



**Illinois Institute of
Technology
Institutional Review Board
Handbook of Procedures
for the Protection of Human Research**

**Revised to Reflect Current Regulations Set
Forth in the Revised Common Rule**

Federal regulations (see Appendix A, *Title 45, Code of Federal Regulations, Part 46*) require all institutions receiving federal funds which conduct research using living humans as subjects establish and operate an Institutional Review Board (IRB). The purpose of the IRB is to ensure the protection of these human subjects. IRBs are guided by the ethical principles embodied in *The Belmont Report* (see Appendix B), and by additional local standards and expectations. Illinois Institute of Technology has a policy (see Appendix C, *Policy for the Protection of Human Subjects*) that establishes our institution's IRB. This policy provides both background and direction for the mission of the Illinois Institute of Technology IRB.

This document, the *Handbook of Procedures for the Protection of Human Research Subjects*, describes how the Institutional Review Board at Illinois Institute of Technology will accomplish its mission. This handbook describes processes for review of research protocols from initial submission through modifications and renewal, as well as procedures to investigate assertions of harm to subjects or potential research non-compliance. This handbook also describes roles that different members of the IRB are expected to play and provides guidance for how these roles ought to be executed.

I. Important Terms and Concepts

Several critical terms are used throughout this Procedures Handbook. It is important that all Principal Investigators, other researchers, and members of the IRB share a common understanding of these terms.

Research means any systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. IRB review and approval is required for research activity that involves human subjects. It is the IRB, not the researcher that determines whether a particular activity is "research." Investigators may not avoid the requirements of the IRB review by referring to their research activities by other names (e.g., holistic investigations, naturalistic interactions, preliminary inquiries). Nor do the planned results of a research activity (e.g., a paper to be presented at a meeting, one submitted for journal publication, or not intended for dissemination at all) alter the requirements for an IRB review.

For purposes of this policy, the following activities are deemed not to be research: (1) Scholarly

and journalism activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including collection and use of information, that focus directly on specific individuals about whom the information is collected (e.g., news reports on specific people); and (2) Public health surveillance activities, including the collection and testing of information or biospecimens that are expressly conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters); (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes; (4) Authorized operational activities (as determined by the federal government) in support of intelligence, homeland security, defense, or other national security missions. The IRB has ultimate authority in deciding where an individual project meets these criteria.

Research Protocol (Protocol) is a description of a planned research activity written in sufficient detail to allow for a review of the proposed research activities by the IRB. Research protocols submitted for IRB review are required to follow a specified outline, detailing just the information necessary for a proper IRB review in clear and plain language. Incomplete protocols, protocols containing confusing or unnecessarily technical language, or protocols involving excessive and unnecessary detail (e.g., the entire first three chapters of a dissertation) are unacceptable and will be returned without review.

Application refers to a complete protocol submission with ancillary details that the IRB reviews in consideration of the approval of human subjects research. Applications are reproduced in Appendix D of this Handbook, available from the Office of Research Compliance, or accessible at their website, research.iit.edu/orcpd/human-subjects-irb. Pertinent ancillary details include: title of the project; name and contact information of Principal Investigator; and names and contact information of any co-investigators. Proof of completed human subjects training certifications by all investigators also must be included with any application submitted to the IRB (see *Qualifications and Training* below). All the sections in the application must be complete prior to IRB review.

Human Subject means a living individual about whom an investigator conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens (e.g., tissue samples from an organ bank).

Review is a process by which the members of the IRB weigh potential risks of research activities against potential benefits. Research protocols are classified into one of three levels of review: exempt, expedited, or full review. In certain categories of exempt research, a limited IRB review also may be conducted as a condition for exemption. This applies to the following exempt researching categories:

- research involving educational tests, survey procedures, interview procedures, or observation of public behavior if the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects;
- research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects;
- storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use; and
- research involving the use of identifiable private information or identifiable biospecimens for secondary research use.

The IRB is responsible for classifying research protocols into one of the defined levels of review, in alignment with federal regulations, depending on the nature of the research activities and the anticipated risks to the human subjects.

Approval means that the IRB has determined that a specific project described in the corresponding application has potential benefits that outweigh risks to the human subjects with little threat to participant welfare. The IRB signifies its approval of a research protocol by issuing a letter to the Principal Investigator stating that the research protocol has been reviewed, approved, and may be conducted. Research protocols having little risk to the subjects may be approved even if the benefit to be gained is likewise small (e.g., class projects where the primary gain is for the student to experience a research process).

