Guidelines for Protocol Submission
Human Participants Research

IRB forms and the Guidelines for Protocol Submission have been adapted from materials developed by New York University, which received grant funding from the National Institute of Health

Introduction

The Guidelines for Protocol Submission (GPS) has been designed to help you:

- Determine if your work must be reviewed and approved by the IRB;
- Understand federal regulations and ST. JOHN'S UNIVERSITY policies concerning human participants in research;
- Receive IRB certification
- Prepare an application for review and approval to the IRB;
- Respond to any concerns or requested revisions the IRB may request after the initial review.

At St. John's University, all research involving human participants (funded or not funded) must be reviewed and approved by the University's Institutional Review Board (IRB) **before** being carried out. The IRB is authorized to review and approve research involving human participants through an agreement with the U.S. Department of Health and Human Services, Office for Human Research Protections called a Federal Wide Assurance (Assurance # M1083).

Review Process

Investigators planning to conduct research with human participants should allow **at least three months** from the initial review meeting date for the review process, since the Institutional Review Board for the Protection of Human Participants in Research (IRB) may request revisions or additional information before granting final approval.

All investigators and faculty sponsors must submit all materials for review to the IRB on the 15th of the month prior to the meeting date. Meeting dates are posted on the IRB web site at link to site.

Notification in writing of the IRB's decision will be sent to applicants approximately ten business days after the meeting. This letter will either:

1. Detail the reasons that approval was not granted and what must be done (e.g., requests for revisions or additional information) to allow the proposal to receive final approval;
2. Grant approval to proceed with the proposed work.

Contact Institutional Review Board Staff

The IRB staff are available assist you with:

- Integrating human participants requirements into your research plan;
- Clarifying the requirements for research with human participants;
- Preparing your application to the IRB;
- Responding to post-review requests from the IRB.

The IRB expects that investigators will make use of the guidance materials on this site. These references explain most human participants issues, and they should be the first stop for information in the human participants review and approval process. For additional questions and guidance, please contact:

- **Dr. Jeffery Olson** | olsonj@stjohns.edu

  IRB Chair | 718-990-5705

- **Ms. Betty Farbman** | farbmanb@stjohns.edu

  IRB Manager | 718-990-6236

- **Ms. Lindsay Pettine** | lindsay.pettine03@stjohns.edu

  irb@stjohns.edu

  IRB Coordinator | 718-990-1440

The IRB is located in Newman Hall, room 108 on the Queens campus.

How to Apply

Does Your Research Need Review?

Human participants research means any activity intended to obtain and record information from or about individuals for research purposes. Some examples are:

- Questionnaires
- In-person and telephone surveys
- Educational tests
- Observation of public or private behavior, including classroom observation
- Interviews and focus groups
- Evaluation and research components of demonstration and training programs
- The collection or study of existing data (e.g., medical or school records)

Research Requiring Approval

Under the University's Federal Wide Assurance, all research activities involving human participants (funded or non-funded) must be approved by the IRB prior to the commencement of the research, if:

- the research is sponsored by the University; or
- the research is conducted by or under the direction of any University employee or agent (e.g., faculty member, researcher, or student) in connection with his/her other institutional responsibilities, no matter where the research is conducted; or
- the research is conducted by or under the direction of any University employee or agent (e.g., faculty member, researcher, or student) using any University property or facility; or
- the research involves the use of the University's non-public information to identify or contact human research participants (or prospective participants) or to provide data for the research; or
- the research involves the use of the University's students, employees, or facilities.

Research activities include:

- Dissertations,
- Master's theses,
- Pilot studies,
- Class projects,
- Non-funded faculty-directed research.

OHRP Decision Charts

The federal Office for Human Research Protections (OHRP) provides decision charts to assist investigators and others in deciding if an activity is research involving human participants that must be reviewed by an IRB under current federal regulations. The charts will assist investigators in determining:

- whether an activity is research that must be reviewed by an IRB
- whether the review may be performed by expedited procedures, and
- whether informed consent or its documentation may be waived.

If the decision charts do no provide enough information provide a clear-cut answer to any of the above criteria, please consult the IRB staff for a determination.

Data Not Requiring IRB Review and Approval

OHRP has issued guidance on the use of certain categories of data that do not require Institutional Review Board approval. These categories include publicly available data, certain biological specimens and samples, and non-public, de-identified data that is not derived from a previous research study.

Can You Apply for Exempt Status?

Investigators may apply to the IRB for Exempt status if their research falls within certain categories of research considered very low risk under Federal regulation.

The designation of Approved as Exempt may only be made by the IRB, not by the investigator. A full application must be submitted for an announced deadline in order for the Committee to determine whether a project should be granted Exempt status.

If granted Exempt status, a project will no longer be under IRB oversight as long as no changes are made to the protocol as approved as Exempt. If changes are planned, those changes must be submitted to the IRB for review and approval prior to being initiated.

Exempt Research Categories

Categories of research which are exempt include:

- The study of normal educational practices in commonly accepted educational settings. This includes research of:
    - regular and special education instructional strategies;
    - the effectiveness of or the comparison of instructional techniques, curricula or classroom management methods.

Note: The fact that the research takes place in the school does not necessarily mean that Exempt status is appropriate. Activities introduced for the purpose of a study do not constitute normal educational practice.

- The use of educational tests, surveys, interviews, or observation of public behavior where:
    - Identifiers are not recorded by the PI; or
    - There is neither a risk of harm to participants nor information sought concerning sensitive aspects of the participant's behavior (this does **not** apply to research involving surveys and interviews with children); or
    - There is neither a risk of harm to participants nor observation of sensitive aspects of the participant's behavior (this does **not** apply to research with children when the investigator(s) participate in the activities being observed); or
    - Participants are public officials or candidates for public office; or
    - Federal statute(s) require(s) without exception that confidentiality of personally identifiable information will be maintained throughout the research and thereafter.
- The collection or study of existing data (all work with participants have been completed), documents, records, pathological or diagnostic specimens, where publicly available or where the information is private but identifiers are not recorded by the PI.
- Taste and food quality evaluation and consumer acceptance studies if:
    - wholesome foods without additives are consumed; or
    - a food is consumed that contains a food ingredient at or below the level found to be safe for use by the Food and Drug Administration (FDA) or the Food Safety and Inspection Service of the US Department of Agriculture; or
    - a food contains an agricultural chemical or environmental contaminant at or below the level found to be safe for use.

