

DEPAUL UNIVERSITY



Research Involving Human Subjects

Category: Academic Affairs - Operational

Responsible Department: Office of Research Services

Responsible Officer: Director of Research Compliance

Effective Date: 09/18/2018

Policy Summary

This policy serves as a guide to the ethical conduct of research involving human subjects, including the use of private individually identifiable data by DePaul faculty, students, and staff when they conduct the research activity under their roles or duties at DePaul or engage themselves or DePaul in the conduct of the research.

This policy arises from the university's obligation to comply with the federal regulations governing human subject research, and, accordingly, the authority to revise this policy lies with the Institutional Review Board, administered through the Office of Research Services.

Scope

This policy affects the following groups of the University:

- Full-Time Staff
- Part-Time Staff
- Full-Time Faculty
- Part-Time Faculty
- Students

The following individuals are required to be familiar with this policy:

- Members of the Institutional Review Board (IRB)
- Office of Research Services Staff
- Faculty, staff, and students conducting human subject research

Policy

A. Introduction

The federal regulations define research as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Human subject is defined as 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.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

All DePaul faculty, students, and staff conducting research human subjects must comply with these policies and procedures, whether their research takes place at DePaul or elsewhere (e.g., other universities, hospitals, schools, institutions, community groups, online) and whether the research is externally-funded, internally-funded, or unfunded.

Although it is the policy of DePaul that all requests for research support for activities to be conducted by faculty, staff, and students are to be submitted through the university, it recognizes that collaborative programs may originate in other institutions. In such instances, while the originating or lead institution may have already conducted its own IRB review in accordance with current federal regulations, the DePaul IRB must also review and approve those activities that will occur under the authority of DePaul or that will engage DePaul or DePaul faculty, staff, or students in the conduct of the research. In some instances DePaul may sign an IRB Authorization Agreement with another institution, to eliminate the need for duplicate review of research protocols.

Everyone in the DePaul community has a responsibility to conduct activities in such a way as to provide maximum protection for the rights and welfare of the communities we serve. DePaul is committed to conducting all of its research activities under the most rigorous ethical standards.

B. Mandate

The University-wide Institutional Review Board was established by DePaul in 2001 and constituted to comply with regulations of the United States Department of Health and Human Services (45 CFR 46). DePaul has agreed to comply with the federal regulations governing human subject research and to adhere to the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (The Belmont Report). This document is available through the IRB webpage at [this link](#).

The establishment of the IRB fulfills one obligation of DePaul's contract with the federal Office of Human Research Protections (OHRP) to ensure that all human subjects research (whether federally-funded or not) conducted by DePaul faculty, staff, and students complies with the federal regulations (45 CFR 46). IRB approval affirms the methodological and ethical quality of the research, and it is the primary responsibility of the IRB to review research activities that involve human subjects or their data to ensure that:

- The risks to the subject are outweighed by the possible benefits to the participant and/or the importance of the knowledge to be gained or its benefit to society.
- Any risks to the research are minimized.
- The rights and welfare of each subject will be adequately protected.
- Subject selection is equitable and fair.
- Informed consent is obtained by adequate and appropriate means.
- There are adequate plans for monitoring the data collected and the safety of the subject.
- There are adequate plans to protect the privacy of the subjects and the confidentiality of the data
- Long-term research protocols (expedited and full-board) are reviewed at specified intervals, at least annually.
- The subject is fully aware of his/her rights, benefits, and the nature of the procedures.

C. Review Boards

1. Institutional Review Board

a. IRB Appointment: Formal appointments of faculty members to the IRB are made by DePaul's President, on the recommendation of a subcommittee of the IRB. This appointment subcommittee is made up of the IRB Chair, the Director of Research Compliance, and the Associate Vice President for Research Services. The subcommittee makes its recommendations to the President, after considering nominations from department chairs, Local Review Board members, IRB members, Faculty Council, and researchers.

b. IRB Membership: The IRB consists of voting members and non-voting, ex-officio advisors. The voting members are diverse faculty from the schools, colleges, and departments most actively conducting human research at DePaul, the Director of Research Compliance, other staff members in the Office of Research Services, and an unaffiliated community representative. The ex-officio advisors are the Associate Vice President for Research Services, other staff members in the Office of Research Services, and their terms are indefinite.

At least one voting member of the IRB must have a non-scientific background and profession. The Director of Research Compliance is appointed for an indefinite term, and all other voting members are appointed for renewable three-year terms. Additional voting members with expertise in specialized fields may be included on reviews as needed, such as when protocols involving prisoner populations are to be reviewed. The votes of these members count towards the IRB's quorum only when they participate in the review of a protocol.

Current membership and contact information for IRB staff are available on the IRB webpage at <http://offices.depaul.edu/ors/research-protections/irb/Pages/about.aspx>

c. IRB Meetings:

The full IRB generally meets every month (except in July and sometimes August) to review research involving human subjects that does not meet the criteria for exempt or expedited review.

Full IRB meetings also include policy discussions and education/training.

d. Expedited and Exempt Review:

Protocols and protocol submissions that qualify for expedited and exempt review are reviewed outside of a convened meeting by members of the IRB. Review items are sent out three times a week to IRB reviewers.

2. Additional Review Boards

a. University Research Council: The URC has established procedures to review the scientific character of the research. If investigators are planning to apply for URC funding for a particular project and the project is a new protocol not previously approved by the IRB, investigators seeking URC funding must submit their protocols involving human subjects to the URC for evaluation before submitting them to the IRB. If the researcher requests URC funding after the research has received IRB approval and/or has already begun, the IRB should receive an amendment notifying them of the change in funding status and any changes to the research based upon the request for new funding and the summary of the research contained in the application for funding. The IRB must ensure that the research as approved by the IRB matches the research as proposed in the URC funding application. The URC requests verification of IRB approval before releasing the funds to the researcher. No research projects involving human subjects will be funded by the URC until appropriate IRB approval has been obtained.

b. Institutional Biosafety Committee: Research that involves biohazardous materials and/or recombinant or synthetic nucleic acid molecules may require the review of the Institutional Biosafety Committee (IBC).

If a protocol requires both IRB and IBC review, the researcher should inform both committees that there will be more than one review of the project and should work with the Director of Research Compliance to coordinate the timing of the respective reviews. IBC review should occur prior to IRB review, as all issues pertaining to the safety of the biohazardous agents used in the research must be resolved in order for the IRB to make a determination regarding the risks for the research. As with other types of human research, work that requires IRB and IBC review can begin only once the researcher has received formal approval from both committees.

c. DePaul Privacy Officer

The Health Insurance Protection and Portability Act (HIPAA) stipulates that certain types of health information, termed "Protected Health Information" (PHI), can be used or disclosed to third parties only in limited instances. In the context of research, the Privacy Rule requires researchers who will use subjects' PHI or disclose subjects' PHI to others to obtain a signed HIPAA Authorization form from research subjects beforehand. In special circumstances a waiver of HIPAA authorization may be requested that allows the researcher to not obtain a written authorization. For more information about HIPAA 1, please contact the Director of Research Compliance.

D. Research Requiring Review

All DePaul-affiliated research that involves human subjects or their identifiable private information requires IRB review. This is true regardless of the location of the research or a project's status as externally-funded, internally-funded, or unfunded.

1. Standard: Human subjects research that requires IRB review includes any research that:
 - is conducted by DePaul faculty, staff, or students, regardless of the location of the research (e.g., DePaul, other institution, community, foreign country) or engages DePaul University or DePaul faculty, staff, or students in the conduct of the research;
 - is performed with, or involves the use of, facilities or equipment belonging to DePaul University; or
 - Is certified by a dean or department head to satisfy an obligation of a faculty/staff appointment at DePaul University, including clinical or adjunct appointments.