Approval Period is a length of time throughout which an approved research protocol may be conducted. Research protocols having certain risks or special circumstances may be approved for a shorter period. The IRB may require additional reporting before granting any requests to extend the approval period.

Approved with Conditions means that a research protocol has been reviewed by the IRB but cannot yet be approved. A protocol review status of Withheld Pending often means a minor issue or issues needs correction or clarification. Such minor issues are typically corrected through additional communication between the Principal Investigator and the Chair and/or Executive Officer of the IRB without necessity for IRB committee review. More substantive changes to a protocol with a status of Withheld Pending may require re-review by the entire IRB. A protocol is most typically held as Withheld Pending for no more than 30 days, during which time it is approved, sent out for additional review, or administratively denied due to insufficient information.

Denial means that the IRB has determined that risks to the human subjects outweigh the benefits gained by conducting that research for a project described in a specific application. Research protocols might also be denied because:

- the protocol is confusing or convoluted and not understood by the IRB (e.g., poorly

written or containing excessive technical language or jargon);

- inappropriate procedures are being proposed to recruit research subjects and/or to secure their participation in the research (e.g., in the informed consent documents and procedures); or
- the Principal Investigator has not convinced the IRB of his or her capacity (training and experience) to conduct the proposed research.

A protocol may also be administratively denied when a Principal Investigator has not responded to requests for additional information or amendments from the IRB in a reasonable timeframe.

Other Activities

Amendments are requested changes to an approved protocol. It is not uncommon for Principal Investigators to request changes to a previously approved research protocol based on initial experiences in the laboratory or field. Proposed changes to the research protocol must be requested using the IIT IRB application. Minor amendments that do not change the overall nature of the approved research protocol (e.g., changing the size of a subject pool, adding additional investigators, changing a field site) may be approved upon review by the IRB Chair. More substantive amendments are reviewed in the same way as the original protocol and may be approved as submitted, may generate questions and/or requested modifications upon IRB review, or may be denied. A principal investigator may not implement any changes to an IRB approved study (including to the protocol or informed consent document) without **prior** IRB review and approval, unless the change is necessary to eliminate apparent immediate hazards to the subjects.

Continuation is a requested re-approval of an approved protocol. As with amendments, it is not uncommon for a researcher to continue the research protocol beyond the time allowed in the initial approval period. A request for a continuation is handled in the same way as a new submission. The investigator(s) must complete an IRB application with a cover memo that specifies:

- any changes to the research protocol that are desired, with a description of those changes;
- description of adverse events that have been reported during the approval period; and
- research activities completed to date and a report of the nature, type, and frequency of any adverse reactions encountered by any human subjects participating in the research.

Requests for continuation are reviewed in the same way as original protocols. Requests for a continuation of the approval period may be approved as submitted, may generate questions and/or requested modifications upon IRB review or may be denied. Continuing review is not required for any protocol originally approved under expedited review procedures unless the IRB explicitly justifies why continuing review will enhance protection of research activities. The IRB will include any applicable justification for continuing review for protocols approved under expedited review and document the justification in the approval letter issued to the Principal Investigator.

Suspension of research activities, during which no research involving human subjects may be conducted, may be required by the IRB. The IRB chair may temporarily withdraw the IRB's approval for a particular research protocol when evidence exists that harm has occurred, or is believed likely to occur. A suspension automatically begins an investigation of the circumstances resulting in suspension. Such an investigation will comply with IRB and university procedures for

investigating research misconduct. Within two weeks of a suspension, the IRB meets to consider the circumstances of the suspension and findings of the resulting investigation to determine if the suspension should be lifted or if the IRB's approval should be withdrawn.

Termination of research activities results when prior approval from the IRB is withdrawn due to substantiated instances of harm, or the potential for previously unrecognized harm to human subjects, and/or confirmed circumstances of non-compliance.

Adverse Event occurs whenever human subjects of a research activity experience physical, psychological, social, or other negative impact as a result of participation in the research activities. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research. Participation in a research activity by a human subject always involves some degree of risk although, in most cases, this risk is minor. The researcher takes significant steps to ensure that risks are minimized. All instances of a research subject's experiencing an adverse event as a result of participation in a research activity will be reported by the IRB to the designated university official for IRB oversight. Some instances might require reporting to other university, local, state, or federal departments or agencies.