Note: Research (except some projects using existing data) is not eligible for Exempt status if it involves:

- minors (under 18 years of age) except in cases of studies of normal educational practice or collection/study of existing data
- prisoners
- fetuses
- institutionalized mentally disabled people.

Materials Required for Submission

All submissions for IRB review must include:

- Original, fully completed application. This includes:
  - Investigator's signature;
  - Faculty sponsor's signature (if required);
  - All applications require a Dean's signature (student or faculty)
  - All applicable attachments (IRB Certification, recruitment materials, consent or permission forms, institutional approval letters, research instruments, and any other additional materials).

  Note: Student investigators should include their mailing address to receive correspondence (i.e. approval letters and extension notifications).

- **3 copies** of the application (including all additional materials).

***** Please note that additional copies of the application and required materials may be requested by the IRB**

Incomplete submissions will be returned un-reviewed to the researcher for revision and resubmission.

Additional Materials

IRB Certification

All individuals submitting applications for review, interacting with human participants or mentoring student researchers must have IRB certification. Certification can be obtained two different ways:

Pick up a copy of Investigator 101 from your department; review the information on the disk in preparation for the IRB exam. IRB exams are given periodically throughout each school semester. Check the IRB webpage for dates in which the exam is given;

You can also obtain certification though the National Institute of Health (NIH). Go to the following link and complete the certification training online:

http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp

Submit a copy of your certification along with your application. Certificates will be considered expired after a period of 5 years.

Recruitment Materials

Any material used to inform potential participants of the opportunity to participate as a participant (e.g. flyers, letters, etc.) should clearly identify the investigator, St. John's University, the school and department, the investigator's status (e.g., faculty, doctoral candidate, etc), the faculty sponsor (if applicable), and the institution.

Materials should give a brief idea of the purpose of the research, what participation entails (including any important participant inclusion/exclusion criteria), and a way for potential participants to contact the investigator if interested in participating.

Recruitment materials should also include sample letters to potential participants and applications to organizations, which are being asked to take part (or are taking part) in the project effort. This includes:

- Assisting in the recruitment of participants;
- Providing space for meeting with potential/actual participants;
- Access to records of individuals or the organization.

Investigators who are planning work with any organization that has an Institutional Review Board must apply to that IRB for review and approval. They then must provide written approval from that IRB to St. John's IRB before the STJ -IRB may provide final approval. Investigators should take into account when planning their research that IRBs vary widely in the time required for review and approval.

Statement to Participants

This statement is provided by the investigator to potential participants prior to obtaining informed consent and carrying out the proposed work. It explains in more detail (than the recruitment materials) the purpose(s) of the research and what the participant will be asked to do if s/he agrees to participate.

The statement is generally provided as a response by the investigator to interest generated through a recruitment effort. It may be written or verbal and may be delivered in person, by phone, by mail, or by email. In some cases, the recruitment material and statement to the participants may be combined in one document.

Informed Consent, Permission Forms and Assent Scripts

Informed consent is designed to provide potential participants, or those who must give permission for potential participants, all the information they need to decide whether or not to participate in a research project.

Consent, permission, and assent materials must be written in language appropriate to the intended participants, but in no case in higher than 10th grade language. If an investigator plans to recruit participants from non-English speakers, or those who do not speak it well, translations should be provided.

The IRB provides a language for consent and other forms (assent); (Provide a link) investigators are expected to use that language unless there is a strong reason to make changes. These changes, if requested, must be justified in the application.

The materials should be on University departmental letterhead in a format which will allow them to be copied and distributed to participants **as is**. Once approved by the IRB, they will be stamped to signify Committee approval. Only stamped forms may be used to obtain a participant's consent.

The following information must be included in all consent forms and permission forms:

- a statement that the study involves research and an explanation of the purpose(s) of the research
- names and contact information of the investigator(s), of the faculty sponsor, including institutional affiliation and status
- Contact information for each investigator and faculty sponsor including school and department, phone number (including a local phone number if the work is to be done out of the United States), university and email addresses
- a description of the procedures to be followed, what the participant will be expected to do, and whether there are any procedures which are experimental
- how long participation will take, including how many sessions will be held if more than one will be needed
- a description of any benefits to the participant or to others which may reasonably be expected from the research, or, more commonly, since the benefits of research to the participants are usually tenuous at best, a statement that there will be no direct benefit to the participants
- a description of any reasonably foreseeable risks or discomforts to the participant, including any intervention which may be offered, OR the statement that there are no risks beyond those of everyday life
- for research involving more than minimal risk, a clear description of the risks and where further information may be obtained (note that no research with minors involving more than minimal risk may be carried out unless it holds the prospect of direct benefit to the participant)
- if the research involves more than minimal risk, a statement concerning the availability of medical treatment or compensation in the event of physical injury resulting from participation in the research. The statement should include the information that:

    1. St. John's University cannot provide either medical treatment or financial compensation for any physical injury resulting from the participant's participation in the research; and
    2. Those inquiries concerning this policy may be made to the principal investigator or the IRB
- if applicable, a disclosure of appropriate alternative procedures or courses of treatment, if any, that may benefit the participant
- a description of any incentives (monetary or otherwise) that may be available to the participant for participation, and information on what the participant will be entitled to, if anything, if they do not complete the study
- a statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits (if the participants are in an educational setting, a statement that non-participation, participation, or withdrawal from the study will have no effect on the academic status or grades of the participant)
- a statement describing how and to what extent the confidentiality of participants' identity and any information about them will be protected and how records identifying the participants will be maintained so as to preserve that confidentiality
- an explanation of any limits of confidentiality, for example, from participation in a focus group, for mandated reporting to the appropriate authorities of indications of harm to self, children, or others, or from any chance that identification of participants might be possible because of the context of the research, a small sample size or the like
- an offer by the investigator to answer questions concerning the study at any time during or after the study
- whom to contact to report a research-related problem or injury to the participant (usually the investigator and, if applicable, the faculty sponsor)
- a statement, including contact details, that information on participant's rights as a research participant may be obtained from the IRB
- if audio- or videotaping is involved, a statement that the participants will be taped and that they have the right to review the tape and request that all or any portion of the tape be destroyed (parental permission forms, however, should not offer parents the right to review their child's tapes)
- if participants might be quoted by name or in any way that might make them identifiable, an attribution statement authorizing (or refusing) this use of their names and/or verbatim responses
- if the research is sponsored by or associated with a commercial enterprise, e.g. product evaluations or clinical trials, the name(s) of the research sponsors.

Research Instruments

All surveys, questionnaires, and other data collection instruments must be submitted for review. If these are no longer than 10 pages, complete copies should be attached to all submitted copies of the Application. If longer than 10 pages, please attach one copy only to the original Application.

Common Mistakes

Lack of Parental Permission Forms, Child Consent Forms, and Assent Script/Procedure

When children are involved, both parental permission and children's consent forms are required. For children under age 12, an oral assent script & procedure (rather than written consent) is necessary.

Inappropriate Referrals to Other Documents

The Application for Review must be complete and include all requested information. Do not include statements such as, "Refer to Research Proposal," or "See proposal."

Complicated or Technical Language

The language in the recruitment materials and consent forms should be age appropriate but not above a 10th grade level (circumstances frequently dictate a lower level). Do not use technical language or terms specific to a discipline. If the consent forms may be best understood in another language, that version must be submitted along with an English translation.

Lack of Investigator Identifiers

The name and status of the investigator, and the University, school, and department identifiers should be in the consent forms, along with the address and telephone number where the researcher can be reached. If the project has a faculty sponsor, identifiers and contact information should be provided for the faculty sponsor. Investigators should be identified in recruitment materials, consent forms, and permission forms.

Overstatement of Possible Benefits

In most research, expected results are tenuous at best. If no direct benefits to the participants due to participation are foreseen, it is appropriate to state this. Payments or course credit are not benefits; they are incentives and should be listed separately from benefits and risks.

Insufficient Explanation of Confidentiality Protection and Its Limits

Methods for maintaining confidentiality of the data (e.g., coding procedures, who has access to the files, how long the data will be kept, etc) should be described in detail in the IRB Application. There are further limits to confidentiality when others may directly know the identity of participating individuals (group interviews or focus groups, etc).

Inappropriate Guarantees of Anonymity

If there is any possibility of linking the information from or about a participant with the participant's identity, then anonymity cannot be promised.

Failure to Explain Impact of Non-Participation

When treatment or services are involved, an affirmation should be included indicating that a decision **not to participate** will not affect the availability of services to which the individual is entitled. When students are involved, an affirmation should be included indicating that non-participation will not affect grades or academic standing.

Lack of Taping Statement

When video or audiotaping is involved, a participant must be told that they may review the completed tape and ask that any or all parts in which they appear or are heard may be destroyed. Parental permission forms should not offer the parent(s) access to their child's tape.

Failure to Obtain Permission from Cooperating Institutions

When cooperating institutions are involved, a letter from an institutional official authorized to give permission should be included. In the case of other universities or medical/dental schools, the approval from their Institutional Review Board must be obtained and submitted to the Committee.

Absence of Translations

Translations of recruitment materials, consent forms, and permission forms into the native language may be appropriate to ensure comprehension for participants whose native language is not English. Investigators must provide the IRB with the recruitment and consent documents in both English and the alternative language(s).

Submit Your Application

Applications should be submitted to the IRB in Newman Hall Rom 108.

Applications will be assigned to the meeting following the deadline for which submission was made (the 15th of the month prior to the meeting date). No applications will be accepted for a particular meeting past the posted submission deadline.

Additional Information

What are the current regulations concerning human participants research?

Current policies and requirements for research activities involving human participants are set forth in the US Code of Federal Regulations, Title 45 Public Welfare, Department of Health and Human Services, National Institutes of Health, Office for Protection from Research Risks, Part 46 Protection of Human Participants.

Part 46 embodies the actual regulations governing activities with human participants, and is usually referred to as the "Common Rule." These regulations are supplemented by policies and regulations of other branches of government and the University.

The policies put forth in the Common Rule apply to all research with human participants that is conducted, supported or otherwise participant to regulation by a Federal department or agency. At St. John's University, as at most other universities in the United States, the **requirements of the Common Rule are applied to all research with human participants** carried out at STJ or by members of the University community.

The Common Rule, along with the body of precedent and interpretation based on it, establishes the requirements for approval of research with human participants, including:

- categories of research that may receive Exempt Status
- procedures for working with minors and other protected populations
- the content and documentation of informed consent
- ongoing review policies.

In order to implement the Common Rule, the University has an assurance on file with the Federal government that allows it to designate an Institutional Review Board (IRB), to oversee the review and approval process for research involving human participants.

The Common Rule also:

- establishes the functions and operations of the IRB and the criteria for IRB approval of research
- sets requirements for IRB membership to ensure diversity of its members, appropriate expertise, and inclusion of a nonscientist and a public member with no other association with the University
- identifies vulnerable participant populations
- establishes the categories of IRB approval and the ongoing requirements for each
- establishes the general requirements for informed consent and its documentation.

Federal regulations as expressed in the Common Rule and administered by individual agencies, are not, however, the only source of policies and requirements for research involving human participants.

State and local laws and policies must also be observed. One such regulation that has a considerable impact on research at the University is the requirement of the New York City Department of Education that all research involving public school personnel, students, or facilities must be approved by:

- The University IRB and
- The IRB of the Department of Education, which is part of the Department's Division of Assessment and Accountability.