2. Additional: The following types of research also require IRB review:
 - ongoing research previously approved by the IRB and requiring continuing review;
 - research conducted in courses that may result in the creation of generalizable knowledge (e.g., publication or presentation outside the classroom);
 - Research at a pilot or feasibility stage (Pilot and feasibility studies, even those with only one human subject, require the same review as full-scale research projects. Applications to the IRB for pilot studies should be identified as such, and subjects should be told during the consent process that the study is a pilot, if the status as a pilot study may reasonably affect the subject's decision to participate in the research.);
 - research involving secondary use of data collected from humans in earlier projects (e.g. using data from one study for a new study), when the data remains individually identifiable or includes individual identifiers or codes that are linked to individual subjects;
 - Research using "waste" and "extra" material (i.e., human tissue or fluids) "Waste" material is material that is collected originally for clinical or diagnostic purposes but is no longer needed. "Extra" material is material that is collected above and beyond what is needed for a clinical or diagnostic procedure but for investigative purposes;
 - oral history research when it meets the definition of research under the federal regulations and includes human subjects;

- ongoing research by faculty or staff that began at another institution and continues to involve the recruitment and enrollment of new subjects or data collection or analysis of identifiable data.; and
- Research projects in which a DePaul researcher provides services to another researcher as a consultant and the activity being performed by the DePaul researcher meets the definition of human subject research.

IRB review is not required if the DePaul personnel:

- 1) Perform commercial or other services that meet the following conditions: a) the services performed do not merit professional recognition or publication privileges; b) the services performed are typically performed for non-research purposes; and c) the DePaul personnel do not administer any study interventions being tested or evaluated under the protocol.;
- 2) Provide prospective subjects with information about the availability of a research study and limit that activity to providing a flyer or protocol summary, providing the researcher's contact information or seeking permission for the researcher to contact the potential subject, and the DePaul personnel do not obtain informed consent;
- 3) Allow external researchers to use facilities, such as their classroom, for the research intervention or interaction.; or
- 4) Obtains coded private information or biological samples from another institution involved in research, when the other institution retains the link to the coded data and the DePaul personnel are unable to ascertain the identity of the subjects.

3. Special Circumstances

a. Student Researchers: DePaul students who wish to conduct research involving human subjects are bound by the same guidelines as DePaul faculty and staff. When a student is the Principal Investigator for the research, a faculty or staff member holding a university appointment must be designated as the faculty sponsor. All requirements established by the IRB for the conduct of the research must be fulfilled. Failure to do so will result in the immediate suspension of IRB approval for the research. DePaul University recognizes it has major teaching responsibilities, including training students to conduct research in a responsible manner. The faculty sponsor has ultimate responsibility for ensuring the student conducts the research ethically and follows the DePaul policies and procedures.

b. Schools: All research conducted by DePaul members at schools or using school populations must have the written permission of the school board and/or principal of the school system involved before the study can begin. It is the responsibility of the investigator to meet any additional requirements of the school system or school in question. In designing projects that involve schools, the investigator must consider special arrangements for recruiting subjects, including obtaining parental permission and student assent, involving teachers, and providing feedback or individual results. These issues should be addressed in the protocol application. Investigators are advised that school systems vary in their requirements, and ample time must be given to address these issues. Researchers conducting

research in a Chicago Public School (CPS) should review the guidance available on the IRB web-site for special considerations and required parental permission language for research conducted in CPS. CPS has a set of guidelines for review and approval of research through their Research Review Board, and IRB approval through DePaul is required prior to applying for Research Review Board approval through CPS. The DePaul guidance document for conducting research with CPS contains the links to the CPS' own web-site and policy document.

c. Medical Records/Computer Databases: The Health Insurance Portability and Accountability Act (HIPAA) is the federal legislation that governs the use and disclosure of Protected Health Information (PHI) for research or otherwise. IRB approval of projects that involve information that may be protected under HIPAA may be withheld until it is ensured that all HIPAA-related requirements have been met. For additional information about the procedures for HIPAA compliance, please contact the Director of Research Compliance.

In all cases, research involving patient chart reviews and/or review of patient data through a computer database or a medical record that contains identifiable information (e.g., name or medical record number, health information linked to the person's identity) must be reviewed and approved by the IRB. This requirement also applies to record reviews and database queries performed for the purposes of research. The term "research" designates an activity designed to test a hypotheses and permit conclusions to be drawn that will contribute to generalizable knowledge. Reviews of patient medical data for non-research purposes do not require IRB review. In all instances, the IRB will comply with state and federal laws and regulations concerning medical record/personal data access.

d. Projects That Do Not Involve Human Subject Research at the Outset: Some grant proposals, such as training grants that will support individual graduate students who will be selected after the grant is reviewed by the funding agency, will require specific IRB review and approval for any human subject activities at some point, but may include no specific plan for research with human subjects at the time of grant proposal submission. In such circumstances, the project director should notify the Director of Research Compliance that such a funding proposal has been submitted to the funding agency and should consult with the grant program director regarding whether they will require either a preliminary IRB review and approval of the grant and a determination of a proposal lacking definite plans for involving human subjects under 45 CFR 46.118 before funds can be released. Once plans for the involvement of human subjects are finalized, the researcher should be prepared to secure IRB approval prior to beginning recruitment and enrollment of subjects and/or data collection from or about human subjects.

e. Course Projects: If the overall objective of a course assignment is to learn about the design and conduct of research projects and/or if data will be collected and analyzed for classroom learning only, then IRB review is not required. In such cases, instructors are responsible for educating students about the protection of human subjects and about ensuring their own safety as researchers. In addition, the course syllabus must include a component for training students about the ethics of collecting information from or about humans. Instructors may opt to require that students complete the online training module available through the IRB webpage, which provides a certificate after training has been completed. Regardless of the

method of training, instructors are required to retain documentation of student training, including names, date of training, and topics covered.

Data collected for a class project and that does not receive review and approval of the IRB prior to its inception may not be used for publication or presentation or thesis/dissertation work but may be disseminated within the institution for administrative and evaluative purposes. Students should be cautioned that the IRB cannot provide retrospective approval, and if there is any possibility that the research will be used in support of a thesis or dissertation, or may be published or used in a presentation, they should obtain IRB approval prior to the onset of the research activity.

Instructors interested in involving students in the collection or handling of data for a publishable or presentable project must obtain the approval of the IRB prior to beginning the research. In such instances, students should be listed in the application materials as research personnel and must be trained accordingly.

Instructors who are uncertain about whether their classroom activities need IRB review should submit their course syllabus to the Director of Research Compliance for evaluation.

E. Types of Review

Several types of review are conducted by the Institutional Review Board to insure that all research involving human subjects conforms with the federal regulations (45 CFR Part 46, "Protection of Human Subjects"):

1. **Exempt Review:** Projects that may qualify for an exemption determination are reviewed by the IRB and/or members of the Office of Research Services staff to determine eligibility. Projects that do not require any type of IRB review are non-reviewable because they do not involve research and/or human subjects, or they do not engage DePaul in the research. During the review, the IRB or ORS staff may grant an exemption determination or refer projects to the IRB for expedited or full Board review.

The following categories of research are eligible for exempt review (45 CFR 46.101(b)):

- **Category 1:** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - research on regular and special educational instructional strategies
 - Research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.
- **Category 2:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND

- Any disclosure of the human subjects' responses outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Note: Survey or interview research and research that involves observation of public behavior where the investigator participates in the activity being observed, and that involves children as subjects, does not qualify for exempt review.

- Category 3: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview procedures, or observation of public behavior that is not exempt under paragraph 2 of this section, if:
 - the human subjects are elected or appointed public officials or candidates for public office; or
 - Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- Category 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.
- Category 5: Research and demonstration projects that are conducted by, or subject to the approval of, department or agency heads, and that are designed to study, evaluate, or otherwise examine:
 - public benefit or service programs;
 - procedures for obtaining benefits or services under those programs;
 - possible changes in, or alternatives to, those programs; or
 - Possible changes in methods or levels of payment for benefits or services under those programs.
- Category 6: Taste and food quality evaluation and consumer acceptance studies:
 - if wholesome foods without additives are consumed; or
 - 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.

A single protocol may involve one or more of the above categories in order to be determined as exempt. Researchers are advised to review the information available on the IRB webpage to confirm the eligibility of proposed research for exemption, as several exceptions to the above categories exist.

When submitting exempt projects, researchers must submit the following documents for IRB review:

- the exempt application,

- an exempt information sheet or otherwise appropriate method of providing information about the research to the subject,
- the survey measures, questionnaires, or data collection tools,
- Recruitment materials (email scripts, flyers, advertisements). and
- Documentation of training, if the training is not the DePaul required CITI training (e.g. training of a collaborator completed at another institution, a DePaul approved alternative to the CITI program).

