Institutional Review Board (IRB) Application

Protocol Checklist

Please refer to the "Guidelines for Human Subjects Research" while filling out this application.

	Yes	N/A
1. Original application form and attachments	☐	☐
2. 3 additional copies of application (all with appropriate attachments; consent letters, institutional permission, research instruments etc)	☐	☐
*Please note that additional copies of this application and attachments may be requested if full board review is necessary		
3. Consent and permission forms; Assent scripts	☐	☐
Is the consent form on St. John's Dept. letterhead?	☐	☐
Is the purpose of the study clearly stated?	☐	☐
Are all investigators and faculty mentors identified?	☐	☐
Is there a clear description of what subjects are asked to do?	☐	☐
Is the amount of time required for participation stated?	☐	☐
Request to audio/video tape or photograph?	☐	☐
Right to review audio/tapes or photographs?	☐	☐
Are risks/benefits identified?	☐	☐
Is there an incentive or fee statement included?	☐	☐
Does the consent form state how confidentiality will be maintained?	☐	☐
Does the consent form state that participation is voluntary and participants can withdraw at any time?	☐	☐
Does the consent form include a statement of the	☐	☐

participants right to not answer questions they do not want to answer?

Is contact information included?	☐	☐
Principal Investigator?	☐	☐
Faculty mentor?	☐	☐
Institutional Review Board?	☐	☐

4. Samples of surveys, questionnaires, etc.	☐	☐
5. All required signatures	☐	☐
6. For recruitment did you include:		
how potential subjects will be identified and contacted?	☐	☐
recruitment letters, flyers or advertisements; scripts for oral requests?	☐	☐
7. Do you outline the procedures to be followed?	☐	☐
What participants will be asked to do?	☐	☐
Where the study will be held?	☐	☐
How much time participation will take?	☐	☐
Who will be working with the subjects?	☐	☐
Are there any participant incentives?	☐	☐
8. Do you discuss identity protection?	☐	☐
If anonymous, how will this be achieved?	☐	☐
If confidential, how will you code or otherwise protect identity?	☐	☐

Who will have access to the data?	☐	☐	
How will data be stored?	☐	☐	
Do you include information about disposition/destruction of data after completion of the study?	☐	☐	
9. IRB approval of cooperating institutions	☐	☐	☐ Pending
10. Permission of cooperating institution responsible for subjects to conduct research among its members	☐	☐	
11. Safety equipment check certification	☐	☐	
12. Signed Statement of Compliance	☐	☐	

Optional: In your judgment, this project/protocol falls within which Project Category

☐ Exempt (Expedited Review to Verify Exemption) ☐ Expedited Review ☐ Full Review

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.

_____

Principal Investigator (Print or type.)

Faculty ☐ Student ☐ Non-St. John's ☐

Please submit this form and all other material to:

Dr. Jeffrey Olson
Chair, St. John's University Institutional Review Board
Newman Hall, Room 230
St. John's University
8000 Utopia Parkway
Queens, NY 11439
Tel (718) 990-1440

Request for Approval of Human Subjects Research Application Form

OHRP Assurance # M1083
NB: All Applications must be typed.

For Office Use Only
Protocol # _____
Submission Date _____

Principal Investigator:
Address (for receiving approval):
Department: **Home Phone**
Project Title:
Co-Investigators:

For Student Research only:
Faculty Supervisor's Name:
Department: **Phone**

Signature(s)
I certify that all information contained in this application is accurate, that no other procedures affecting human subjects will be employed in this research and any modifications in this project that may have the potential to affect subjects will be submitted for St. John's University Institutional Review Board approval prior to use.

Principal Investigator_____**Date**_____

Co Investigators_____**Date**_____

_____**Date**_____

For Student Research only:
I certify that I will directly supervise this research and will assure that all provisions of approval will be faithfully employed by the investigator.

Faculty Supervisor_____**Date**_____

Academic/Administrative Review: All STUDENT projects submitted to the St. John's University Institutional Review Board must carry the signature of the department chair or administrative supervisor. **All applications require a dean's signature.**

Department Chair or Administrative Supervisor_____**Date**_____

Dean_____**Date**_____

Site(s) of Research: (See # 4, below).