Significant/Serious Adverse Event is defined by Office of Human Research Protections (OHRP) as any adverse event that:

1. results in death;
2. is life-threatening (places the subject at immediate risk of death from the event as it occurred);
3. results in inpatient hospitalization or prolongation of existing hospitalization;
4. results in a persistent or significant disability/incapacity;
5. results in a congenital anomaly/birth defect; or
6. based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

IRBs have authority to suspend or terminate approved research that, among other things, has been associated with unexpected serious adverse events to subjects. In order for IRBs to exercise this important authority in a timely manner, they must be informed promptly of those adverse events that are unexpected, related or possibly related to participation in the research.

Unanticipated Problem is defined by OHRP include any incident, experience, or outcome that meets **all** of the following criteria:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

2. related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

IRB notes that an incident, experience, or outcome that meets the three criteria above generally will warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects or others. Examples of corrective actions or substantive changes that might need to be considered in response to an unanticipated problem include:

- changes to the research protocol initiated by the investigator prior to obtaining IRB approval to eliminate apparent immediate hazards to subjects;
- modification of inclusion or exclusion criteria to mitigate the newly identified risks;
- implementation of additional procedures for monitoring subjects;
- suspension of enrollment of new subjects;
- suspension of research procedures in currently enrolled subjects;
- modification of informed consent documents to include a description of newly recognized risks; and
- provision of additional information about newly recognized risks to previously enrolled subjects.

Non-Compliance occurs when a Principal Investigator, or any other researcher under the direction of the Principal Investigator: (a) engages in research activities other than those approved by the IRB; (b) continues to engage in approved research protocol activities beyond the time period specified in the approval period, or (c) engages in research activities involving human subjects without IRB approval. Instances of non-compliance will be addressed with IRB and university procedures for investigating research misconduct. All instances of non-compliance will be reported by the IRB to the designated university official for IRB oversight. Some instances may require reporting to other university, local, state, or federal departments or agencies.

Qualifications and Training refers to the requirement that proper qualifications through education, experience, and training to conduct pertinent research duties have been established. This requirement applies to all research personnel and appointed IRB members. The IRB requires that each appointed member have a current résumé or curriculum vitae attesting to personal education and experiences on file. Additionally, appointed members must have updated human subjects training certification on file. This training is available through CITI Program (www.citiprogram.org). Research staff, including investigators and co-investigators, also must submit proof of human subjects training certification with each IRB application. If a protocol employs research activities that require additional training or certification, then the IRB may impose requirements in line with university policies for all research personnel conducting research activities under that protocol.

II. IRB Application Procedures

This section describes procedures for initial review of IRB applications.

1. Research Investigator Completes IIT IRB Application

The first step in obtaining IRB approval for research involving human subjects is for the research investigator to complete the *IRB Application* (see Appendix D). This form may be obtained from the Office of Research Compliance by accessing their website research.iit.edu/orcpd/human-subjects-irb. The form asks for: title of the project; name, mailing address, and telephone number of the Principal Investigator; and names, mailing addresses, and telephone numbers of any co-investigators. Only IIT university faculty or staff may serve as Principal Investigators for an IRB research protocol. A student investigator must be named on the form as being a co-investigator, with the faculty or staff member providing appropriate direction to the student researcher. The faculty member has ultimate responsibility of all segments of the research.

Each item in the IRB application must be completed or indicated as being not applicable. No particular length of submission is required. Rather, the narrative should explain each of the recommended areas in sufficient detail for a proper review.

The Principal Investigator signs the application attesting to the submission materials' correctness and agreeing to follow the procedures established by the IRB. The signed application is then submitted to the Office of Research Compliance at irb@iit.edu.

2. Initial Application Review

Staff in the Office of Research Compliance review each completed application and assign an IRB tracking number. Any application with missing or incomplete sections is returned to the Principal Investigator for correction. Once an application is complete, it is submitted to the IRB Chair or designee for review with recommendations pertaining to the level of IRB review appropriate based on the research activities.

EXEMPT REVIEW DETERMINATIONS

- a. If the IRB Chair determines the application qualifies for one of the defined exemptions (see 45 CFR 46.104(d)), then the application is approved and an approval letter is issued to the Principal Investigator citing the specific exemption.
- b. Exempt Categories: the following categories of human subjects research are exempt:
 - i. Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
 - ii. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures,

or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 2. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
 3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
- iii. (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 2. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
 3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
- (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
- (iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
- iv. Secondary research for which consent is not required: Secondary research uses

of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

1. The identifiable private information or identifiable biospecimens are publicly available;
 2. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
 3. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
 4. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.
- v. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.
1. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be

published on this list prior to commencing the research involving human subjects.