For projects classified as exempt, researchers are responsible for ensuring that all collaborators' requirements have been met prior to beginning recruitment. For example, researchers conducting exempt educational research in schools are responsible for ensuring that they have met any school district requirements for conducting research, as well as any school-specific requirements (e.g., getting approval from the principal) prior to beginning recruitment. In light of this obligation, the IRB advises researchers to secure a letter of support from an appropriate person at each collaborating institution (e.g., the president, chief executive officer, principal) for the researcher's own records..

Presuming that the required items have been submitted and provide sufficient information to make an exemption determination, the IRB will notify the researcher by email that the IRB has received the project and determined it to be exempt. Once researchers have received confirmation of an exemption determination from the IRB, they are free to begin recruitment and data collection. If a project has been submitted for exempt review and is determined to be ineligible for exemption, the researcher will have to satisfy the additional requirements of expedited or full review, as needed.

Researchers are not required to submit renewal (continuing review) information for exempt projects. The ongoing obligations of researchers on exempt projects are to submit their materials for additional review (via an amendment) if substantive changes are proposed (e.g. changes in the design or focus of the research project, revisions to the consent/information sheet for subjects, addition of new measures or instruments, and any change to the research that might alter the exemption status, either add additional exemption categories or make the research no longer eligible for an exemption determination) or if additional personnel will be added to the research team, and to close the protocol via a final report when the research is completed or before leaving DePaul. Researchers with questions about whether a change is substantive and requires additional review should contact the Director of Research Compliance.

2. Expedited Review: An expedited review procedure exists for the review of research protocol submission involving human subjects that meet the criteria for expedited review as outlined in the regulations (45 CFR 46.110). These include protocols that involve minimal risk to subjects and meet the criteria for one or more of the expedited categories, research eligible for expedited continuing review, or minor changes to previously approved research (Amendments). At DePaul protocol submissions that are eligible for expedited review are reviewed by one or more of the voting members of the IRB. The IRB reviewers are experienced reviewers designated by the chairperson from among members of the IRB (such as when the IRB Chair is unavailable or has a role in a project being reviewed) in accordance with the requirements set forth in 45 CFR 46.110. The IRB reviewers have the authority to determine that projects do not require any type of IRB review (i.e., are non-reviewable), to determine projects meet the criteria for an exemption

determination, to approve projects that are eligible for expedited review, and to refer projects on to the convened IRB for full Board review. The IRB members also review submissions such as continuing review applications and amendments that meet the criteria for expedited review.

Research for which the IRB may use the expedited review procedure is defined (authorized in 45 CFR 46.110) as any research that involves no more than minimal risk to the subjects and in which the only involvement of human subjects will be in one or more of the categories described below:

- 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 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 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:
 - 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
 - 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. 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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)
- Category 8: Continuing review of research previously approved by the convened IRB as follows:
 - 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
 - where no subjects have been enrolled and no additional risks have been identified; or
 - 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.

In addition, researchers are advised to take note of the following:

- The activities listed above should not be deemed to be of minimal risk simply because they are included on this list. Inclusion in this list merely means the activity is eligible for review through the expedited review procedure when the specific

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

- The categories in this list apply regardless of the age of subjects, except as noted.
- The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that the risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- The expedited review procedure may not be used for classified research involving human subjects.
- The standard requirements for informed consent, its waiver or alteration apply regardless of the type of review--expedited or full (convened)--used by the IRB.
- Categories one (1) through seven (7) pertain to both initial and continuing IRB review. Categories 8 and 9 pertain only to continuing review.

The convened IRB is informed about all protocol submissions reviewed and approved via expedited review at the next available convened meeting after the approval occurs.

3. Full Board Review: Projects or protocol submissions that require IRB review, but are not eligible for exemption or expedited review or for which it is determined require an additional level of scrutiny, such as when the research involves vulnerable populations, are reviewed by the convened IRB. IRB members who have an interest in projects under review may participate in Board discussion only to provide information, but must recuse (remove themselves from the room) themselves from the final IRB discussion and voting on the submission.

Although researchers may request exemption or an expedited review, determination of such resides solely at the discretion of the IRB. The level of review a project receives depends in part on the risks posed to subjects by the research. The probability and severity of possible harm (physical, psychological, social, or economic) may vary from minimal to significant. According to the federal regulations (45 CFR 46.102), a project poses minimal risk when "the probability and magnitude of harm or discomfort anticipated in the research are no greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological tests." For example, the risk associated with drawing a small amount of blood from a healthy adult in a research procedure is no greater than the risk associated with a routine physical examination. This definition of minimal risk serves as one benchmark to determine the appropriate level of review for proposed studies.

The second criterion used to determine the appropriate level of review for a project is whether the project fits within one or more of the exempt or expedited categories of research as described by the federal regulations. Research that involves minimal risk and meets the criteria for one or more of the expedited review categories, generally receives expedited review.

If a protocol involves greater than minimal risk to the subject or does not meet the criteria for one or more of the expedited categories, it must receive convened/full review by the IRB. The IRB reviewers, IRB Chair, or the Director of Research Compliance reserves the right to move any protocol to the convened/full level of review, if they believe an additional level of scrutiny may

be required, such as when vulnerable populations will be enrolled, or the research focuses on sensitive information. Convened/full review is required for research involving prisoners.

F. Renewal (Continuing Review)

All research that has been approved by the IRB via expedited or full Board review must undergo continuing review as frequently as determined by the Board to be appropriate (at least annually), when any of the following conditions applies:

- Data collection is ongoing; or
- There will be additional contact with subjects; or
- Analysis of research data continues, and the data remain identifiable, meaning that
 - There are identifiers associated with the data or
 - There are codes associated with the data that can be linked to identifiers.

When submitting the renewal application, the investigator must include all information on progress made to date, the number of research subjects seen, and any problems encountered. If recruitment and enrollment of subjects is ongoing, the submission should include a copy of any consent documents or recruitment materials that will continue to be used. If changes to the research are being made at the time of continuing review, an amendment form and a revised protocol incorporating any revisions may be submitted along with the continuing review application. If any protocol documents are revised in the amendment, copies of the revised documents (consent documents, recruitment materials, and revised measures) must be submitted for review.

G. Study Termination/File Closure

Researchers must notify the IRB when research that has been approved by the IRB is no longer active, so that the IRB protocol file can be closed. Closure of a project's IRB file is appropriate when:

- Data collection has been completed; **and**
- There will be no additional contact with subjects; **and**
- Data analysis is complete or analysis of research data continues, but the data are completely de-identified, meaning that:
 - There are no identifiers or codes associated with the data or
 - If there are codes associated with the data, the link between the codes and identifiers has been irretrievably destroyed.

Transcriptions that meet the above criteria may be retained, so long as the actual audio/videotapes have been destroyed. Voice or video recordings, even if unlabeled, are considered identifiable.

When investigators with active protocols leave the institution, they must notify the DePaul Office of Research Services, so that arrangements can be made to close the protocol file.

Under the Federal regulations, investigators must retain their research records (e.g. submissions to IRB, copies of approval letters and approved study documents, copies of correspondence to and from the IRB, and signed consent documents) for a minimum of three years after the completion of the research (closure with the IRB).

H. Special Circumstances

1. Amendments (Revisions) to Approved Protocols:

When changes are being made to research procedures or methods (including but not limited to recruitment and enrollment processes, funding source or status, inclusion/exclusion criteria, changes in the target population, changes in proposed subject number, changes in performance sites), documents, or research personnel, an amendment must be submitted for IRB review. The amendment submission should include the completed amendment form, a revised protocol (if applicable), and any revised materials (e.g. consent documents, recruitment materials, etc.) altered by the amendment.

Some revisions may be eligible for exempt or expedited review. Substantial revisions, particularly ones that increase risk posed to subjects, may require review by the convened IRB.

2. Unanticipated Problems (Adverse Events) Reports and Subject Complaints: Unanticipated problems involving risks to subjects or others (UPIRSOs) or adverse events and subject complaints that involve risks to subjects must be reported in writing to the Office of Research Services within 72 hours. When an unforeseen or unexpected adverse reaction is research-related, serious, and indicates that changes need to be made to the research to prevent harm to subjects, all research activities must be suspended immediately.

In reporting an unanticipated problem, adverse event or subject complaint, researchers should:

- Describe the incident in sufficient detail as to allow an informed review of the occurrence;
- Describe any necessary changes to the protocol to minimize risk to subjects in the future or the rationale if no changes are being made;
- Describe any steps taken to address the occurrence;
- Describe any necessary changes to the consent and any plans for re-consenting current subjects or provide the rationale if no changes to the consent are necessary;
- Explain why the overall risk/benefit relationship of the research is still acceptable in light of the information concerning this incident.

