



# **BACKGROUND AND PROCEDURES FOR HUMAN SUBJECT RESEARCH**

**INSTITUTIONAL REVIEW BOARD**

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IRB members are appointed by the President for three-year, rotating terms according to the provisions of 45 CFR 46.107.



## PART I. --UNIVERSITY PHILOSOPHY AND COMMITMENT IN HUMAN SUBJECT RESEARCH

**1.1 -- Commitment to Respect for the Human Person** - St. John's University is guided by the ethical principles governing all research involving humans as subjects, as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the "Belmont Report") and by the principle of respect for human persons as taught by the Catholic Church. This commitment is binding on the institution regardless of whether the research is subject to Federal regulation or with whom conducted or source of support (i.e. sponsorship.)

**1.2 --** The University's commitment to the preservation of the rights of human subjects is founded first of all on its dedication to respect the human person. Theologically, the fundamental basis for respect of the person is the conviction that the human person is created in "the image and likeness" of God (Genesis 1, 27).

**1.3 --** Additionally as a humanistic institution, the University understands itself as committed to the promotion and development of human persons in their historical setting -- here and now defined, described, open to full development and completion.

**1.4 --** Finally as an educational institution established in and by society, the University judges each person to be capable of open-ended enrichment, fulfillment and human flourishing.

**1.5 --** In view of this foundational esteem for the human person, the University commits itself to promote and protect:

**1.5.1 -- *Human Privacy***, i.e. the right of each individual to have personal information protected through professional confidentiality.

**1.5.2 -- *Human freedom and autonomy***, i.e. the right to make life shaping decisions expressed through informed consent.

**1.5.3 -- *Justice***, i.e. any threats to the individual's welfare, any risks to safety or wholeness are adequately minimized and balanced by the benefits that are anticipated. (Cf. Belmont Report.)

**1.6 -- Responsibility** - In the fulfillment of its commitment to the human person, the University locates primary responsibility for respect of this commitment with the individual investigator.

**1.7 --** Additionally, the University accords *supervisory responsibility* for the fulfillment of its commitment to the human person to the **INSTITUTIONAL REVIEW BOARD**.(cf. Part III) This policy applies to all research involving human subjects conducted by faculty, staff or students of St. John's University, regardless of the source of funding, or the location of the study, as per registered OPRR Multiple Project Assurance #M1083, June 1996.



## **PART II. -- DEFINITIONS**

**2.1 Research**-- A systematic investigation designed to develop or contribute to generalizable knowledge.(45 CFR 46.102.d)

**2.1.1 -- Exempt research** -- is any research activity that is not subject to review under the federal policy for the Protection of Human Subjects.(cf. IV.2 below). This determination is made by the IRB.

**2.1.2 -- Expedited research** -- is any research activity that requires less than full review by the entire IRB. (Cf. 4.5 below)

**2.1.3 -- Full Review Research** -- is any research activity that requires review by the entire IRB at a regularly convened meeting.(cf. 4.9 below)

### **2.1.4 -- Additional Categories of Review**

***Initial Review*** -any review of research which examines a research protocol for the first time.

***Continuing Review***-- any review conducted at intervals appropriate to the degree of risk, but not less than once per year, since the IRB may not approve research for more than twelve months. A continuing review may follow the procedure for full review or for expedited review, depending on the applicable criteria of review.

***Modified Review***-- is any review of a project in which some material changes(s) has occurred since the previous IRB review.

***Unfavorable Review***-- is any review which refuses IRB approval for proposed research. Such rejection can be made only through a Full Review procedure.

**2.2 Human Subject** -- A living individual about whom an investigator conducting research obtains (1)data through intervention or interaction with the individual, or (2) identifiable private information. (45 CFR 46.02.f)

**2.3 Minimal Risk** -- Risk is judged minimal when the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.(45 CFR 46.102.1)



### **PART III. -- THE INSTITUTIONAL REVIEW BOARD**

**3.1 Authority** --The IRB is that mechanism established by the University to exercise its responsibility to protect the rights and welfare of human subjects in various categories of research in any way related to the institution. Its jurisdiction includes approval, disapproval, modification, ongoing review, verification of changes, or suspension or termination of approval. The goal of IRB review is to facilitate University research, while at the same time protecting human subjects. IRB approval signifies only that the rights and welfare of human subjects have been appropriately protected.