In addition, the University may institute policies affecting the requirements for approval that extend Federal, state or local requirements to nonfunded projects as well.

For example, effective October 1st, 2000, the National Institutes of Health requires that, for all NIH-funded projects:

- principal investigators, co-investigators and all key personnel complete a formal education program in the regulations governing research activities involving human participants
- the University certify, in order that an award may be made, that the principal investigator and key personnel in the project have successfully received that education.

What are the investigator's responsibilities?

While the regulations for research involving human participants are established by the Federal government, the University is responsible for their implementation through the development of internal policies and procedures.

However, primary responsibility for incorporating and adhering to the regulations and policies rests with the principal investigator. In carrying out any research work with human participants, it is the responsibility of the principal investigator to:

- Know, understand and adhere to the ethical principles and applicable Federal, State, local and institutional regulations, relating to research activities with human participants
- Consider and incorporate these principles and regulations and the welfare of potential participants in all aspects of the design and execution of research projects
- Fully complete the IRB Application, including all necessary documentation and associated information (for example, IRB approvals from cooperating institutions, interview schedules and questionnaires, consent and permission forms)
- Submit the Request to the IRB at the appropriate point in the research development process. Timing may be particularly important if external support is being sought for the project since most federal and many other sponsors require IRB approval as a condition of award. Sponsors may delay or withdraw an award if approval is not available at the appropriate time. The IRB, therefore, strongly recommends that all researchers applying for external support submit an IRB Application to the IRB within 60 days after submission of the proposal for funding.
- Receive full approval from the IRB before initiating any research activities with human participants and do only such work with human participants as has been approved by the IRB.
- Train and supervise research staff in all aspects of the ethics and individual responsibilities of research involving human participants
- Fully inform potential participants of the purpose and nature of the research work in which they are being asked to participate (what will be involved in participation, that under all circumstances participation is fully voluntary, and that participants are entitled to protection of their privacy) and ensure appropriate consent for all participants.
- Submit changes in the project to the IRB for review and approval prior to their initiation.
- If the project has not received Exempt Status, complete and submit an annual renewal before the end of the current approval period

- Notify the IRB immediately of any adverse outcomes or effects involving human participants and of the steps taken to remedy such outcomes or effects.

How should researchers select and recruit participants?

Recruitment

The preferred method of recruitment is to disseminate information about the research study to potential participants and to ask them to contact the investigator if they are interested in participating. Names and addresses should never be directly requested from referral sources unless permission has been given by individuals to release their names.

Researchers should also avoid recruitment from among their own patients or students due to the nature of the existing relationship and the unavoidable potential for coercion or the perception of coercion by potential participants.

In certain cases in which reaching a specific population by disseminating information is difficult, a participant's right to privacy may be superceded by a desire to minimize coercion. In such cases, a researcher might propose a method of contacting potential participants directly rather than having their doctor, teacher or supervisor do the recruiting. In a corporate setting, for example, a researcher might be given direct access to a personnel e-mail roster to be used in approaching participants directly so that the employer and supervisors will not know which employees are potential or actual participants.

Although indirect methods of recruitment are always preferable, the IRB will look at the balance between the right to privacy and the problem of potential coercion. Some acceptable and non-intrusive means of recruiting participants include:

- Placing an advertisement in a newspaper, journal, or other periodical requesting that interested persons who meet relevant criteria contact the investigator;
- Posting a sign or placing flyers in a public area or, with permission from the appropriate authority, in a private area (e.g., store, library, health club, etc.) requesting that interested persons who meet the relevant criteria contact the investigator;
- Obtaining names from public records, such as telephone directories;
- Obtaining names from organization membership or client records which the investigator has legal access and for which s/he has obtained permission from the appropriate authority.

If participants from another institution, such as another university, school system, or medical center, are to be recruited for a study, IRB approval from that institution, or, if the institution does not have an IRB, written permission from an

authorized official representing the institution, is required and should be submitted with the Application for Review. Full approval may not be granted until such permissions are received.

Selection

Selection of participants should be equitable and inclusive of all appropriate groups so that the burdens and benefits of research are reasonably distributed. If women and / or minorities or other specific groups are excluded from a participant population, a scientific justification is required as part of the Application.

In addition, protected populations such as prisoners, pregnant women, children, or institutionalized mentally disabled people may only be studied under certain conditions and with special safeguards. However, researchers should be careful not to overprotect vulnerable populations and as a result exclude them from research which may be beneficial to them or which may have results skewed because of their exclusion.

Investigators should try to list inclusion and/or exclusion criteria in recruitment materials, so that potential participants who would not qualify for inclusion in the study do not make a wasted effort in contacting the researcher. Common criteria are age, geographic location, English or foreign language fluency, health status or presence of a particular disease or condition.

Working With Minors

Children are considered particularly vulnerable to coercion and are therefore a "protected" population as research participants. In New York State, children are defined as those who are under 18 years of age; they are considered minors, people who have not reached the legal age for consent to treatment or procedures involved in research.

If researchers are planning to include minors as participants in their research, additional material must be included in the Application for Review submitted to the IRB, including:

- a Parental or Guardian Permission Form including all elements of informed consent as they refer to the participant; and,
- for participants 12 to 18 years old, a children's written consent form; or
- for children under 12 years of age, the script for an oral assent procedure which explains the task(s) involved, stresses the right not to participate and to withdraw without penalty at any time, and requires an active indication of willingness to participate. Assent is thus defined as an affirmative agreement rather than tacit consent to participate in the

research or an unclear response after the participants have been fully informed about the project.

What is informed consent and how is it documented?

Informed consent is at the core of the code of ethics governing the use of human participants in research. The informed consent process ensures the voluntary nature of a participant's involvement and the clear and full understanding of procedures, risks and benefits of participation, and rights as a participant.

Although informed consent is generally documented in writing and by the signature of the participant, the consent form is just part of the process by which investigators ensure that participants understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate.