On receiving notification of such incidents, the IRB reviews the report to determine whether revisions to the protocol or consent documents are merited. The Principal Investigator will be notified of the results of the review, including whether it is necessary to submit revised materials. If the UPIRSO or adverse event was serious and the research was halted, the IRB will inform the Principal Investigator when research activities may resume.

A summary of all serious adverse event reports, UPIRSOs, and subject complaints will be distributed to the full Board in the meeting agendas, at the meeting following the completion of the review of the event. When deemed necessary by the IRB sub-committee, an event may be reviewed by the convened IRB.

Finally, as it is often difficult for the IRB to put into context the nature and potential consequences of the adverse events (serious and not serious), unanticipated problems, or subject complaints, the IRB asks that the continuing review application summarize information on UPIRSOs, adverse events, and subject complaints. Investigators are required to track these types of events submitted to the IRB.

This approach provides the IRB with information needed to fulfill their responsibilities under Health and Human Services (HHS) regulations. It is the responsibility of every investigator to review individual events that occur and take corrective action on an ongoing basis, if necessary.

3. Suspension or Termination of Research: The IRB may suspend or terminate any research associated with unexpected serious harm to subjects or research that is not being conducted in accordance with the IRB's policies, recommendations or restrictions.

I. Categories of IRB Action

1. Full Approval: The IRB may fully approve a new project, amendment, or a renewal as submitted (i.e., without requesting revisions or additional information). When the IRB approves a new project, an amendment, or a renewal, it issues official copies of all revised approved informed consent documents, which are valid for a period of time specified by the IRB. The expiration date of the consent documents (as well as recruitment materials and verbal scripts) is indicated in the approval memo for the renewal, as well as on the consent documents.

Once a project has been fully approved, the researcher may begin recruitment and data collection.

2. Modifications and/or Additional Information Required: The IRB may request that the researcher make minor revisions, provide clarification, or submit additional information or materials when reviewing a new project, an amendment, or a renewal.

When the IRB requests modifications or additional information, the researcher may not begin recruitment, data collection, or data analysis. In most cases, revisions and additional materials submitted by the researcher in response to the concerns of the IRB are reviewed by the ORS staff, but, at times, materials submitted in response to the IRB's request for modification or additional information will be reviewed by the IRB Chair or other voting IRB members.

If the issues identified by the IRB have been resolved, the project may be fully approved.

3. Deferral: The IRB may defer its decision after initially reviewing a protocol at a convened meeting, particularly when the changes proposed or the questions raised by the IRB are significant or sufficient information has not been provided to make a risk determination or all the required approval determinations indicated in the regulations under 45 CFR 46.111. In such cases, revised and/or additional materials submitted by the investigator will be re-reviewed by the convened Board.

4. Disapproval: The IRB may disapprove a protocol when the research places the subjects at risk that outweighs the benefit or the value of the knowledge to be gained or raises such serious ethical questions as to be unacceptable. In the event that the disapproval of a project is foreseen, the investigator will be invited to attend the meeting to discuss the protocol. The IRB will issue a written letter to the investigator outlining the reasons for disapproval. Research protocols may only be disapproved by the convened IRB.

5. Reports of Action: The IRB is committed to providing timely response and constructive feedback that facilitates the progress of the research. Written Reports of Action of the IRB's decisions will be sent to investigators generally within one week of review by the convened Board or the sub-committee.

In cases of where the IRB requests modifications or additional information or defers the research, the investigator should make the necessary revisions and respond to the IRB's questions regarding the protocol within four weeks. If the Principal Investigator is unable to meet this deadline, an extension may be requested by contacting the Office of Research Services. In the event that a Principal Investigator is unable to provide the necessary revisions within the extended period, the protocol or submission file will be closed and in order to re-initiate IRB review, the Principal Investigator may be required to resubmit application materials for that submission. When appropriate extenuating circumstances exist, there may be additional extensions granted by the Office of Research Services at the request of the investigator.

J. Research Subjects

1. Subject Recruitment: Subjects are recruited for research protocols at many different times using many different methods. It is the investigator's responsibility to be certain that subjects are recruited at appropriate times and that they are given ample time to consider their research participation. Stressful times, such as the beginning of a school term, when the subject is emotionally upset, or immediately before holidays, should be avoided whenever possible. Members of the IRB are available to discuss individualized recruitment proposals. All recruitment letters, advertisements, and announcements are subject to IRB review and approval and should be submitted with the protocol application. Recruitment or informational materials developed after the IRB approval of a project must be submitted to the Board as an Amendment for review and approval prior to being incorporated into a project. Researchers should refer to the guidance document on the IRB website for information about recruitment material content.

2. Convenience Sampling/Disadvantaged Populations: Investigators should have a valid reason for using a specific population, particularly when the population may be considered disadvantaged or vulnerable. The mere accessibility of research subjects is not sufficient rationale for using them in a research study.

3. Adult Volunteers: Investigators should avoid recruiting research volunteers from staff under their supervision or students in their own classes. The IRB suggests that potential subjects be recruited from individuals outside the department of the investigator or from classes of other professors. In this manner, individuals who are interested will seek out the investigator and will not feel coerced by being approached by an investigator in a position of authority over them. (See item 9 below)

4. Inclusion of Minorities: All competent individuals, regardless of race, ethnicity, creed, color, religion, sexual orientation, gender identity, or economic status should be treated equally. In the context of research this means that all people should be accorded the autonomy to decide whether to participate in research. Minorities and non-English speaking people should not disproportionately bear the burdens and risks of research. If they choose to participate, they

must be assured that they share the benefits of the research as well. If the research protocol holds out the prospect of direct benefit, minorities and non-English speaking individuals should not be excluded from the research unless there are sound scientific justifications for such exclusion. Each protocol will be considered on its own merits.

The IRB is responsible for independently assessing the investigator's opinion of risk/benefit and inclusion/exclusion criteria and if necessary, challenging the investigator's determination. The IRB has the right to require that minorities and non-English speaking people be included in any research project that involves the use of human subjects. Specifically, this practice may mean that the written informed consent and the verbal consent surrounding the obtaining of informed consent must be rendered in a language and manner sufficient to ensure that the subjects understand to what they are consenting. This may involve the translation of informed consent forms and/or the use of interpreters.

5. Inclusion of Women: Federal research policy requires that investigations must include both genders in study populations so that research findings can be of benefit to all. This policy applies to all research involving human subject and human materials and applies to males and females of all ages. If one gender is to be excluded or disproportionately represented in the study, a clear scientific rationale for exclusion or inadequate representation must be provided. If women are to be excluded, then the proposal must present an acceptable justification for the exclusion.

6. Inclusion of Children: Federal policy at the National Institutes of Health (NIH) requires that children (i.e., individuals under the age of 21 as defined by NIH) must be included in all research involving human subject, unless there are scientific or ethical reasons to exclude them. If children are to be excluded, then the proposal must present an acceptable justification for the exclusion. Federal regulations governing human subject research define children as person who have not attained the legal age of consent in the applicable jurisdiction. In the state of Illinois, in general, the legal age of consent is 18. There are exceptions under Illinois law that may allow a child under the age of 18 to consent to certain activities or procedures.

7. Snowball Recruitment: Often researchers have an initial pool of contacts and hope those people will "nominate" other qualified potential subjects. This kind of sampling is commonplace in case study and qualitative psychological, sociological, and anthropological research. However, it also may be used in genetic studies where it is necessary to recruit relatives of the initial subject for direct interviews and/or tissue sampling, etc. This recruitment procedure is sometimes inappropriately labeled "cold calling."

The following excerpt from the Belmont Report regarding voluntariness compels IRBs to pay close attention to snowball recruitment procedures:

"Unjustifiable pressures usually occur when persons in positions of authority or commanding influence---especially where possible sanctions are involved--- urge a course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins."

For example, suppose a highly respected individual in the community (say a local elected official, teacher, member of the clergy, or tribal elder) provided the name of a potential contact. When the nominee is contacted, the person might be unduly influenced to participate in the project because of the stature of the nominator.

