

IRB APPLICATION INSTRUCTIONS

The IIT Institutional Review Board (IRB) reviews research proposals that involve human participants. Even projects with minimal participation, such as surveys or questionnaires, require some procedural IRB review. There are nine sections to these instructions:

Section 1:	Requirements for Submission
Section 2:	Is my Research Eligible for Expedited Review, Exempt Review or Full Committee Review?
Section 3:	Students as Subjects
Section 4:	Confidentiality of Identifying Data
Section 5:	Informed Consent
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Section 7:	Ethics in Research/Training Requirement
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Section 1: Requirements for Submission

All applications and supporting material must be typed. Handwritten applications will not be accepted.

Requirements for applications vary depending upon the type of research. While some applications will require review by the convened IRB committee, some research using human subjects in certain restricted ways may be eligible for expedited review. Please see **Section 2** of these instructions to determine whether your research falls into any of the nine categories of research that are eligible for expedited or exempt review.

- All applications must be submitted electronically to irb@iit.edu. You must submit the signed signature page via email.
Tip: To allow adequate time for review, the protocol application and supporting documents should be submitted to the IRB office no later than 30 days prior to the project's anticipated start date.

Committee Review: If your application requires full IRB review, submit the application prior to the monthly deadline shown on the IRB webpage at:

www.iit.edu/research/services/orcpd/irb_deadlines.shtml

The deadline for submission is 5:00 pm on the date indicated and will be strictly enforced. If you miss the deadline, your IRB submission will be reviewed at the following scheduled meeting. An investigator with authority to revise the protocol must be present at the meeting at which the protocol is reviewed. The investigator attending the meeting will be asked to provide a brief summary of the research protocol.

Important Note: The materials and documentation brought before the convened IRB should be finished products, not works in progress. The convened committee is not the place to review a rough draft or to finalize your research plan. All necessary information must be entered in the IRB application format. Do not simply copy text from a grant application or refer to grant sections that are attached as appendices.

IRB approval is valid for one year for federally sponsored research and two years for other research. If you need your project to continue beyond the approval expiration date, the investigator(s) must submit a renewal application for review and approval.

Within about five business days of receiving your application, the IRB office will email you an acknowledgment receipt containing an IRB protocol number. Send an email to irb@iit.edu if you do not receive an email within the time frame or if you have any questions.

Section 2: Is my Research Eligible for Expedited Review, Exempt Review or Full Committee Review?

IS THIS HUMAN SUBJECTS RESEARCH?

Ascertain whether or not your project is defined as human research by reviewing the two definitions below and determining whether each applies. If both definitions apply to your research, you are involved in research with human subjects. If only one or neither definition applies to your research, you are not involved in human subjects in research and likely do not require IRB review.

- **Research** means a systematic investigation designed to develop or contribute to generalizable knowledge.
- **Human Subject** means a living individual about whom an investigator conducting research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information.

IS THIS HUMAN SUBJECTS RESEARCH ELIGIBLE FOR EXPEDITED REVIEW?

Under certain circumstances, research involving human subjects is exempt from Federal regulation requiring full IRB review. If your research activities involve human subjects and fall entirely within the parameters of one or more of the following categories, please check the “expedited review” box in **Section A, Question 13** of the Application.

Category 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.

Category 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.

Category 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.

Category 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.

Category 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). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes.

Category 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.

Category 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..

Category 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.

IS THIS HUMAN SUBJECTS RESEARCH ELIGIBLE FOR EXEMPT REVIEW?

If your research activities involve human subjects and fall entirely within the parameters of one or more of the following **categories**, please check the “exempt review” box in **Section A, Question 13** of the Application.

- (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 (b)(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.

IS THIS HUMAN SUBJECTS RESEARCH ELIGIBLE FOR FULL COMMITTEE REVIEW?

The IRB generally reviews research proposals that involve greater than minimal risk or a particular vulnerable population as defined in the regulations. The list below gives examples of research proposals reviewed by the IRB. Also, please be aware that the Chair of the IRB may in some cases ask the committee to review a proposal that falls outside of the list below.

- Invasive physiological or medical research
- Research where there is a risk that confidentiality could be violated and if breached could result in potential criminal or civil liability or damage to a subject's financial standing, employability, or reputation.
- Research involving prisoners

Section 3: Students as Subjects

IRB Policy on Student Participation as Subjects in Research

This policy applies to recruitment of students when participation as a subject in research is a requirement for a course or is a basis for extra credit in a course. Such recruitment is acceptable when:

1. Participation in research is one of several persuasively comparable options available to a student for fulfilling the course requirement or obtaining optional course credit;
2. Students are informed of the availability of alternatives prior to or at the time of recruitment, and as part of the informed consent process.
3. When research participation is a course requirement, the research experience must be judged by the academic unit to be relevant to the course and have educational value. This determination is not required for courses offering only extra credit.

While the course instructor has discretion in determining course credit and appropriate alternatives to research participation, it is the responsibility of the researcher to take reasonable steps to ensure that alternatives are offered and credit is awarded in compliance with this policy.

Section 4: Confidentiality and Disposal of Identifying Information

IRB Policy on Maintenance and Disposal of Identifying Records:

Identifying records that are linked to research data (e.g. names, social security numbers, video recordings, etc.) should be maintained in a secure location, and only as long as required for completion of the research. It is expected that all identifying records will be disposed of within no more than six years after the data are collected in a manner that protects participant confidentiality.

IRB Policy on Maintenance and Disposal of Informed Consent Documents:

Signed consent documents represent a record that can link participants to the research, and therefore should be treated with the same care given to other identifying information. Signed consent documents should be maintained by the researcher(s) in a secure location for six years after the subject has completed research participation. After six years, the documents should be disposed of in a manner that protects participant confidentiality.