Thus, Investigators are responsible for:

- assessing the participant's understanding of the explanation given, ensuring the appropriateness of the setting and circumstances surrounding the request to participate
- responding fully and honestly to any questions or concerns potential participants might have
- providing sufficient time and privacy for potential participants to decide whether or not to participate

Investigators must also consider the additional requirements that may be necessary for the consent process used for protected populations. For example, minors must have parental or guardian permission to participate in research and must also, as discussed in the previous chapter, provide consent or assent, depending on the age of the child, to become participants.

Consent/Permission Form Information

The following information must be included in all consent forms and permission forms:

- a statement that the study involves research and an explanation of the purpose(s) of the research
- names and contact information of the investigator(s), of the faculty sponsor, including institutional affiliation and status
- Contact information for each investigator and faculty sponsor including school and department, phone number (including a local phone number if

the work is to be done out of the United States), university and email addresses
- a description of the procedures to be followed, what the participant will be expected to do, and whether there are any procedures which are experimental
- how long participation will take, including how many sessions will be held if more than one will be needed
- a description of any benefits to the participant or to others which may reasonably be expected from the research, or, more commonly, since the benefits of research to the participants are usually tenuous at best, a statement that there will be no direct benefit to the participants
- a description of any reasonably foreseeable risks or discomforts to the participant, including any intervention which may be offered, OR the statement that there are no risks beyond those of everyday life
- for research involving more than minimal risk, a clear description of the risks and where further information may be obtained (note that no research with minors involving more than minimal risk may be carried out unless it holds the prospect of direct benefit to the participant)
- if the research involves more than minimal risk, a statement concerning the availability of medical treatment or compensation in the event of physical injury resulting from participation in the research. The statement should include the information that:
    1. St. John's University cannot provide either medical treatment or financial compensation for any physical injury resulting from the participant's Involvement in the research; and
    2. Inquiries concerning this policy may be made to the principal investigator or the IRB
- if applicable, a disclosure of appropriate alternative procedures or courses of treatment, if any, that may benefit the participant
- a description of any incentives (monetary or otherwise) that may be available to the participant for taking part, and information on what the participant will be entitled to, if anything, if they do not complete the study
- a statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue involvement at any time without penalty or loss of benefits (if the participants are in an educational setting, a statement that non-participation, participation, or withdrawal from the study will have no effect on the academic status or grades of the participant)
- a statement describing how and to what extent the confidentiality of participants' identity and any information about them will be protected and how records identifying the participants will be maintained so as to preserve that confidentiality
- an explanation of any limits of confidentiality, for example, from participation in a focus group, for mandated reporting to the appropriate authorities of indications of harm to self, children, or others, or from any

chance that identification of participants might be possible because of the context of the research, a small sample size or the like
- an offer by the investigator to answer questions concerning the study at any time during or after the study
- whom to contact to report a research-related problem or injury to the participant (usually the investigator and, if applicable, the faculty sponsor)
- a statement, including contact details, that information on participant's rights as a research participant may be obtained from the IRB
- if audio- or videotaping is involved, a statement that the participants will be taped and that they have the right to review the tape and request that all or any portion of the tape be destroyed (parental permission forms, however, should not offer parents the right to review their child's tapes)
- if participants might be quoted by name or in any way that might make them identifiable, an attribution statement authorizing (or refusing) this use of their names and/or verbatim responses
- if the research is sponsored by or associated with a commercial enterprise, e.g. product evaluations or clinical trials, the name(s) of the research sponsors.

Exceptions and Waivers

The IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent provided that the investigator documents and justifies in the IRB Application that:

- the research involves no more than minimal risk to the participant;
- the waiver or alteration will not adversely affect the rights and welfare of participants;
- the research could not practicably be carried out without the waiver or alteration;
- the participants will be given additional pertinent information after participation, whenever appropriate.

Under Federal regulation, the IRB may waive the requirement for investigators to obtain a signed consent form for some or all participants if it finds:

- the only record linking the participant and the research is the consent document and the principal risk is potential harm resulting from a breach of confidentiality. (Each participant must be asked whether she/he wants documentation linking her/him to the research. The participant's wishes will govern.) OR
- the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

In cases where documentation requirements are waived, the IRB may require investigators to give participants a Project Summary, which is a written statement about the research that includes all the elements of informed consent but does not require the participant's signature.

How must researchers deal with protected populations?

Federal regulations require that human participants committees give special consideration to protecting the welfare of protected participants. Special provisions exist for research involving:

- children and minors
- prisoners
- pregnant women and fetuses.

In addition, the IRB pays particular attention to such populations as:

- the institutionalized mentally disabled
- the elderly
- the economically or educationally disadvantaged.

In general, these regulations allow IRBs to approve research with these populations that is of minimal risk or that will benefit the participants directly. Review and approval of research involving vulnerable populations may require additional time if outside expertise is needed for further evaluation of the application for approval.

For a full discussion of guidelines for research with protected populations, please refer to the OHRP's IRB Guidebook.

How do researchers protect minors?

A minor in New York State is defined as an individual who is under the age of 18. In order to participate as participants in research, all minors must have formal parental permission, received by the researcher in an approved format and a process approved by the IRB. For details, read the NIH policy concerning parental permission.

Written consent is also required from children if they are age 12 to 18. Those younger than 12 need to agree (give their assent) to the research. This assent process should be verbal. For details, read the NIH policy concerning assent.

Special considerations when working with minors include:

- The participant's ability to comprehend the consent form or assent procedure: The language in the consent form or assent procedure must be tailored to the age and educational level of the children so that they will be able to understand all the information required for informed consent.
- Vulnerability of minors to coercion: The consent or assent process should take into account the vulnerability of minors to obeying adults and giving in to peer pressure. The researcher should take special care to emphasize the voluntary nature of the participation, stress the fact that no penalties will result from nonparticipation. For example, researchers who work with young children often use a phrase in the assent process such as "if you do not want to be in the study, that is okay. Everyone will like you just as much anyhow." Using one's own students or patients as participants is strongly discouraged due to the high potential for coercion.
- The need for affirmative consent or assent: When a minor age 12 or older or an adult signs a consent form, they are making an affirmative consent; that is, it is clear that they are giving active consent to participate. The assent process for children under 12 years of age also requires active consent, although it must be verbal. Researchers should always ask children directly, "Do you want to do this?" and accept as assent only a definite yes. Again, researchers should stress voluntary participation and take special care to make sure the language of the assent is appropriate to the age of the participants.