**3.2 Membership** -- The IRB will consist of at least five members, drawn from both genders where possible. Its members are drawn from varied professional groups, of whom at least one has primary responsibility in non-scientific areas and one in scientific areas. At least one member is not otherwise be affiliated with the University.

**3.3 Characteristics** -- IRB members should bring varied expertise and experience to the Board's deliberations. Members should demonstrate sensitivity to community values and attitudes, to the vulnerability of certain categories of subjects, and have a thorough knowledge of institutional norms, applicable law, and standards of professional conduct. In particular cases, ad hoc consultants with particular competencies may be added to the Board.

**3.4 Meetings** -- The IRB of St. John's University has scheduled its meetings on the first Monday of each month during the academic year. Proposals involving human subject research should be presented to the Board through its Chair for its review at least two weeks prior to a scheduled meeting.

**3.5 Responsibility** -- It is the responsibility of the IRB to assure that researchers minimize risks to their subjects, that risks are proportionate to anticipated benefits, to certify that an opportunity for informed consent is provided all subjects, and that the rights and welfare of human subjects are in fact protected, including the right of confidentiality.



#### **PART IV. - THE REVIEW PROCESS**

**4.1 General Criteria for Approval of Human Subject Research** (45 CFR Part 46.111). The IRB must determine:

- That any risks to subjects are minimized and are necessary to proper and scientifically valid conduct of the research;
- That any risks are proportionate to benefits expected for subjects or for the advancement of knowledge;
- That the selection of subjects is equitable and just;
- That informed consent will be sought and appropriately documented;
- That the research proposal makes adequate provision for the monitoring of data to insure subject safety. It is the investigator's responsibility to report in writing any injuries to human subjects or other adverse events as promptly as possible;
- That the privacy of subjects and the confidentiality of data are adequately protected;
- That any participating institutions/sites have indicated appropriate approval of participation;
- That no University student be required to participate as a subject in any research project as a course requirement without appropriate informed consent. Courses that involve a human subject research requirement must indicate that participation as a subject is always voluntary and an alternative to participation must be offered;
- That subjects be safeguarded from coercion or undue influence.
- That investigators do not attempt to recruit subjects in their own classes.

**4.2 Elements of a protocol** -- Hence the following elements should be covered in the protocol submitted to the IRB (see *Application Form* for specific format):

**Purpose** -- including hypotheses, method of statistical analysis.

**Duration** -- including participation time required of individual subjects.

**Subject recruitment and selection** -- numbers, control subjects, categories excluded with reasons for exclusion, advertisements used in recruitment, inducements (money, gifts, raffles, etc.).

**Locations** -- if other than University sites, document approval of supervisors, on letterhead.

**Background** -- previous research directly relevant to subject issues in this protocol, if any.

**Research Design** -- if not using standard questionnaires or rating scale, include copies;

**Potential risks** -- Describe any risks which are greater than those incurred by normal day-to-day activities. Categorical denial of risk is not permitted.

**Consent procedures** -- Describe the PROCESS by which opportunity for informed consent will be given, and supply any consent or assent documents or text as appropriate to the subjects and the risk involved.

**Measures for protection of subjects, including procedures for the protection and storage of data** -- must be adequate to guarantee confidentiality; if subjects are truly anonymous confidentiality is moot.

**Potential benefits** -- to the subject personally and/or to society. High risk protocols may not be performed with children unless the actual subjects themselves stand to benefit from a successful outcome of the research.

**Risk/Benefit ratio** -- how do the potential benefits justify the risk involved?

**4.2.1 Additional institutions** -- If the researcher is participating in a larger project that has received IRB approval from another institution, the researcher must clearly explain his/her role in the project. This would apply, for example, to Clinical Pharmacy students working under a grant at their hospital site.