- vi. Taste and food quality evaluation and consumer acceptance studies:
 - 1. If wholesome foods without additives are consumed, or
 - 2. 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.
- vii. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).
- viii. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
 - 1. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);
 - 2. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;
 - 3. An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.
- c. For exempt determinations which require limited IRB review as a condition for exemption, the IRB must make the determination that the research conducted is within the scope of broad consent. The IRB Chair and Research Compliance staff will confirm this for any research that requires limited IRB review as a condition for exemption.

EXPEDITED REVIEW DETERMINATIONS

- a. If the IRB Chair confirms the application qualifies for expedited review, the application is approved based on the appropriate expedited review category set forth in the federal regulations (see 45 CFR §46.110(a)). All research activities and interventions must fall within one or more of the expedited review categories. Additions to, or extrapolations from, the expedited review categories are not permissible. The full committee may review research activities and interventions that fall entirely within one or more expedited review categories if the IRB documents that the research presents more than minimal risk to participants.
- b. Expedited Review Categories (OHRP):
 - i. Clinical studies of drugs and medical devices only when condition (a) or (b) as

- indicated below 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.
- ii. 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.
 - iii. 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.
 - iv. 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.
- v. 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).
 - vi. Collection of data from voice, video, digital, or image recordings made for research purposes.
 - vii. 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.
 - viii. 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.
 - ix. 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.

FULL IRB REVIEW DETERMINATIONS

- a. If the IRB Chair confirms the application qualifies for full IRB review, Research Compliance staff sends a copy of each IRB application via e-mail to all members of the IRB.

3. Convened IRB Committee Meetings

Research applications that require a full review must come before the convened IRB at a regular or special meeting. Prior to that meeting, each IRB member and the IRB Chair will review the applications under consideration. An investigator whose application is under review must attend the meeting. During the time allotted, the IRB Chair or designee will ask the investigator to summarize the application. IRB members may ask questions of or make suggestions to the investigator. As necessary, subject matter experts may be consulted by the IRB for their opinion. This may require postponing discussion and/or approval until the next IRB meeting. After discussion concludes, voting is conducted by ballot. As in all business before the IRB, a majority vote of the members present is required before any action may be taken. Per federal regulations, a quorum must be maintained at all times. A quorum is defined as one more member beyond 50% of total voting members of the IRB. In addition, a non-affiliated, non-scientist member of the IRB must be in attendance. If any IRB member recuses him or herself, the quorum is lost, and IRB activity ceases.

4. Review Outcomes: Approvals, Approved with Conditions, and Denials

All research applications brought before the IRB, whether exempt, expedited, or full review, must be approved as submitted, approved pending minor revisions, or denied with recommendations for major revisions. The IRB Chair or designee is empowered, on behalf of the IRB committee, to approve all expedited proposals that have received satisfactory review. Proposals that, in the opinion of the IRB Chair or designee, are still deficient after a Principal Investigator's response to a request for minor revisions, may be brought before the convened IRB for consideration. Only the convened IRB may approve a proposal requiring a full review, or deny approval to any proposal.

After an expedited review of an application has been conducted by the IRB Chair or designee, the IRB Chair or designee will inform the Executive Officer indicating approval of the application. An approval letter, signed by the IRB Chair or designee, will be sent to the Principal Investigator. A copy of this letter is also kept in the Office of Research Compliance.

On other occasions, the IRB Chair or designee may determine that approval of the application as submitted is not appropriate. In this case, the IRB Chair or designee will notify the Principal Investigator that approval for the proposal has been withheld pending certain revisions. The notification will detail items requiring attention and time frame for submitting revisions. The Principal Investigator submits revisions directly to the Office of Research Compliance. In certain cases, the IRB Chair or designee may contact the Principal Investigator directly to explain any required revisions or discuss ways the Principal Investigator might meet the requirements of the IRB. If the Principal Investigator responds to the issues discussed to the satisfaction of the IRB Chair or designee, the application may then be approved with the revisions implemented.

The Principal Investigator may conduct research protocols approved under this procedure for a period not to exceed the approval period. The starting and ending dates of the approval period will be stated on the approval letter sent to the Principal Investigator. In certain cases, the IRB may require a shorter approval period as well as interim reporting on the progress of the research and the status of the human subjects as a condition of approval. The exact period of approval, and any conditions, will be stated in the approval letter.

5. Questions and Appeals

Any person may request an appointment with the IRB Chair, or an opportunity to address the IRB at a regular or special meeting, for any purpose related to the business of the IRB including appeals of decisions by the IRB or IRB Chair.

The IRB Chair should strive to be available for questions from Principal Investigators. Experience has shown that most issues can be addressed through short telephone conversation or email exchange. As necessary, the Chair or Executive Officer will be available for personal meetings, discussions with research teams or laboratories, and presentations before academic

units.