How do researchers safeguard other protected populations?

Prisoners

Special regulations have been designed to protect prisoners because of their vulnerability due to incarceration. Their imprisonment could affect their ability to make a truly voluntary decision without coercion as to whether or not to participate as participants in research. A prisoner is any individual involuntarily confined or detained in a penal institution. This includes individuals who have been:

- sentenced to such an institution under a criminal or civil statute
- detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution
- detained pending arraignment, trial, or sentencing.

Research involving prisoners is only allowed when:

- any possible advantages accruing to the prisoner through participation in research are not so great that his / her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired

- the risks involved in the research are commensurate with risks that would be acceptable to nonprisoner volunteers
- procedures for selecting participants within the prison are fair to all and not participant to arbitrary intervention by prison authorities or prisoners. Control participants if included must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project
- the information about participation in the study is presented in language which is understandable to the prison population
- adequate assurance exists that parole boards will not take into account a prisoner's participation in the research when making decisions about parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his / her parole.

All research with prisoners must be reviewed by a designated prisoner advocate member of the IRB. A prisoner advocate is someone with the appropriate background and experience to represent the best interests of prisoners who might be recruited as participants in research. Such a person could be a current or former prisoner, an attorney or other professional who has dealt extensively with prisoners' rights, or someone with similar experience.

Biomedical or behavioral research may involve prisoners as participants only if the proposed research solely involves the following:

- study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the participants
- study of prisons as institutional structures or of prisoners as incarcerated people, provided that the study presents no more than minimal risk and no more than inconvenience to the participants
- research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere); and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults
- research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or wellbeing of the participant.

Pregnant Women and Fetuses

For clinical or drug studies, no pregnant woman may be involved as a participant in research unless:

- the purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs
- the risk to the fetus is minimal.

No fetus in utero may be involved as a participant in any activity unless:

- the purpose of the activity is to meet the health needs of the particular fetus and it will be placed at risk only to the minimum extent necessary to meet such needs
- the risk to the fetus imposed by the research is minimal
- the purpose of the activity is to develop important biomedical knowledge which cannot be obtained by any other means.

Special regulations that are particularly important in clinical research also exist for the involvement of Fetuses ex utero, including nonviable fetuses, dead fetus, fetal material, or the placenta.

Researchers should also be sensitive to the fact that potential and current participants may not yet know that they are pregnant. Thus the researcher in any study in which activities might impact a pregnancy or fetus, for example, involving X-rays or fMRI, should make clear that if a participant thinks she might be or might become pregnant during the study, she should not participate.

For further information, read the Federal regulations about research involving pregnant women and fetuses.

Cognitively Impaired or Mentally Disabled Persons

As a general rule, all adults, regardless of their diagnosis or condition, should be presumed competent to consent unless there is evidence of serious mental disability or cognitive impairment that would impair reasoning or judgment. Mental disability alone should not disqualify a person from consenting to participate in research; rather there should be specific evidence of incapacity. In such cases, a guardian or legal representative may give consent for the individual.

This presents significant difficulties for researchers, particularly when dealing with the institutionalized. Firstly, there are no commonly accepted criteria for determining competence to consent to participation in research, particularly in those persons whose mental or intellectual state may fluctuate. Additionally, some individuals who may be incompetent or of doubtful competence may have no legal guardian to consent to or refuse participation on their behalf and there may be no clear legal guidance available on who might serve as a guardian or representative.

Given these difficulties, researchers are expected to have a very strong justification for using cognitively impaired persons in research and must clearly make the case that this population is not being included simply because of convenience or availability.

Additional Categories

Special consideration may also be needed when research is proposed with terminally ill, traumatized, and elderly/aged persons.

What are researchers' obligations when cooperating institutions are involved?

Letters of approval are required from cooperating institutions or organizations when they are involved in research conducted by STJ employees or students. Approval is needed when:

- research is conducted on their premises
- participants are recruited from their institutions
- data are obtained from these institutions.

The approval must take the form of formal notification of approval from the cooperating IRB if it exists, which is the case at most hospitals and universities and in many school systems, or from the Director or equivalent administrator of an organization without an IRB.

An institution or organization is usually considered as participating in a research project when its staff, facilities, or records of individuals are used in conducting the research. A hospital would be considered as participating in research if, for example, participants were recruited through its outpatient clinic.

Most school systems have established procedures for gaining access to their students or teachers for research recruitment. In New York City, the Department of Education has established its own IRB. University investigators doing research in NYC schools must have, in addition to IRB approval:

- Department of Education IRB approval
- Approval from the appropriate superintendent, principal and teacher, if applicable.

What are researchers' obligations when doing research in foreign countries?

Foreign governments vary in their approach to research ethics. The Council of Europe, for example, developed guidelines in 1985 which were further reinforced by those published by the European Union in 1990. In addition, recent collaborative efforts between the World Health Organization and the Council for International Organizations of Medical Sciences have resulted in proposed international guidelines for human participants research that could be used in many areas of the world.

These guidelines mainly reflect those principles expressed in the Declaration of Helsinki.

Common to all the guidelines are:

- Prior approval by an independent review board
- Obtaining informed consent from prospective participants
- Favorable risk to benefit ratio
- Equitable selection of participants
- Protection of data confidentiality
- Privacy of participants.

Recent issuances from world organizations also emphasize the special consideration which is needed when research is conducted by investigators from more developed countries on human participants in less developed countries and that informed consent needs to be obtained in a way that is sensitive to the particular culture and to the potential for exploiting the participants.

When the Federal government funds international research, it requires that the procedures prescribed by the study offer protections that are at least equivalent to those provided in the US.