Consideration of minimal risk is likely to play an important role in IRB review of snowball recruitment procedures. For example, it would make a significant difference whether the research involved extramarital affairs or substance use as opposed to family meal time routines or leisure activities. Contacting individuals in this fashion for a study on sensitive topic issues may create an embarrassing situation, which should be avoided. Moreover, the original subject is being placed in the position of being asked to disclose information about a third party without that party's consent.

One means of reducing the risks in snowball recruitment is for the researcher to gently ask subjects whether they would be willing to pass some information about the study they just completed to other potential subjects. The researcher may give the original subject an information sheet or recruitment flyer that they can give to people they think might be interested and qualified. Then these potential subjects can contact the researcher if they are interested. The researcher must provide the IRB with a copy of all recruitment materials, including information sheets or recruitment flyers (which must agree with the DePaul policies for recruitment material content) he/she will give to the initial contact to distribute. If the potential subject were interested in study participation, they would be free to contact the researcher. This option avoids the ethical issues surrounding the use of a cold calling process or of one person providing identifiable sensitive information about another person who has not consented to this release of information.

8. Advertisements and Recruitment Materials: Advertisements and other recruitment materials may be used to recruit subjects and, in such cases, are considered part of (the beginning of) the informed consent process. All advertisements or recruitment materials must be submitted to the IRB for review and approval, including flyers, newspaper ads, radio and television announcements, bulletin board tear-offs, email letters or announcements, and posters. Advertisements or recruitment materials should be submitted with the application or as soon as the Principal Investigator develops them, so that they can be approved before they are used. Advertisements and recruitment materials should not claim, explicitly or implicitly, that the research is treatment or is superior to any current practice.

Investigators who wish to post recruiting notices on university bulletin boards or advertise in newspapers, publications, or on television/radio may need IRB approval and approval from other DePaul offices for posting. If using radio or television advertisements, the text for the commercials should be submitted for IRB review and approval. Then when the final commercial is produced, the recording must be submitted for additional IRB review and approval. The IRB must see and hear the final version of the advertisement to ensure that nothing visual or auditory is inappropriate to the context of the information presented.

9. Students and Employees: In some cases, it may be permissible to recruit one's students or employees for participation in research. Researchers, however, should take precautions not to unintentionally or subliminally coerce anyone into studies. Subtle or unintentional coercion may

occur when a potential research subject is also a student, employee, colleague, or subordinate. For this reason, researchers should limit using their own students or employees as research subjects. Recruitment through bulletin board advertisements or by a third party is preferable to direct recruitment. Information about how students and colleagues will be recruited and rewarded should be included in the information submitted to the IRB.

a. Students: If there is a good scientific reason for including students, researchers should:

- Inform students in the consent form/information sheet that their participation will not influence class standing, grades, or other benefits under the control of the researcher;
- Limit the use of extra credit points as a reward for participating (they should be used only when the research is closely tied to the course subject matter and they should not raise a student's grade by a whole step, e.g., from a B to an A);
- Keep financial rewards commensurate with the risks of participation;
- Limit the use of class time to recruit subjects or collect data;
- Inform students who might participate about the review process, the rationale for the study, the process of data collection, and the researcher's interest; and
- Include in the research protocol plans for minimizing the risk of coercion in the recruitment process. For example, having a co-investigator who does not have a direct relationship with the students conduct the recruitment and/or informational or consent process.

b. Colleagues & Employees: Researchers who include colleagues or subordinates as research subjects must be able to provide a rationale other than convenience for selecting them and must show that the recruitment method does not lead colleagues to think they will be compromised by not participating.

10. Special Considerations for Cross-Cultural Research: Researchers engaged in cross-cultural research should give particular attention to the use of culturally appropriate assessment instruments and procedures, the language(s) used in the conduct of the research and the language preference and language variability of the research subjects. Researchers developing studies involving members of an unfamiliar racial, ethnic, cultural, linguistic, gender or sexuality group should develop an appropriate level of familiarity with, but would not be limited to, the language, behavior, social mores, customs and traditions of that group. A researcher should consider consulting social and behavioral scientists and others who are more knowledgeable of, and experienced with, the intended study group before constructing a protocol.

K. Informed Consent

1. General: Informed consent is defined as consent freely given by a subject in a research project based upon full disclosure of the procedures, risks, and benefits, and it is to be obtained from every person participating in a research program falling under the jurisdiction of the IRB, if the project has not been determined to meet the exemption criteria. Achieving informed consent is one of the most difficult, but important aspects of research investigations and should be understood as an interactive process between researcher and subject, rather than the mere

collection of signed consent documents from subjects. In fact, a consent process might be entirely verbal and not involve obtaining a signature on a form.

The IRB is required to demonstrate that consent procedures are adequate and effective. The IRB's duties in making certain that informed consent is obtained may include:

- aiding the investigator and subject while consent is obtained for complicated procedures,
- interviewing subjects regarding their experiences as subjects in research projects at the subject's request,
- making itself available to answer subjects' questions, and
- auditing subject records.

Assistance for the consent procedure is available to any investigator who desires it. In circumstances it deems appropriate, the IRB may require involvement in the consent procedure by an IRB representative

All informed consent documents should be distributed to subjects and parents/legal guardians on regular paper showing the IRB approval stamp as issued by the IRB with the approval letter. The pages of the consent form need to be numbered in the following manner: 1 of 2, 2 of 2, etc. Additionally, the documents should have a running footer indicating the version date, and when appropriate an identifier. When the documents are revised, the version date is then updated to the current version date. Consent forms should include all information about the study any reasonable person would need and want to know before agreeing to participate in the project. At the minimum, consent forms should provide a description and explanation of study procedures, risks and discomforts, potential benefits, contact information for the investigator and the Office of Research Services, and treatment alternatives (if appropriate).

The consent form should be written in the second person ("You/Your Child") and at a language level appropriate for the subject. The document should not use language such as "you understand" or exculpatory language that leads the subject to believe that they are being made to give up rights. Remember that the subject is primarily interested in what will happen to him or her rather than what will happen to the material, samples, or data collected. Since many Americans cannot read above the 8th grade reading level, adult consent forms should aim for 6th-8th grade readability. Assent forms should be written at a level appropriate for the age, experience, maturity, and condition of the minors who will be asked to participate. If the researcher plans to enroll children ranging from 7 to 17, then multiple assent documents or processes may be necessary in order to ensure the language is appropriate to the age group and comprehension level of the child. Additional requirements for obtaining parent/ legal guardian permission and subject assent will depend upon the risk/benefit determination. Investigators should seek assent and parent/legal guardian permission in circumstances that provide the subject and/or parent/legal guardian with sufficient information and timelines to consider participation. If it appears that subjects, parents, or guardians are incapable of understanding the information contained in the informed assent/parent/legal guardian permission documents due to factors such as mental incompetence, the IRB should be notified.

The consent (parent/legal guardian permission or assent) form used for research programs is not a legal document in the sense that either the form or the language has been circumscribed by

judicial decisions or legal precedence. It should be pointed out, however, that defective informed consent documents can be the basis of adverse legal decisions.

The assent/consent/parent/legal guardian permission documents or scripts (for verbal processes) (and, when appropriate, translations and back translations) for each study must be submitted to the IRB with the protocol and must be approved prior to the commencement of any research activity that involves the use of human subjects. Whenever time permits, the IRB recommends that researchers submit English versions of all assents/consents/parent/legal guardian permissions for review and approval prior to arranging for the translation of these documents, in order to minimize the number of revisions to the translations.

2. Special Circumstances

a. **Subjects Who Are Not Fluent/Literate in English:** In cases of a language barrier, it is the investigator's responsibility to be certain that the subjects receive the informed consent form in a language they understand. Investigators must obtain the assistance of a person fluent in that language to translate the informed consent form and/or to serve as interpreter. When a written consent form is translated into another language, a copy of the translated form must be reviewed and approved by the IRB prior to incorporation into a study. Any translated verbal consent scripts must also be approved by the IRB. All translated informed consent forms must be translated back into English (ideally by a different translator) to ensure the quality of the translation. If the investigator is the translator or the translator is not a professional service, the IRB application materials should include information about the translator's qualifications for providing the translation services. When planning on enrolling subjects who are non-English speaking it is important for the investigator to assess whether it is feasible to communicate with the subject throughout the research process and whether the language barrier might lead to errors in the research. It is important to remember that consent is a process that is ongoing throughout the research and does not end once the consent document is signed.

b. **Assent of Children Participating in Research Projects:** Federal regulations require the IRB to assure that additional protections are provided for children participating in research, depending upon the degree of risk/benefit that the IRB determines is involved. Such protection may include obtaining a child's assent or "affirmative agreement" to participate, and obtaining permission of parents or legal guardians. The assent of children and adolescents participating is required by regulation except when the IRB determines a child is not capable of providing assent or the research is of potential direct benefit to the well-being of the child and is available only in the context of research. The DePaul IRB considers the age of assent to begin at age 7. Because Illinois law defines the age of consent or adulthood as age 18 (with some exceptions), children ages 7-17 should assent to research. For children under the age of 7, only parent/legal guardian permission is required. It may be necessary to have both verbal and written assent processes, or multiple written assent forms with differing levels of information in order to address the age and comprehension level of children in different age groups.