Site Supervisor: **Phone**

Length of Study: **Starting Date**: **Length of Subject Involvement**:

Funding Source: ☐ **St. John's** ☐ **Fed/State/City Govt. agency**:

☐**Other**:

APPROVAL: The St. John's University Institutional Review Board has examined the human subject research protocol and finds the proposal acceptable
[ ] with the conditions attached; [ ] without conditions

EXEMPT_____**APPROVED**_____[**Expedited**_____] [**Full Review**_____]
Notification to IRB required when study is complete: **YES**_____ **NO**_____

_____ **Date**_____
Chair/Secretary/Member of IRB

NB: St. John's University Institutional Review Board approval of research projects is valid for **ONE YEAR ONLY**. Approval of the continuation of the research is possible on a yearly basis for two additional years. Beyond this period, a new proposal must be submitted.

Protocol

Completed applications must be received by the 15th of the month prior to committee review. All applications received after that date will be reviewed in the following cycle.

Please answer all questions on this form to the best of your ability. Most rejections or delays in approval of IRB protocols are results of the applicant's failure to provide clear and complete answers to each relevant question. Identification of subjects, consent process, and level of risk are especially important issues.

Do not attach a thesis or dissertation proposal. The IRB will return, without review, any proposal that does not follow the instructions. You may, of course, cut and paste appropriate text from a proposal if it answers the question. The spaces on this form will expand automatically to accommodate your responses in the appropriate spaces.

1. **Method (Check all applicable.)**

☐Files ☐Observation ☐Test ☐Treatment ☐Interview ☐Questionnaire
☐Task
☐Other: Explain

2. **Please indicate the category that best describes the present protocol**:

Faculty-supervised student initiated research:
Master's thesis:
Doctoral dissertation:
Faculty/Administrator research:
Other (please describe) :

3. Provide a brief description of the proposed research in **layman's terms** (you may attach.) Include an explanation of the purpose of the research and summarize the procedures to be used with subjects. Please include all proposed research procedures, e.g., how psychological or physiological intervention will be conducted, anticipated subject behaviors, investigator's behavior during procedure, etc.

NB: THE BOARD WILL NOT REVIEW ANY OTHER DESCRIPTION OF THE PROTOCOL EXCEPT WHAT YOU PROVIDE IN THIS FORM; DO NOT REFER TO AN ATTACHED COMPLETE DISSERTATION OR THESIS PROPOSAL. If you attach your dissertation/thesis proposal to answer this question or any other question in this form, your application will be returned without review.

4. **Who are the subjects you propose to involve in your protocol? Describe them (e.g., secondary school teachers; St. John's undergraduates; elderly residents of a nursing home; fourth grade math students, etc.):**

5. **Subject Demographics**:

Age range:

Gender:

Total number: (include control groups)

Protected classes:

Fetuses, pregnant women, or human ova in vitro fertilization:

Students:

Children:

Prisoners:

Mentally ill or persons whose decision-making capacity may be impaired:

Describe any unique or special characteristics of your proposed subject group:

6. How will subjects be selected for participation? (e.g. random sample, students in class, institutionalized population, etc.) If subjects are drawn from an institution or organization, **please document permission of institution. Copies of recruitment materials (flyers, advertisements, scripts etc) must be sent in for approval with this application.**

7. **Specify remuneration to be received by subjects, if any. (e.g. money, course credit, etc.). Please indicate specific amounts.**

8. Attach copies of all testing instruments, interview protocols, and questionnaires. Provide web address and hard copy of any Internet surveys. Fair Use copyright provisions are understood to apply to IRB protocol submissions (not to actual use of copyright instruments in research itself). If an excessive number of pages are involved, contact the Chair or the Secretary for direction. Include any explanatory or introductory material to be given to subjects.

