEN SO INFORMED AND THAT I GIVE MY CONSENT.

NATURE AND PURPOSE: I am being asked to participate voluntarily in the above-titled research project. This project is being conducted by Barack Obama as part of the PY201 Research Methods course taught by Dr. Joshua Schoenfeld at Saint Joseph's College of Maine. The purpose of the project is to increase our understanding of the role of hope in politics.

SELECTION CRITERIA: I have been chosen at random to participate in this research project.

PROCEDURES: If I agree to participate, I will be asked to complete a confidential survey that includes questions about my personality and my political opinions.

RISKS: The risks of my participation are minimal. The survey may contain questions of a personal nature, but I will answer questions only if I feel comfortable doing so. I understand that I am free to stop participating in this research project at any time I wish.

BENEFITS: There is no direct benefit to me from my participation. However, I may contribute to a better understanding of the role of hope in politics.

CONFIDENTIALITY: To ensure confidentiality, I will not write my name on the survey. The information I provide will be coded with an identification number and will not be connected with my name in any way. All reports will be prepared in a way that protects the anonymity of participants.

PARTICIPANT COSTS AND SUBJECT COMPENSATION: The only cost to me will be my time. Completing the survey will take about 10 minutes. I will not be compensated for my participation.

CONTACTS: I can receive additional information about this research project by contacting Barack Obama at telephone 123-456-7899 or email BarackObama@TheWhiteHouse.com, or Dr. Joshua Schoenfeld at telephone 207-893-7924 or email jschoenfeld@sjcme.edu.

AUTHORIZATION: I understand the nature, purpose, procedures, risks, and benefits of my participation in this research project. I understand that I can stop participating at any time. A copy of this signed consent form will be given to me.

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Participant's Signature Date

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