The protocol application is designed so that IRB members can review pertinent information and can determine whether special protections are required. In determining a child's

capability of providing assent, the IRB takes into account the age, maturity and psychological state of the child involved. Even when not required by regulation, the IRB always encourages investigators to involve children in the consent process when appropriate and feasible.

c. Waiver of Parental Permission for Adolescent Research: Currently, federal regulations allow for the waiver of parental permission when requiring such permission may not be considered reasonable. This situation may occur in specific areas of adolescent health research such as research on sexually transmitted disease, birth control usage, high-risk behaviors, AIDS prevention, etc. Whenever it is reasonable to obtain parental permission, it must be obtained. In situations when an investigator determines that parental permission is unreasonable, an investigator may request a waiver of parental permission. The IRB must carefully consider the investigator's request and determine whether the waiver of permission falls within the federal regulations.

As with any request for a waiver or alteration of consent, investigators must provide additional specific information via a waiver/alteration request form when requesting a waiver of parental permission. The IRB's determination as to whether parental permission may be waived is final.

L. Compensation

It is sometimes desirable to offer compensation to subjects and/or their parents for their participation in research projects. Such compensation may take the form of taxi fare or other reimbursement for travel expenses, babysitting fees, lunch, or cash remuneration in lieu of the above. The IRB recommends that when possible, children receive a small gift or gift certificate. In all instances, compensation should not be so large as to act as an inducement for subjects to participate regardless of how minimal the risk may be. In most cases, it is not acceptable to require that a subject complete the research before offering compensation. If a subject withdraws from the study, he/she must be compensated for the portion of the study that was completed. In other words, compensation should be pro-rated over multiple visits or activities, if the research involves more than a one-time interaction or intervention. The amount of compensation should be specified in the consent, parent/legal guardian permission, or assent form, but should not be represented as a benefit of participation. In cases where the compensation is pro-rated, the per-visit or activity and the total possible compensation should be provided. The IRB reserves the right and has the obligation to review and approve all forms of compensation, and may determine that a particular incentive causes undue influence. In this case, the IRB will suggest an alternative incentive or incentive amount.

The DePaul Vice President for Finance has published guidelines for payment of research subjects: <http://financialaffairs.depaul.edu/payment/voucher.htm> Additionally, the IRB has created template language for the information sheet, consent, parent/legal guardian permission, and assent documents that helps to explain to the research subject that in order to receive payment, they may need to provide additional information to the researcher so that DePaul can be compliant with United States Internal Revenue Service (IRS) tax laws.

M. Confidentiality

Confidentiality is one of the most important concerns to research subjects. Confidentiality refers to data and how it is treated or protected from disclosure after it is collected for the research. Issues of confidentiality should be considered on an individual protocol basis and clearly addressed in the protocol. The Principal Investigator, therefore, should take precautions to avoid unnecessary recording and releasing of identifying information unless mandated by law. At all times, identifiable data stored electronically, in hard copy, or on audio or video tape must be stored securely. In addition, researchers should have procedures in place for the destruction or proper storage of identifiable data at the conclusion of a project. Researchers who wish to retain individually identifiable data after the conclusion of a study, should justify the retention of the identifiable data in the original IRB submission. The IRB Chair and the Office of Research Services staff are available to discuss and assist investigators with confidentiality issues and concerns.

N. Privacy

Privacy is also an important issue to consider when designing and conducting human subject research. Privacy refers to the individual and the methods used to access the individual or to gather information about an individual. Issues of privacy usually arise related to the recruitment process, such as how subjects are identified or contacted. In general, the researcher should consider whether a particular recruitment procedure or data collection method could be construed by subjects as an invasion of their privacy.

Procedures

The primary procedures for securing and maintaining IRB approval are included below. If you require additional procedural information relating to this policy, contact the Office for Research Services.

A. Application Process for Principal Investigators

1. Preliminary Review & Discussion:

Any DePaul-affiliated individual planning a research project that involves human subject research may discuss the project with the Director of Research compliance, ORS staff, or members of the IRB. Investigators are encouraged to use these resources to assist them in developing the protocol application. The researcher should review all the information available to them on the ORS website and if they cannot determine the correct level of review or which form to complete, they should contact the ORS research protections staff for assistance.

2. Protocol Forms & Applications: To request IRB review, the investigator must complete and submit an exempt application or an expedited/full Board application and appropriate supplemental materials to the IRB by sending the materials via email to ORP@depaul.edu. Required supplemental materials vary based on review classification and are as follows:

Materials Required for <u>Exempt Projects</u>	Materials Required for All Other Projects (<u>Expedited/Full</u>)
Exempt application	Expedited/full Board application
Exempt info sheet	Consent/parent/legal guardian permission/assent forms, as appropriate
Measures, data collection tools, interview scripts	Measures, data collection tools, interview scripts
Recruitment materials (e.g., e-mails, scripts, flyers)	Recruitment materials (e.g., e-mails, scripts, flyers)
Copy of Collaborative IRB approval	Copy of Collaborative IRB approval*
Copies of Letters of collaboration or support* CITI training completion for PI and Faculty Sponsor and Human subject training certification for non-affiliated collaborators, if applicable When federally funded, the grant proposal submitted to the funding agency	Copies of Letters of collaboration or support* CITI training completion for PI and Faculty Sponsor and Human subject training certification for non-affiliated collaborators, if applicable When federally funded, the grant proposal submitted to the funding agency

Application forms and assent/consent templates are available on the IRB webpage. In some cases, it may be appropriate to submit materials that are not listed above (e.g. grant narratives, thesis proposals).

Failure to submit required materials may result in the delay of IRB review.

3. Mandatory Human Subjects Training: Since October 1, 2000, federal funding agencies have required that investigators provide a description of the training in the protection of human subjects that was completed by each individual identified as "key personnel" in the proposed research. Key Personnel are defined as individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, such as those individuals responsible for the design, conduct or reporting of a research project. The conduct of research refers to anyone who will interact with research subjects: (recruit, consent subjects, or collect data) or have access to research

data (through data retrieval, entry, analysis or storage). The description of education will be submitted in a cover letter with their grant and contract applications.

As a consequence of DePaul's participation in the Federal Wide Assurance program, all individuals involved in human research must complete an appropriate training program, regardless of whether external funding has been obtained. Additionally, DePaul requires continuing education every 3 years for investigators that continue to conduct human subject research. DePaul University has subscribed to the CITI on-line training program for researchers to meet this initial and continuing educational requirement. Additional information regarding the educational policy and how to access the CITI on-line training program is available on the IRB web-site.

DePaul researchers may fulfill their continuing education training obligation by attending human research training seminars presented at another institution or through national or regional training conferences focused on human subject research. Researchers are advised to contact the Director of Research Compliance or the IRB Chair in advance to determine whether training at another institution would satisfy DePaul's training requirement.

In addition to requiring researchers to complete human subject research training, the DePaul IRB requires all faculty sponsors, members of the IRB, and Office of Research Services staff who are responsible for IRB support to be trained. Depending upon the role of the individual in the DePaul human subject protection program, the number of training modules that must be completed to meet the training requirement may differ. Please refer to the IRB web-site for a description of the training categories.

Finally, the Office of Academic Affairs makes limited funding available to IRB members who are interested in attending training seminars hosted by Public Responsibility in Medicine and Research (PRIM&R) or other academic institutions. IRB members who are interested in attending a qualifying training seminar should contact the Director of Research Compliance to determine whether funds are available and for more information.

