EXPEDITED/FULL REVIEW RESEARCH PROTOCOL FOR THE COLLEGE OF SAINT ROSE INSTITUTIONAL REVIEW BOARD FOR RESEARCH WITH HUMAN PARTICIPANTS

College policies and federal laws require that each research project involving studies on humans be reviewed with respect to: 1) the rights and welfare of the participants, 2) the appropriateness of the methods used to secure informed consent, and 3) risk and potential benefit of the investigation. Federal guidelines define research as a formal investigation designed to develop or contribute to generalizable knowledge and a human participant as an individual about whom an investigator (whether professional or student) conducting research obtains a) data through intervention or interaction with the person, or b) identifiable information.

Indicate below the type of review you are requesting (check one):

_____ EXPEDITED REVIEW (Submit original form/attachments plus 3 copies)

Research requiring an expedited review presents moderate psychological or physical risk to participants beyond that normally encountered in people's daily lives (see FAQ page on IRB website for more information on what is considered a risk). Asking participants to recall traumatic events or report sensitive personal information such as drug use or sexual behavior are examples of studies presenting a moderate risk to participants. Because of the potential for psychological or physical harm, researchers must develop procedures for mitigating the impact of these risks on participants, and ensure that participants provide informed consent. Therefore, the expedited review protocol form requires researchers to explain their procedures for obtaining informed consent, mitigating risk to participants, and maintaining confidentiality of the data, so that the IRB is able to determine if the rights and welfare of research participants will be adequately protected. Expedited protocols are reviewed by a subgroup of the IRB consisting of faculty representing the Schools of Education, Math and Sciences, and at least one other School.

Any research with minors or dependent adult populations will require an expedited review, unless it involves normal classroom procedures in a classroom setting (see the Exempt Protocol form for more details on this exception). With minors or dependent adults, generally both informed consent by a legally responsible party and assent by the participant are required.

OR

_____ FULL REVIEW (Submit original form/attachments plus 6 copies)

A full review is necessary for research in which the risk to participants is high and/or the risks may be difficult to mitigate. Research involving testing of a new medical or psychological therapy is an example of a study that would require a full review. The same issues are addressed as in an expedited review, but the entire IRB will meet to review the application. A full review will require two weeks for completion of the review process.

APPLICATION INSTRUCTIONS

For either type of review, applications must be typed or clearly printed in black ink. Completed applications (protocols including attachments, plus copies) should be submitted by 4PM Wednesday to the Math & Science Office in room 255 Science Center. Applications received after 4 PM Wednesday will be included in the review cycle beginning the following Wednesday. Incomplete protocol packets (or too few copies) will be returned, without review, to the researcher for completion. The expedited review process requires one week and a full review requires approximately two weeks. Researchers will be notified of denial or acceptance of their protocol following the committee's review. Researchers will be notified on Thursdays of IRB decisions.

Under some circumstances protocols may be approved contingent upon the provision of additional information ("approval pending" status). Under these circumstances, the additional information must be provided before approval will be given and data are collected.

Approved protocols remain active for one year from their approval date unless the researcher specifically indicates a shorter duration. Procedures extending beyond one year must be resubmitted to the IRB for an extension at the end of the first year. Any substantive changes in an approved protocol must first be subjected to review by the IRB before the changes are implemented.

All research involving human participants conducted under the auspices of The College of Saint Rose must receive IRB approval before the initiation of data collection. Investigators who have questions about the forms or the review procedures are invited to contact the Committee chairperson or any member of the IRB (members are listed on the IRB home page).

Attachment Checklist (Check only those items included):

- ❑ Project Description (Project Description Section II)
- ❑ Interview and/or survey questions (Project Description Section II)
- ❑ Descriptive statement (cover letter) or verbal script introducing interview and/or survey questions (Research Operations Section III)
- ❑ Copy of form used to obtain permission to acquire participants from different 'non-public' settings (Participant Population Section IV.B)
- ❑ Approval letter for access to records (Participant Population Section IV.D)
- ❑ Verbal script or letter for contacting participants (Participant Population Section IV.E)
- ❑ Informed consent form for independent adult participants (Informed Consent Section V.A)
- ❑ Verbal script for oral consent for independent adult participants (Informed Consent Section V.A)
- ❑ Parental and/or legal guardian consent form (Informed Consent Section V.B.1.a)
- ❑ Signed attending physician consent form (Informed Consent Section V.B.1.b)
- ❑ Other consent form permitting the inclusion of special participant groups (Informed Consent Section V.B.1.c)
- ❑ Informed assent form(s) or verbal script for oral assent or documentation indicating why informed assent/consent will not be obtained from special participant groups (Section V.B.2)
- ❑ Debriefing procedure (Section V.C.4)

Enclose a self-addressed stamped envelope or regularly accessed email address to expedite your notification. Applications can be delivered to room 255 Science Center or mailed to:

Human Subjects Research Review
Committee Attn: The Math & Science Office
School of Mathematics and Sciences
The College of Saint Rose
Albany NY 12203

The materials included in this packet, other forms, and FAQ's are available at www.strose.edu on the internet, click on Current Students & Faculty, then Institutional Review Board (IRB).