What types of decisions can the IRB make?

The IRB must first decide whether a new application meets the criteria for exempt status under one of the federally defined categories or whether it needs to be considered for full review.

Once a proposal is reviewed by the IRB and no outstanding questions or requests for revision remain, the IRB may deem an application approved as:

- **Approved**

  The project may be undertaken for a one-year period starting with the first date of the meeting at or for which the application was reviewed. Changes to any aspect of the protocol, however, must be submitted to the IRB for review and approval prior to being instituted.

  To maintain approval to continue the work subsequent to the end date of the initial approved year, the investigator must submit and have approved an Application for Extension prior to the expiration of the current approval.

- **Approved, Continuing**

  The principal investigator has submitted an Application for Extension which has been reviewed and approved by the IRB. He/she may thus continue project activities involving human participants for an additional period of one year.

- **Approved, Exempt**

  As long as no changes are made to the protocol, the project will not be participant to an annual review or further IRB scrutiny. Changes to any aspect of the protocol, however, must be submitted to the IRB for review and approval prior to being instituted.

- **Approved, Modified**

  Modifications to the protocol, procedures or participant pool planned by the investigator may be carried out. Modifications that are, in the IRB's view, minor and not likely to affect the privacy, informed consent, or wellbeing of the participants will be considered an Appraisal, a notification to the IRB. Those that are more extensive will require additional review by the IRB. In order to receive this approval, submit an Amendment Application.

If the IRB does not consider that an IRB Application may yet be approved, it may deem the Application as Pending and request revisions and / or clarification that it feels are necessary to bring the proposed project into full compliance with the requirements for involving human participants.

In these cases, the application will be considered either:

- **Approved, Pending**

  The IRB has reviewed the application, and has in general considered it favorably, but requires that revisions, additional information or clarification be provided to ensure that all rights of the participants are being protected.

- **Exempt, Pending**

  The IRB has reviewed the application, concurs that as presented it is likely to qualify for exempt status, and has in general considered it favorably.

  However, it requires that certain revisions, additional information or clarification be provided to ensure that all rights of the participants are being protected.

Pending status may also be applied to Extensions and Amendments if the IRB feels that it needs more information or clarification to complete reviews in this category.

It is important to note that there are two levels of pending status:

- Technical: The requested changes are such that review and approval or requests for further revisions may be delegated to a IRB subcommittee.
- Substantive: The requested changes are of sufficient seriousness that the IRB has decided that responses must be reviewed by the IRB in a full meeting of the Committee.

The IRB may also deem an application:

- **Deferred**

  The IRB has identified issues in the research purposes or procedures that are sufficiently serious and substantive that extensive revision is necessary before the IRB may make an appropriate review.

  In such cases, the IRB will provide the investigator with the name of an IRB member who can advise and assist in reworking the application. Revisions to Deferred applications must be reviewed by the IRB in a full-convened monthly session.

- **Noncompliant**

  Noncompliant applications are most commonly the result of the investigator's failure to complete and have approved application for continuation of the project within the required time frame. These applications may also be the result of carrying out activities with human participants that have not been previously approved.

  Noncompliance status can have serious implications for a project:

  - sponsor funds cannot be expended for any expenses incurred in such a period
  - a report may need to be filed with the Federal government about the occurrence of noncompliance
  - data from participants enrolled during a period of noncompliance may not be used.

Decisions of the IRB are final and binding for the University. They are not participant to change by other University offices or authorities.

What should investigators do during the application process and the course of their projects?

The regulations for research involving human participants are established by the Federal government in conjunction with state and local requirements. The University is responsible for their implementation by developing internal policies and procedures.

Primary responsibility for incorporating and adhering to the regulations and policies, however, rests with the principal investigator and the research staff. In carrying out any research work with human participants, the principal investigator is responsible for:

- Knowing, understanding, and adhering to the ethical principles and current Federal, state, local and institutional regulations, relating to research activities involving human participants
- Considering and incorporating these principles and regulations and the welfare of potential participants in all aspects of designing and carrying out the research
- Fully completing the IRB Application, and providing all necessary documentation and associated information, including when appropriate, IRB approvals from cooperating institutions and the application for waiver of HIPAA authorization.

- Submitting the completed application to the IRB at the appropriate point in the research development process (timing may be particularly important if external support is being sought for the project)
- Responding to any requests from the IRB for revision or additional information and clarification as part of the approval process
- Receiving full approval from the institutional IRB before initiating any research activities with human participants and completing only such work with human participants as approved by the IRB
- Training and supervising research staff in all aspects of the ethics and individual responsibilities of research involving human participants
- Informing potential participants fully of the purpose and nature of the research work in which they are being asked to participate
- Assuring the voluntary nature of participation and that of the data obtained
- Informing participants of the extent to which their privacy will be protected
- Submitting modifications to the project to the IRB for review and approval before implementing them
- Completing and submitting an annual Extension Application to continue the research before the end of the current approval period if the project is not deemed exempt
- Notifying the IRB immediately of any adverse outcomes or effects involving human participants and the steps being taken to remedy such outcomes or effects.

Glossary

Approved

Approved means “formal, written approval from the IRB for proposed work.”

Assent

Verbal agreement by an individual not regarded as able to give legally valid written informed consent (e.g., a minor under age 12) to participate in research.

Assurance

The formal, written, binding commitment that is negotiated with the Federal Government in which an institution promises to comply with applicable regulations governing research with human participants and stipulates the procedures through which compliance will be achieved.

Belmont Report

A statement of the basic ethical principles governing research involving human participants issued by the National Commission for the Protection of Human Participants in 1978.

Beneficence

An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: 1) do not harm; and 2) protect from harm by maximizing possible benefits and minimizing risk.

Coercion

Coercion is defined as pressure, or undue enticement or influence. In research involving human participants, the principle of voluntariness is a cornerstone of the informed consent process. This means that consent should be obtained without exercising coercion. Examples of coercive situations include an investigator using his or her own patients or students as participants, or an employer acting as a participant recruitment agent for an investigator from

among its own employees. It could also include such things as excessive monetary compensation, a promise of special consideration for participation or withholding of services that would otherwise be available.