**4.2.2 Signatures** -- Each research protocol submitted to the IRB shall be signed:

- For faculty and staff: by that person's dean or supervisor.  
This signature indicates the signer's belief that the research meets professional standards of the appropriate discipline and that in the opinion of the supervisor or dean the protocol fulfills all IRB requirements.  
Grant proposals requiring Human Subjects approval may be submitted to the IRB from the Office of Grants and Sponsored Research, but in every case it is the responsibility of the researcher to see that timely and complete submission to the IRB is made.
- For students: by a supervising faculty mentor and, in the case of dissertation proposals, by the dissertation committee and the dean.  
This signature indicates the faculty member's belief that the research meets professional standards for the discipline and that in the mentor's opinion the protocol fulfills all IRB requirements. In all cases, final approval shall be the responsibility of the IRB.



**4.3 Exemption from Review** -- Research proposals are exempt from the Federal Policy for the Protection of Human Subjects when the ONLY involvement of human subjects falls within one or more of the following categories:

**4.3.1** -- Research conducted in established or commonly accepted educational settings, involving normal educational practices. NOT EXEMPT are any dissertation or thesis projects or any surveys of school children.

**4.3.2** -- Research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior, unless (1) information obtained is recorded in such a way that human subjects can be identified, directly or through identifiers linked to the subjects; AND (2) any disclosure of the subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability or reputation.

**4.3.3** -- In addition, research may be exempt if the human subjects are elected or appointed public officials or candidates for public office, OR federal statute(s) require(s) that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

**4.3.4** -- 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 way that subjects cannot be identified, directly or through identifiers linked to the subjects.

**4.3.5** -- Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate or otherwise examine (1) public benefit or service programs, (2) procedures for obtaining benefits or services under those programs, (3) possible changes in or alternatives to those programs or procedures, or (4) possible changes in methods or levels of payments for benefits or services under those programs.

**4.3.6** -- Taste and food quality evaluation and consumer acceptance studies, (1) if wholesome food without additives are consumed or (2) if a food is consumed that contains a food ingredient at or below the level and for the 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.

**4.4 Exclusions from Exemption** -- Research involving:

- Pregnant Women
- Fetuses
- Human In Vitro Fertilization
- Prisoners
- Survey/Interview Research involving children
- Observation of public behavior involving children (except when the investigator does not participate in the activities being observed.)
- N.B: Removal of some categories of exemption is being considered for research involving children and funded by the DOE.) [Cf. also OPHR Reports for particular guidelines for research involving AIDS studies.]

**4.5 Decision Regarding Exemption** -- is reserved to the IRB. Exemption will be determined by the IRB and entered as such in its records. Research or protocols not submitted to the IRB may not be designated "exempt."

**4.6 AN EXPEDITED REVIEW** -- may be accorded when research involves:

- The collection of hair, nails, teeth.
- The collection of excreta, etc.
- Routine non-invasive recording methods (if 18 yrs or older)
- The collection of no more than 450 ml. of blood by venipuncture (from healthy adults)
- The collection of plaque and/or calculus.
- Voice recordings
- Moderate exercise of healthy volunteers
- Existing data, records, specimens.
- Individual or group behavior or characteristics of individuals if subjects' behavior is not manipulated and does not involve stress.
- Drugs or devices (if IND or IDE not required)
- Minor changes in previously approved research.

**4.6 A CONTINUATION REVIEW** must be conducted if the research lasts longer than 12 months or whenever the degree of risk requires it. Full review procedures must be followed unless the research meets the expedited review criteria.

**4.7 A MODIFICATION REVIEW** is required whenever changes are made in previously approved proposals. This review may be through an expedited procedure if the changes are minor.

**4.8** A review may result in **DISAPPROVAL** -- whenever the IRB determines that the protocol fails to meet either federal or institutional criteria for approval.

**4.9 A FULL REVIEW** of a research protocol:

- Will be required if subjects will be deceived in any way.
- Must be conducted at a convened meeting.
- A majority of IRB members must be present
- A member concerned with nonscientific areas must be present.
- Must conclude that all requirements of 45 CFR 46.111 will be satisfied.
- A majority of IRB members must approve the proposal.
- IRB members with conflicting interest in the research project must remove themselves from participation.
- Must notify investigators and the institution of its decision -- approval, modification, disapproval.