Certification: (to be completed by the primary investigator and/or faculty advisor)

I certify that the information concerning the procedures to be taken for protection of human participants is correct. I will seek and obtain prior approval for a substantive modification in the protocol and will report promptly any unexpected or otherwise significant adverse effects encountered in the course of study.

_____ _____
Signature of Primary Investigator(s) Date

In the case of student research, the application should be reviewed and signed by the faculty supervisor. It is the responsibility of the faculty supervisor to ensure that students have properly completed this form.

_____ _____
Signature of Faculty Supervisor Date

Approval: (to be completed by the IRB)

This research project has been reviewed according to college policy and has been approved.

_____ _____
Human Subjects Research Committee Chair Date

I. General Information:

A. Name: _____

B. Email Address: _____

C. Phone #: _____

D. Mailing Address: _____
(Please include a self-addressed stamped envelope if you wish to receive a hardcopy of the committee's decision)

E. Date of Application: _____

F. Dates of Project: From Date of Approval to _____ (not greater than 1 year)

G. Project Title: _____

_____

_____

H. Type of Project: _____ Faculty / Staff / Administrator Research

_____ Student Research

I. Department or College Unit: _____

J. School:

_____ Art & Humanities _____ Math & Sciences _____ Business _____ Education _____ N/A

II. Project Description including the following (clearly typed on a separate sheet and attached to this form):

A. A clear statement of the purpose of the research project.

B. A description of exactly what will be done to or for the participants.

C. A clear description of the methodology, including identification of variables, operational definitions, and experimental design when appropriate. If study involves interview or survey procedures, please attach actual scales and/or questions that participants will be asked.

III. Research Operations:

Check as many of the following as are applicable to your research:

_____ Obtaining information from archives or files.

_____ Observing, filming, video/audio-taping participant.

_____ Testing, questioning, surveying, interviewing, psychometric measurement. (Attach any descriptive statement/cover letter or verbal script that will be used to introduce the procedure to participants. Attach interview questions, survey questions, etc.)

_____ Changing participants through education, training, therapy, behavior modification:

_____ with the intent to produce change. _____ with no intent to produce lasting change.

IV. Participant Population:

A. Type and Number (mark all that apply):

1. Adults: _____
2. Minors (up to 18 years of age): _____ (Specify Age Range: _____)
3. Disabled: _____
4. Special Minority Groups: _____ (Please Define: _____)

B. Institutional Affiliation of Participants (mark all that apply):

1. No Affiliation*: _____ (Please specify where participants will be acquired: _____)
2. College of Saint Rose: _____
3. Other School* (please specify): _____
4. Prison* (please specify): _____
5. Hospital* (please specify): _____
6. Other* (please specify): _____

*Please attach the **signed** form granting permission from the appropriate source when acquiring participants from places other than common public spaces (e.g. principal, teacher, mall owner, prison warden, hospital chief).

C. Total Number of Participants: _____ (Note: the use of additional participants must first be approved by the IRB)

D. Describe how are participants chosen (records, classes, referrals, canvassing, etc; be specific). If participants are chosen from records, indicate who gave approval for use of records and attach approval letter.

_____

E. Describe how participants are to be initially contacted (ads, telephone, letter, sign-up sheet, classroom contact, etc.). Be specific. Attach appropriate documentation (e.g. copy of verbal script or letter).

_____

F. Will participants receive inducement before or rewards after the study? The issues to be addressed here are the extent to which: (a) compliance is voluntary, (b) the inducements are not excessive, and (c) participants can receive the inducement in other ways if they do not want to complete the research (in the case of extra credit or course credit)

No _____ Yes _____ Please explain if yes: _____

G. Will the identity of individuals who participate in the study be made a part of any permanent record available to a supervisor, teacher, or employer?

No _____ Yes _____ If yes, please explain and address the extent to which there is risk of an individual's participation (or lack thereof) changing the way a supervisor, teacher, or employer thinks of him/her and/or otherwise adversely affecting the participant, and how that risk is to be mitigated.

_____

_____

V. Informed Consent:

Documentation of procedures for obtaining informed consent is required for approval of your research by the IRB (unless the project is approved as having exempt status, see Exempt IRB Protocol Form). You must employ one of the following formats for obtaining consent:

1. A **written consent document** embodying all of the basic elements of informed consent as outlined below. This may be read to the participant or to his/her legally authorized representative (e.g. parents in the case of minors), but in any event, s/he or his/her legally authorized representative must be given adequate opportunity to read it. This document is to be signed and dated by the participant or authorized representative. **A sample copy of the consent form must be attached.** The researcher should retain all signed consent forms and store them apart from any data that is collected.