Section 5: Informed Consent

Informed consent is a legal requirement for research involving human subjects:

‘No investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.’ (45 CFR 46.116).

If the subject is a minor, at least verbal assent should be obtained from the child in addition to the required written consent by the parent/guardian. The language of the consent form should be non-technical and understandable to all subjects who will be requested to consent to participate. A list of simple language appropriate for consent documents can be found at the following link:
<http://www.seattlechildrens.org/doc/glossary-resource.doc> .

Each subject must be given a consent document, whether or not the procedure includes collecting a signature on the form. The requirement of signed consent may be waived by the IRB in instances where (1) the only record linking the subject to the research would be the consent document and (2) the principal risk would be potential harm resulting from a breach of confidentiality.

The following elements must appear in your consent form:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of procedures which are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the subject. 'Risk' and 'discomfort' include psychological as well as physiological effects. In some survey or interview research, often the risk is breach of confidentiality.
3. A description of what will be done to minimize or prevent the foreseeable risks. For example in survey or interview research, sensitive data are kept securely to prevent a breach of confidentiality.
4. A description of any benefits to the subject or to others which may reasonably be expected from the research.
5. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
6. A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
7. For research involving more than minimal risk, an explanation as to whether any compensation will be given and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained.
8. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject. This should include the name and phone number of the Principal Investigator(s) and the Executive Officer of the IIT Institutional Review Board (312-567-7141).
9. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits or services to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty.
10. A statement that absolves IIT of responsibility for any injuries or medical conditions that may be suffered by the participant during the course of the research unless those injuries or medical conditions are due to IIT's negligence.
11. A statement that the participant has received a copy of the consent form.
12. Any consent form distributed to a research subject must first be approved and stamped by the IIT IRB office.

Note: Please use the title of '**Consent Document**' rather than 'Informed Consent' on your consent form.

SAMPLE CONSENT FORM

(This is only a sample. Do not copy portions unless they apply to your research.)

CONSENT DOCUMENT

You are being asked to participate in a research study. Participation in this research study is voluntary and you may withdraw from the study at any time without penalty. Your identity will be coded to ensure confidentiality.

The purpose of this study is (describe in layperson's terms). As a participant in this study, you will spend approximately ½ hour today for interviewing and completing questionnaires, and approximately one hour in a psychophysiological research laboratory during a subsequent session.

While in the laboratory, sensors will be placed on your finger to measure blood flow, a blood pressure cuff will be placed on one bicep muscle to measure blood pressure, and electrodes will be placed on your right wrist and left ankle to measure heart rate. These measurement procedures are standard and should involve no discomfort. During the study, you will be asked to complete an information processing task for several minutes.

As part of today's session, you will be measured for height, wrist circumference, weight, and blood pressure and complete several questionnaires concerning coping style and life stress. You will also be interviewed concerning your exercise habits, diet, smoking, and general medical health. Although participation involves no future obligation, you may be contacted for future assessment sessions and may have the opportunity to participate in additional research if you so wish. You will be paid \$10 for your participation in the session.

Risks: This research presents no risks other than risk of breach of confidentiality. We are committed to respect your privacy and to keep your personal information confidential.

Any further questions about the research and your rights as a participant will be answered if you contact the project director {Name, Department, Number/Email}. The IIT Counseling Center is available to you, free of charge, to discuss your situation or your feelings. IIT Counseling Center can be contacted at 312-567-7550. **(NOTE: IIT Counseling Services are only available to IIT students. Participants who are not IIT students should be referred to appropriate counseling resources.)**

Illinois Institute of Technology is not responsible for any injuries or medical conditions research participants may suffer during the time of the research study unless those injuries or medical conditions are due to IIT's negligence. Questions and complaints can be addressed to the Executive Officer of the IRB at 312-567-7141.

AFFIRMATION OF PARTICIPANT:

I have read the material above and any questions I asked have been answered to my satisfaction. I agree to participate in this activity, realizing that I may withdraw without penalty at any time.

I have received a copy of this consent form. (For paper consent forms only; for online consent forms, add the following sentence: Please save or print a copy of this consent form for your records.)

Subject Signature

Date

This consent form is valid only if stamped by Executive Officer of IIT IRB. (For signed consent forms only)

For online forms: Remove the signature and date field.

*Please note the above consent form template uses sample language only.

Section 6: Risk

The concept of risk goes beyond physical risk, and includes risk to the subject's dignity and self-respect, as well as psychological, emotional, or behavioral risk. *Minimal risk* means that the risks of harm anticipated are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Section 7: Ethics in Research

Mandatory Training Requirement: IIT requires all individuals involved in the conduct of human subjects research to complete human subjects protection training. IRB approval will be withheld if these training requirements have not been met. Training is required every three years; proof of completion must be provided with each protocol application submitted to the Institutional Review Board (IRB).

Either of the following satisfies training requirements:

- CITI Basic Course (citiprogram.org)
- NIH online training (<http://phrp.nihtraining.com/index.php>)

Please visit our website for additional information regarding training:

<http://www.iit.edu/research/services/orcpd/compliance.shtml>

Ethical Guidelines from DHS OHRP (Office of Human Research Protections): You may obtain OHRP Reports via the following website:

<http://ori.dhhs.gov/human-subject-research-0>

Section 8: Contacts

IRB Chair: Patrick Corrigan corrigan@iit.edu.

For IRB Protocol Applications: Contact 312-567-7141 or irb@iit.edu.