**PART V. -- INFORMED CONSENT**

**5.1. Informed Consent** is constituted by adequate disclosure on the part of part of the investigator. Legally effective informed consent must:

- Be obtained from the subject or a legally authorized proxy.
- Involve disclosure in language understandable to the subject or the proxy. Normally this should be expressed in a "lay abstract," i.e., a 1-4 pp. overview of the research written in language comprehensible to a non-professional person with a 12<sup>th</sup> grade education.
- Be obtained in circumstances that afford the subject an opportunity to freely participate and that minimize coercion.
- May not induce the subject to waive legal rights or release the investigator, sponsor, or institution from liability for negligence.

**5.2 -- Adequate disclosure** in informed consent must:

- Explain that the study involves research, describe its purposes and expected duration of participant's involvement.
- Describe procedures to be followed and identify procedures which are experimental.
- Describe potential benefits to subject or others, as well as risks or discomforts.
- Disclose alternative procedures, if such exist.
- Describe the extent to which confidentiality will be assured.
- If more than minimal risk is involved, describe whether compensation and medical treatment are available if injury occurs.
- Name contact persons for questions regarding research, subject rights (with telephone number; this should include the Chair or Secretary of the IRB).
- Certify that participation is voluntary, without penalties or loss of benefits if subject chooses to withdraw, and that he\she may do so at any time.



**5.3** -- In addition, *an IRB may require* (45 CFR 46.116b):

- Notification that research may involve unforeseeable risks.
- Description of circumstances under which subject's participation may be terminated by the investigator without subject's consent.
- Enumeration of added costs to subject resulting from decision to participate in research.
- Statement that new findings developed during research which may relate to subject's willingness to continue will be provided to subject.
- Clinical consequences of subject's decision to withdraw from research, if any.
- Approximate number of subjects involved in study.

**5.4** *Exceptions when IRB may waive requirement of Informed Consent* or alter its elements if documented that:

- Research involves no more than minimal risk.
- Rights and welfare of subjects will not be adversely affected.
- Research is not practicable without waiver or alteration.
- Subjects will receive pertinent information after completion of research.
- Research is subject to state or local government officials and is designed to study, evaluate or examine public benefit of service programs or proposed changes in programs, procedures, methods or levels of payment.

**5.5 DOCUMENTATION OF INFORMED CONSENT** -- The researcher may use written form approved by the IRB and signed by the subject or a legal representative. In addition, the person signing the form must be given a copy of the consent form.

*Two types of consent forms are acceptable:*

**5.5.1** -- A written consent document that includes all the basic elements of informed consent.

**5.5.2** -- A short form which states that all elements have been presented orally to the subject. This form requires the following:

- A written summary of what is to be said which receives prior approval of the IRB.
- A witness at the oral presentation.
- The signatures of subject (or representative), witness and investigator.
- Copies of short form and summary given to subject (or representative.)

**5.6 WAIVER OF DOCUMENTED CONSENT**-- The requirement to obtain a signed consent form may be waived for some or all subjects if:

- The only record linking the subject and the research would be the consent document and the principal risk would be harm resulting from breach of confidentiality; each subject must be asked whether documentation is desired.
- The research presents no more than minimal risk and involves no procedures for which written consent is normally required.

Even in these cases the IRB may require investigator to provide subjects with written statement regarding the research.



## **PART VI. -- PROCEDURES FOR IRB REVIEW**

**6.1 – Time:** The schedule of IRB meetings must be respected in the submission of proposals for review.

**6.2 -- Documents** -- The following documents must be submitted at the time that IRB approval is sought (see online application form):

- Checklist for IRB Review.
- Signed consent form(s).
- Copy of written oral presentation (if short form approval is sought).
- Application form.
- Approval page with appropriate signatures

**6.3 *Notice of IRB action*** will normally be sent to the primary investigator within one calendar week following IRB review. The original of the approval page belongs to the investigator

## **PART VII. RECORDS**

**7.1** The primary investigator is responsible to keep original consent documentation for at least three (3) years from the date of termination of the research.

**7.2** The IRB keeps a record of all protocol actions and Board decisions.

## **PART VII. UNIVERSITY AND FEDERAL REGULATIONS**

Copies of the University Assurance of Compliance with OHRP, of the Text of Federal Regulations governing IRB procedure (45 CFR 46), and the Belmont Report are available from the IRB Chair, Newman Hall 244, ex 1440 or at the [IRB Web site](#) and at the [OHRP Web site](#).