2. **Oral consent**, in which the participant is told about the basic elements of consent described below prior to the start of data collection. No signed document is necessary on the part of the participant. However, **a verbal script of the oral consent presentation must be attached**. (This method of obtaining consent is usually approved for low-risk research procedures.)

Informed consent, whether written or oral, should NOT include any language implying that the participant is made to waive, or appear to waive, any legal rights, or release the institution/agents from liability or negligence. Sample informed consent forms can be found on the Saint Rose IRB website. Basic elements that must be included in informed consent are:

1. A fair explanation of the purpose of the study.
2. Description of the procedures to be followed, including an identification of any procedures which are experimental.
3. Description of potential risks and/or discomforts reasonably to be expected.
4. Description of any potential benefits to participants and/or society reasonably to be expected.
5. A statement that participants should be over the age of 18 (if applicable to the study).
6. An offer to answer any inquiries concerning the procedure(s).
7. An instruction that the participant is free to withdraw his/her consent and to discontinue participation in the project or activity at any time without prejudice to the participant.
8. A statement of confidentiality.

A. General Informed Consent Procedure for Independent Adult Participants (if independent adult participants are not involved, skip to Section B):

Describe procedures used to obtain informed consent from the participant or justify why informed consent will not be obtained (e.g., in an unobtrusive observational study of naturally occurring, public behavior). If only partially informed consent will be obtained (e.g., in a deception study), justify this procedure and explain how risks to participants will be avoided. Attach a copy of the informed consent form or verbal script for oral consent.

_____

_____

B. Consent for Special Participant Groups:

Use of 1) clinical patients or 2) participants not able to give personal consent, for reasons of age (participants <18 years old), mental state, legal or other such status, requires both **informed consent by a legally responsible party and assent by the participant.**

1. Who will be providing consent/permission for participation of these participants? This is required in addition to assent of the participants. Please check all that apply, and attach a copy of the informed consent form.

   a. Parent and/or Legal Guardian: _____

   b. Attending Physician: _____

   c. Other (please specify): _____

2. Please attach a copy of the informed assent form(s) or verbal script(s) for oral assent. If you are not using assent procedures, please attach documentation indicating why. See the IRB web site for sample assent forms.

C. Assessment of Risk to Participants:

If you check YES to any of the statements below you should specifically justify the risk in your attached research description and complete section D below. Will your research involve:

	YES	NO
1. possible invasion of privacy of participant or family, including use of personal information or record?	_____	_____
2. the administration of physical stimuli other than auditory and visual stimuli associated with normal classroom situations?	_____	_____
3. deprivation of physiological requirements such as nutrition or sleep; manipulation of psychological and/or social variables? (e.g., sensory deprivation, social isolation, psychological stress)	_____	_____
4. deception as part of the experimental procedure? (if study involves the use of deception, the protocol must include a description of this fact and an attachment of the "debriefing procedure" which will be used upon completion of the study)	_____	_____
5. requesting information which an individual might consider to be personal or sensitive? (e.g., asking questions about sexuality, body image, criminal behavior, etc.)	_____	_____
6. the presentation to the participant of any materials which they might find offensive, threatening, or degrading? (e.g., failure feedback, offensive/disturbing pictures, etc.)	_____	_____
7. the requirement of physical exertion beyond normal classroom situations?	_____	_____
8. other (please specify): _____	_____	_____

D. Minimization/Mitigation of Risk to Participants:

If any of the items in section C have been checked “yes,” describe what precautions have been or will be taken to minimize and /or mitigate those risks. If you checked “no” for all items in section C, PLEASE INDICATE WHY THIS IS THE CASE.

_____

_____

_____

E. Confidentiality of Data:	YES	NO
1. Will any data be made part of any permanent record that can be identified with the participant?	_____	_____
2. Will any demographic information be collected for this experiment (e.g. age, sex, ethnicity, race, employment, height, weight, family, marital status, etc.) that will not be kept separate from other research data OR that may be linked to a participant's research results?	_____	_____

3. Describe the steps that will be taken to ensure the confidentiality of the data. Additionally, if “yes” was checked to question #2 above, please indicate if there is a risk of individual participants being identified due to small numbers of people in certain demographic categories, and if so, how the researcher will protect participants from being identified or linked to their data through their demographic profile.

_____

_____

	YES	NO
4. Will confidentiality be maintained indefinitely?	_____	_____

If yes, fully explain all of the following: the use of codes or pseudonyms; how and where data will be securely stored; and how and when data will be destroyed.

_____

_____