Documentation of completion of training through the CITI program is automatically sent to the Office of Research Services, so there is no need for the investigator to send copies of training in with the application. However, if outside collaborators have differing educational programs or the DePaul faculty, staff, or student is using an alternative training program to meet the DePaul education requirement, documentation of human subjects research training must be sent to the Office of Research Services with the research application so that it may be placed on file with the Director of Research Compliance. Researchers also should retain copies of training documentation for themselves and all research staff in their own records.

4. Review Dates & Timelines: The amount of time it takes the IRB to approve a project depends on a number of factors, including whether the protocol qualifies for exempt or expedited review and the amount of time the researcher takes to respond to IRB requests for revisions or additional information.

In addition, protocols that are externally funded may have agency-imposed requirements for the timing of IRB review. For this reason, it is important for researchers to be aware of the funding agency requirements and the IRB's projected review date. Because certification of IRB approval

to a funding agency can be made only after final approval by the IRB, researchers should work with the Office of

Research Services to coordinate the timing of grant notification of likely funding and IRB submission for projects that are likely to receive externally funding. It is important to initiate the IRB review process as soon as there is any indication of receiving funding, as the investigator must allow the IRB sufficient time to review the application. Just in time IRB protocol approvals cannot be guaranteed.

a. Exempt & Expedited Reviews: Projects eligible for exempt or expedited review are usually reviewed within 7-10 business days of submission to the IRB by the investigator. During certain periods of time, the review may take up to 15 business days. Initial reviews may result in full approval, or a request for modifications/ additional information. If modifications are requested, the IRB will again have 15 business days to review each subsequent round of modifications; however, we try to process each protocol as speedily as possible.

In order to accommodate vacation schedules, the timeframe for exempt/expedited reviews during the summer, and during spring or winter breaks may be longer.

b. Full Board Reviews: Protocols requiring full IRB review must be submitted a minimum of 2 weeks before the next scheduled date of the IRB meeting. Please check the IRB web page for meeting dates and submission deadlines.

An electronic version of all study materials must be submitted to the IRB. Initial full Board reviews may result in full approval, deferral, a request for modifications/additional information, or disapproval.

5. Investigator Presence at Meetings: Due to time limitations, confidentiality concerns, and the number of protocols reviewed at each meeting, it is the practice of the IRB not to have investigators present at meetings while their protocols are undergoing review. If it is anticipated that the Board will have serious concerns with a protocol or questions about the protocol, the investigator may be asked to attend the meeting. Under other extenuating circumstances and if time permits, the Chairperson may invite an investigator to attend the meeting.

B. Protocol Development

1. General: The IRB, in dealing with research protocols, is primarily interested in safeguarding the rights and well-being of human subjects and exploring the ethical implications of the proposed procedures. However, as mandated by the federal regulations, the IRB must also review the scientific design to ensure that the risks to subjects are minimized using sound research design.

The most important factor in presenting an application to the IRB is detail and clarity. Most of the questions and reasons for deferral or requests for modification/additional information have to do with ambiguous or uncertain statements in the protocol, or a lack of information, especially about procedures, recruitment, risks, benefits, and informed consent.

The emphasis of the protocol should be on the involvement of the human subject in the study, but the protocol also should supply information that demonstrates that the activities proposed have a sound scientific rationale. Since both scientists and laypersons review the protocol, it should be written in non-scientific language, using specialized terminology only when necessary and with definitions of the specific terms. When abbreviations are used, the protocol should use the full term the first time the abbreviation is introduced. The use of abbreviations should be minimized as much as possible. The consent form must be written at a level appropriate for the intended research subject. The Director of Research Compliance and the ORS staff are available to assist investigators in preparing protocols and consent forms.

2. Items to Include in Protocol

- a. Specific Objectives of the Project:** These may be presented as hypotheses, aim, goal, or as research questions. Please state your aims, goal, hypothesis, or questions in a manner that is consistent with your methodology providing evidence to evaluate these hypotheses. The study design should be capable of proving or disproving the hypotheses or reaching the goal or aim. Finally, the question: "What will be learned from the proposed study?" should be answered.
- b. Plan of Work:** This section should describe the proposed study from start to finish. In particular, researchers should use this section to:
- Outline in detail how subjects will be recruited and selected and how data will be collected and interpreted;
 - Make clear how the methodology directly addresses the research questions, aim, or hypothesis proposed above;
 - Describe the type of design being used (i.e. randomized, quasi-experimental, pilot study, qualitative);
 - Outline the procedures to be performed on, with, or by each group of subjects and what other things might be involved with being a subject (i.e., allowing access to records);
 - Clearly explain the timing and setting of the procedures and the data to be collected; and
 - Discuss the methods for monitoring data collection during the course of the study, if applicable.

When questionnaires and behavioral/psychological assessments are part of the research, discuss the rationale for the questionnaire/assessment and submit a copy of the measure with the completed protocol application.

- c. Subject Population & Recruitment Procedures:** These sections must describe the exact population that is to participate in the protocol and should provide specific inclusion and exclusion criteria. In addition, it is important to address how and when research subjects are to be identified and approached for recruitment. Potential subjects must be given adequate time to consider their involvement in the research project. Copies of all recruitment materials (e.g. letters, advertisements, etc.) should be included with the protocol submission.

- d. Risks:** List the risks, discomforts, hazards, or inconveniences to the subject, indicating their probability, magnitude, duration, and intervals of likely occurrence. Remember that risk includes not only physical pain or discomfort, but also psychological or sociological harm, invasion of privacy, loss of confidentiality, harassment, and lessening of an individual's dignity. For example, the use of interviews, questionnaires, or review of a child's school records may produce psychological discomfort, embarrassment, or breach in confidentiality of the information and should be considered as risks. Inconveniences such as loss of time or pay are included in this category. In addition, indicate what will be done to minimize the effects of risks, discomforts, or inconveniences as well as what precautions will be taken to avoid or reduce potential risks. When using records or personal data, state what steps will be taken to insure confidentiality.
- e. Potential Benefits:** List the potential benefits of the research project. Potential benefits can apply directly to the subject in question, or be indirect, such as possible improvement for others, or to the advancement of scientific knowledge. It is important in every instance to evaluate the risk/benefit ratio of a study and to state the rationale for believing the potential benefits to the subject, others, or society outweighs the risks. In cases of no direct benefit, the investigator should demonstrate that risks are so minimal as to warrant a benefit that may consist only in the furtherance of general scientific knowledge.
- f. Confidentiality:** Describe what provisions will be made to protect the privacy of the subject and the methods that will be used to maintain the confidentiality of the data.
- g. References:** Provide as appropriate, i.e., journal articles.

C. Informed Consent/Assent

1. Drafting Informed Consent Documents: To facilitate writing of informed consent forms, the IRB has devised a standardized format that may be used to develop project-specific consent documents. Because consent forms can be the subject of differences of opinion regarding wording and terminology, those who have not had an opportunity to develop consent forms are encouraged to seek advice and assistance from the members of their department or the IRB before preparing the forms. Researchers are strongly encouraged to use the templates provided by DePaul on the IRB webpage. Those who need to create consent forms based on templates provided by a collaborating institution are advised to ensure that the forms include the following information.

a. Description and Explanation of Procedures

- Describe the purpose and objectives of the study and the reason the individual is being asked to participate;
- State clearly that the study, treatment, or evaluation is RESEARCH;
- State clearly and concisely in non-technical language the basic procedures or treatments. All testing, evaluations, and interventions related to the research being conducted must be described. Describe any data that will be collected about the subject and how it will be collected. Descriptions should be concise but

informational. They should describe the actual research procedures and what else might be asked of the subject (i.e., request permission to review educational records or other data sources);

- Briefly describe the type of questions that will be asked, if studies involve questionnaire administration;
- Describe what controls are and why controls are needed, if there are normal controls;
- Explain the randomization process in lay person's terms, if such a process is to be used;
- State the time commitment for the subject;
- Indicate plans for compensation, if any, taking care not to construe compensation or incentives as benefits of the research; and
- State any plans to inform subjects of significant research findings during or after the study relevant to their continued participation or treatment.

b. Risks and Discomforts

- List in simple terms the potential risks and any expected side effects (including discomfort) that are likely to occur.
- Indicate the likelihood of the side effects occurring.
- State actions taken to counteract any adverse effects.
- Address the reversibility of any side effects/adverse reactions.
- Indicate what can or will be done beforehand to minimize risk or discomfort.
- Address any inconveniences to the subject regarding time or cost.
- Identify the possibilities of psychological harm, invasion of privacy, loss of confidentiality, embarrassment, or social injury.
- State if risks of an experimental procedure are not known.
- Describe exactly how confidentiality will be maintained.