Covered entity

The Privacy Rule under HIPAA defines a covered entity as the following: a health plan, health care clearinghouse, or health care provider that transmits any health information in electronic form in connection with any of the HIPAA standard transactions, which include billing and claims verification.

Deception

Deception is the deliberate withholding of information from the participant by the researcher in order to achieve the scientific goals of the study. Deception is not permitted in studies with more than minimal risk. A debriefing for participants is required for all studies involving deception and must include an explanation of what the deception was and why it was scientifically necessary.

Exempt Status

Certain categories of research deemed very low risk under Federal regulations may be granted Exempt Status once the appropriate review has been conducted by the IRB.

If Exempt Status is granted, the study will no longer be under continuing review by the IRB, unless procedures are revised which deviate from those originally reviewed by the IRB.

Only the IRB may grant Exempt Status and thus all requests for such status must be reviewed by the IRB.

Full Review

Full review refers to projects that are reviewed by the full IRB in a convened meeting. All applications which are not granted Exempt Status must receive full review.

Generalizable knowledge

Generalizable knowledge means that the information derived from the activity will be applicable to similar studies.

Guardian

An individual who is authorized under applicable state or local law to make decisions on behalf of an individual.

HIPAA

The Health Insurance Portability and Accountability Act (HIPAA) is the Federal legislation that authorized the Secretary of the Department of Health and Human Services to write the medical privacy regulations known as the “Privacy Rule.” The Privacy Rule governs all uses and disclosures of Protected Health Information (PHI) by persons and entities participant to these regulations.

Human participant

A human participant is a living individual about whom an investigator obtains either:

- data through intervention with the individual
- identifiable private information.

Data pertaining to the person may be obtained by:

Interaction — talking with someone or eliciting information through a questionnaire, interview, or focus group

Intervention — drawing a blood sample or taking a DNA swab

Records review — collecting or renewing information from medical, school, or other records.

Human participants research

Human participants research means any activity intended to obtain and record information from or about individuals for research purposes. Examples of human participants research include:

- Questionnaires
- In person and telephone surveys
- Educational tests
- Observation of public or private behavior, including classroom observation
- Interviews and focus groups
- Evaluation and research components of demonstration and training programs
- Collection or study of existing data (for example, medical, school, or other records).

Informed consent

Informed consent is a person's voluntary agreement, based upon adequate knowledge and understanding of the relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. The informed consent process ensures the voluntary nature of a participant's participation and reflects respect for people and individual autonomy fundamental to the protection of human participants.

Institutional Review Board (IRB)

An Institutional Review Board (IRB), in accordance with federal regulations, is the specially constituted committee established by an organization to protect the welfare of the human participants recruited to participate in research. The Board reviews all proposed research with human participants to ensure that the participants' rights and welfare are adequately protected.

St. John's University's IRBs are composed primarily of faculty members from disciplines in which research involving human participants is integral to the discipline's work (for example, psychology, theology, biology, speech, and pharmacy)

Investigator (Principal Investigator)

The scientist or scholar with primary responsibility for the design and conduct of a research project.

Justice

An ethical principal discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances similarly.

Legally Authorized Representative

A person authorized by either by statute or by court appointment to make decisions on behalf of another person.

Minimal risk

Minimal risk is the probability and magnitude of physical or psychological harm that is no greater than that normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy people.

Minor

Persons who have not attained the legal age for consent to participate in research, as determined under the applicable law of the jurisdiction in which the research will be carried out. In New York State, and as standard used by the IRB, a minor is defined as a person less than 18 years of age. Special protections are in place to protect minors involved in research activities.

Nuremberg Code

A code of research ethics developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during the 1950's and 1960s for protecting human participants.

Privacy Rule

The Privacy Rule governs all uses and disclosures of Protected Health Information (PHI) by persons and entities participant to these regulations. The Department of Health and Human Services Secretary was authorized by the Federal regulation, the Health Insurance Portability and Accountability Act (HIPAA), to write the Federal medical privacy regulations known as the Privacy Rule.

Protected Health Information (PHI)

All uses and disclosures of Protected Health Information (PHI) by persons and entities governed by HIPPA (the Health Insurance Portability and Accountability Act) (HIPAA) are protected by the Privacy Rule, the Federal medical privacy regulations written by the Department of Health and Human Services Secretary.

Protected population

A protected population is a group of particularly vulnerable participants, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons for whom special consideration needs to be given. The Federal government has specific regulations on research involving protected populations.

Protocol

The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and/or to an agency for research support.

Research

Research means a systematic investigation designed to produce generalizable knowledge.

Respect for Persons

An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy by protected.

Risk

Risk is the possibility of harm or injury (physical, psychological, social or economic) occurring as a result of participation in a research study.

Secondary Data

Secondary data is information that was collected in the course of another study or is part of a publicly available set of data.

Investigators wishing to use secondary data not publicly available must have authorization from the owner of that data, usually the Principal Investigator of the original study, to make use of the data. Should the data include Protected Health Information, the investigator may also need a HIPAA authorization or other HIPAA approval since the HIPAA Privacy Act does not allow for the secondary use of data in the same manner, as does the Common Rule.

Standard Educational Practice

Standard Educational Practices are normal educational practices in commonly accepted educational settings. Many research activities involving standard educational practices may be granted Exempt Status. Activities that are introduced for the purposes of the study do not constitute normal educational practice.

Surveys

Studies designed to obtain information from a number of respondents through written questionnaires, telephone or in-person interviews, door to door solicitation, or similar procedures.

Systematic investigation

A systematic investigation means that the research information is designed so that conclusions may be drawn and others can review these conclusions.

Therapy

Treatment intended to alleviate a disease or disorder.

Voluntary

Free of coercion, duress, or undue inducement or influence. Used in the research context to refer to a participant's uncoerced decision to participate or to continue to participate in a research activity.