9. Informed Consent: Provide a brief explanation of all information to be given to subjects participating in research. Please attach **a copy of Informed Consent Form, or explanatory oral summary of the project, which you propose to read to each subject if you wish to obtain Oral Informed Consent,** which is permissible only in certain low-risk protocols for non-protected populations (NB: A witness signature will be required if you use this method.)

****All consent/assent forms must be on St. John's University Department letterhead.** In the case of minors, **parental consent must be obtained in writing.** Explain how will you also obtain verbal *assent* from individual child subjects. Parental consent is a necessary but not sufficient condition of research with children; a child must be asked personally to participate and may refuse even if the parent has approved.

(NB: A copy of the signed consent form must be given to each subject or parent. The investigator retains the original signed form for 3 years.) See the online statement, "Elements of Informed Consent" and Guidelines for Human Subjects Research for contents of a consent process.

10. **Explain steps to be taken to safeguard subjects' right to confidentiality. What personal identifying indicators will be kept on subjects? (e.g. names, SS #, etc.) How will personal information be stored, who will have access to it, and when will it be ultimately disposed of? If audio- or videotapes are produced, subjects must know they are being taped. Note that the subjects' right to confidentiality is absolute. (Could the study be done anonymously? If so, confidentiality is moot.)**

11. **If another institution's IRB has reviewed this research, attach documentation of its approval or indicate the status of the review. Indicate clearly the role of the St. John's University researcher in any such protocol approved by other institutional IRB's.**

12. **If the subjects will come into contact with any mechanical or electrical equipment, document how a safety equipment check can be verified by the Chair/Dean/Safety Officer.**

13. **Risk/Benefit Analysis**

- **What benefits are anticipated for subjects themselves, society at large and human/scientific knowledge?**

- **What risks/discomforts are anticipated for subjects? (e.g. physical, psychological, social, legal).**

- **What consequences (e.g., psychological, physical, social) are anticipated or possible for subjects?**

- **What responses are available or planned to minimize any harmful effects or reactions during the study?**

14. **If this project proposes to use deception, explain why this is necessary to accomplish the research goals. While some projects may require it as an integral part of the research method, deception can never be justified simply for the convenience of the investigator. Explain in detail how and when subjects will be debriefed**.

IF YOU HAVE COMPLETED AN IRB CERTIFICATION WORKSHOP, PLEASE ATTACH A COPY OF YOUR CERTIFICATION.

Statement of Compliance*

If the Institutional Review Board approves this project, I agree to:

- ✓ Execute the research plan as described in this application protocol, including obtaining informed consent from all subjects by the process approved by the IRB.
- ✓ Submit any revisions required as condition of the IRB approval.
- ✓ Report to the IRB any change in the research plan, which may affect the use of human subjects, prior to its implementation.
- ✓ Report within 3-5 business days (of occurrence or notification by sponsor) to the IRB any problems, which arise in connection with human subjects including any serious and/or unexpected adverse events.
- ✓ Report progress to the Department Chairman and the IRB, as required, and apply for extension annually until the protocol is completed.
- ✓ Report to sponsors and agencies as required.
- ✓ Notify the IRB if, for any reason, the project is terminated prior to its expected termination date.
- ✓ Maintain records of research, including consent documents, for a minimum of three (3) years beyond the termination of the study or as specified by the funding agency/sponsor of the project.
- ✓ Submit all recruitment materials for IRB approval prior to use.

There may be random audits of research protocols by the IRB.

FAILURE TO COMPLY WITH ANY OF THE ABOVE REGULATIONS MAY RESULT IN CLOSURE OF THE STUDY.

I hereby assure compliance to the above and acknowledge responsibility for all activities and investigators involved in this project.

_____

Date **Signature of Principal Investigator** **Title**

IF YOU ARE A STUDENT please have your supervisor sign this document on the space provided below.

I have read the attached project description and the execution of the project has my endorsement. I understand that it is my responsibility as Faculty Supervisor to closely supervise research to ensure continued protection of human subjects.

_____

Date **Signature of Faculty Supervisor** **Title**

**IRB forms and Principal Investigator's Guide to Human Subjects Research have been adapted from materials developed by New York University, which received grant funding from the National Institutes of Health.