III. Amendments of Human Subject Research Proposals

On occasion, a research application may need to be amended from the original application that was approved by the IRB. The Principal Investigator must request an amendment when a change in the research protocol is desired. Such a request must be in writing in the form of a revised application with a cover letter detailing the reasons for the amendment(s) and the proposed amendment(s). This letter and any supporting documents (such as changes to instruments or informed consent documents) is sent directly to the Office of Research Compliance.

The IRB Chair may approve all requests for amendments that are minor in nature. Minor amendments are those that do not change the basic nature of the research effort. Examples of minor amendments include: expanding the subject pool size (due to a low initial participation rate), changing a data collection form to make it easier for subjects to read it, or adding an additional field site similar to those already being used.

Requested amendments that are not minor in nature will initiate a review of the revised protocol at the same level as the initial proposal. As with an initial review, the requested amendment may be approved, approved with conditions pending minor revisions, or denied. If approved, the revised protocol will carry the same approval period as the original approval.

IV. Procedures for Investigating Adverse Events and Non-Compliance

The IRB oversees protection of human subjects of research. The IRB does this by investigating complaints of subjects suffering adverse or significant adverse events, or of Principal Investigator or co-investigators not following their approved research protocols. Principal Investigators are required to follow the research protocols that have been submitted and approved, or amended, by the IRB. Principal Investigators are also required to promptly report to the IRB any adverse or significant adverse events experienced by research participants.

Initial reports of adverse or significant adverse events or possible non-compliance should be brought to the attention of the IRB Chair and the Office of Research Compliance. The Chair, in consultation with the Executive Officer to the IRB and other IRB members as might be required, conducts the initial investigation. The purpose of the initial investigation is to determine, as quickly as possible, two points. First, does the assertion of an adverse or significant adverse events or non-compliance contain merit worth further investigation? Second, are any human subjects at risk if the research study is allowed to continue?

To answer these questions, the Chair or designee representing the interests of the IRB may: interview the Principal Investigator and co-investigators, human subjects, and others; examine research records requested from the investigators; and personally inspect research facilities and equipment. This initial investigation should take place as quickly as possible, typically within a few days of receiving the initial information. If no adverse or significant adverse events

or possible non-compliance is uncovered, no further action is necessary. The IRB Chair may temporarily suspend the research protocol if the initial investigation uncovers information supportive of an adverse or significant adverse events or non-compliance and if human subjects might be at risk if the study is allowed to continue. Should this occur, the Chair or designee will notify, verbally and in writing, the Principal Investigator, his or her academic unit head, and the Executive Officer to the IRB that the research has been temporarily suspended.

Complaints of adverse or significant adverse events or possible non-compliance that the Chair has found to have merit, regardless of whether a research protocol has been temporarily suspended, will be brought by the Chair to a special meeting of the IRB committee within two weeks of the Chair's determination. At this meeting, the IRB committee will be presented with whatever evidence has thus far been collected. The Principal Investigator, co-investigators, and any others with relevant information will be invited to present information to the committee. The IRB will then decide if further investigation is needed or if sufficient information is available to determine whether an adverse or significant adverse events or non-compliance has occurred. The IRB will also decide if the research protocol should be continued as originally approved, reinstated (if temporarily suspended by the Chair), suspended pending further investigation or revisions by Principal Investigator, or terminated.

The sole function of the IRB is to provide protection for the human subjects of research by approving, requiring modification in, or denying approval of proposed research. When the IRB suspends approval for a research project, no further research involving human subjects may be undertaken. The Principal Investigator will need to submit to the IRB amendments to the protocol sufficient to satisfy the conditions of the suspension before the research can be resumed. When the IRB withdraws its approval for a research project, the project is considered terminated and no further research involving human subjects may be undertaken. A new protocol must be submitted, reviewed, and approved.

There may be certain agencies, both within and outside the university, which require notification whenever a research protocol involving human subjects is suspended or terminated. The IRB Chair and the institutional representative ensure that these notifications are made in a timely fashion. Principal Investigators must be aware that a suspension or termination of IRB approval can result in the freezing of internal or extramural grant accounts, the return of equipment or other resources, and further investigation by other entities (such as the student affairs office, academic unit heads, deans, and outside funding and governmental bodies).

Appendices

A: Title 45, Code of Federal Regulations,
Part 46

B: The Belmont Report

C: Illinois Institute of Technology Policy for the Protection of Human
Subjects

D: IRB Application Form