In addition to the above, it may be appropriate to include the following types of additional information in describing the risks and discomforts:

- **Discussion of Possible Unknown Adverse Reactions** (for example, "Since this is a new investigational/intervention/treatment, all the side effects are not known. Although no serious adverse effects have been reported, it is possible that unknown side effects may occur. You/Your child are advised to discuss with the researcher any unusual side effects or symptoms you are experiencing while participating in this study.")
- **Discussion of Distressing Topics** (for example, "The interviewer may ask you to discuss issues or events that might bring back bad feelings or that might upset you. You may stop the interview at any time and you do not have to answer any questions that make you feel uncomfortable. If you become upset and appear to need further assistance, the investigator will arrange for an appropriate referral to a professional with training and experience for the type of assistance needed.")
- **Discussion of Sensitive or Embarrassing Topics** (for example, "There are no physical risks; however, many of the questions deal with sensitive and private information (i.e., sexual habits, birth control, and drug usage). You

may be embarrassed by some of the questions. You do not have to answer any questions that make you feel uncomfortable and you may withdraw from the study at any time. Again, we will make every effort to maintain and assure the confidentiality of your participation and your answers.")

Finally, the following statements are **required** in special circumstances:

- **For research that may uncover unreported suspected child abuse or neglect:** "You should know that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court or to tell authorities if you report information about a child being abused or neglected or if you pose a danger to yourself or someone else."
- **For some research presenting more than minimal risk:** "If you were injured as a result of this research, you should seek medical treatment through your regular doctor or medical care plan. There are no plans for the researchers to pay for treatment of an injury that is a result of being in the study. However, you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research. If you were injured as a result of the research you should contact: [\[insert name and contact information for the investigator.\]](#)."

c. Potential Benefits

- State in a clear, honest, non-altruistic manner any reasonably expected benefits. Since it is impossible to predict the likelihood of a benefit, phrases such as "It is hoped that..." should be used. For example, "It is unknown whether this intervention will provide a direct benefit to you/your child. Based on the testing that has occurred previously, it is hoped that you/your child's problem will be better controlled with the use of this intervention. In addition, if the results of the behavioral testing show that you/your child has some learning problems, such as difficulties in reading, problem-solving, etc., we will discuss them with you and send a copy to your primary physician."
- If applicable, explicitly state that there is no potential for direct benefit to the individual subject. For example, "You/Your child will not directly benefit from participation in this study, but we hope the results will lead to improvement in...[e.g., scientific knowledge about this issue; the way professionals use the information about this issue when dealing with practical problems; or the way professionals may use the information about this issue to create future prevention programs or treatment procedures]."
- Address, but do not overstate, the potential value of the data to future subjects or society as a whole.
- If appropriate, offer the results of testing, questionnaires or interviews to the research subject or to the child's school or physician if the parent or subject requests it.
- ***Monetary compensation and free testing should NOT be listed as a benefit.***

d. Alternatives/Ability to Withdraw

- If the proposal provides an intervention, list any alternative intervention procedures to the ones described in order to give the subject a clear choice in whether or not to participate.
- State the risks and benefits of each alternative procedure described.
- State when there are no alternatives to a particular intervention.
- Make clear in all consent forms that refusal to participate will not affect in any manner the relationship of the subject to anyone or any institution associated with this research.
- State that the subject has the option to withdraw from the project at any time without negative consequences.

e. Contact Information: Towards the end of every consent document, the researcher should tell subjects how they can get additional information about the study or about their rights as research subjects. Generally, the IRB asks that the researcher's contact information be provided for study-specific questions, although in some instances it may be appropriate to provide someone else's contact information. Subjects should be instructed to contact the Director of Research Compliance, if they have questions about their rights as research subjects.

In addition, the assent/consent/parent/legal guardian permission form should state that the subject will receive a copy of the form to keep.

f. Witnesses to Signatures: In some cases, it may be appropriate for researchers to provide for a witness to observe and attest to the assent/consent. For example, witness signatures may be required for projects involving experimental medical techniques and vulnerable populations. Generally, the witness will attest to the signatures only. In cases where witnesses need to attest to the explanation, a member of the IRB may agree to fulfill this function.

The IRB's decision about whether a project falls under either or both of these categories is final.

g. Additional Research Responsibilities with Respect to Consent: The parent/legal guardian permission/assent/consent form containing the original signature must be kept in the investigator's files. All original parent/legal guardian permission/ consent/assent forms must be retained for three years after the completion of the research. A copy of the consent form must also be given to the subject.

If new information arises or a change occurs in the research procedure during the course of a study, the investigator has the obligation to inform the subject and seek new consent. The investigator then should revise the consent forms accordingly, or create a consent addendum, if appropriate, and send the revised form to the IRB for approval.

2. Special Circumstances

- a. Subjects Who Are Not Fluent/Literate in English:** In cases of a language barrier, it is the investigator's responsibility to be certain that the subjects receive the informed consent form in a language they understand. Investigators must obtain the assistance of a person fluent in that language to translate the informed consent form and/or to serve as interpreter who reads a translated IRB approved script. When a written consent form or a verbal consent script is translated into another language, a copy of the translated document must be reviewed and approved by the IRB prior to incorporation into a study. All translated informed consent documents must be translated back into English (ideally by a different translator) to ensure the quality of the translation. Spur of the moment translation of the consent process is not allowed.
- b. Assent of Children Participating in Research Projects:** Federal regulations require the IRB to assure that additional protections are provided for children participating in research, depending upon the degree of risk/benefit that the IRB determines is involved. Such protection may include obtaining a child's assent or "affirmative agreement" to participate, and obtaining permission of parents or legal guardians. The assent of children and adolescents participating in the research is required by regulation, except when the IRB determines a child is not capable of providing assent or the research is of potential direct benefit to the well-being of the child and is available only in the context of research.

The protocol application is designed so that IRB members can review pertinent information and can determine whether special protections are required. In determining a child's capability of providing assent, the IRB takes into account the age, maturity and psychological state of the child involved. Even when not required by regulation, the IRB always encourages investigators to involve children in the consent process when appropriate and feasible.

- c. Waiver of Parental Permission for Adolescent Research:** Currently, federal regulations allow for the waiver of parental permission when requiring such permission may not be considered reasonable. This situation may occur in specific areas of adolescent health research such as research on sexually transmitted disease, birth control usage, high-risk behaviors, AIDS prevention, etc. Whenever it is reasonable to obtain parent/legal guardian permission, it must be obtained. In situations when an investigator determines that parent/legal guardian permission is unreasonable, the IRB must carefully consider the investigator's request and determine that the waiver of permission falls within the federal regulations.

As with any request for a waiver or alteration of consent, investigators must provide additional specific information via a waiver/alteration request form when requesting a waiver of parental permission. The IRB's determination as to whether parental consent may be waived is final.

- d. Research Involving the Use or Disclosure of Protected Health Information (PHI):** Researchers who intend to use or disclose PHI as part of a research program are

required to develop a HIPAA Authorization form and to receive approval from the DePaul Privacy Officer, in addition to the IRB. Researchers should submit such research for IRB review first and work with the Director of Research Compliance to ensure approval by the Privacy Officer. A template for a combined HIPAA Authorization/consent form is available for customization on the IRB webpage.

3. Approval of Informed Consent Documents: Approved informed consent forms will be stamped with an approval date and an expiration date, generally one year after the approval date of the project. When submitting annual updates for continuing review of projects, researchers should submit the most recently approved assent//parent/legal guardian permission/consent forms to receive updated stamps or, if necessary, revised forms for review and approval. All consent forms distributed to subjects should be a copy of the IRB-stamped consent forms, unless this is not possible such as when providing the consent online. In this instance the researcher must be sure to use the same version approved by the IRB. Under no circumstances may an expired consent form be used to document an individual's agreement to participate in a study.

Divisional Collaborations

None.

Contact Information

Office of Research Services, Institutional Review Board (IRB)

<http://offices.depaul.edu/ors/research-protections/irb/Pages/default.aspx>

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Appendices

None.

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