

## **Saint Joseph College Institutional Review Board**

The purpose of the Institutional Review Board (IRB) is to assure that all research involving human subjects, conducted under the sponsorship of the College, conforms to related state and federal regulations. Additionally, the IRB is charged with assuring that all human subjects research comply with the College's fundamental commitment to safeguard the rights and welfare of participants.

The review process is designed to fulfill those two purposes. It is intended to help the researcher comply with federal regulations in addition to protecting the welfare of human subjects. IRB review is required for all research involving human subjects conducted at Saint Joseph College, or under its sponsorship at another location. Review is also required for research carried out under the sponsorship of another institution if the research is performed at Saint Joseph College. This applies even if the study has already been approved by the IRB at the sponsoring institution. Finally, the policies apply to all research that is large or small in scale, short or long term, funded or not funded and conducted by any member of the College community including faculty, staff and students, provided the study involves the use of human subjects.

Required of all researchers is the submission of a certificate verifying completion of the Protecting Human Research Participants course offered by the National Institute of Health Office of Extramural Research with proposal submission. Access to the required NIH course can be found at the following URL: <http://phrp.nihtraining.com/users/login.php>. Prior to completing the certification course online, researchers may wish to read the [Belmont Report](#) as a means of gaining a fundamental knowledge of the issues and background need for protecting human participants.

If you have any questions or need assistance with Institutional Review Board policies or procedures please contact Dr. Rick Halstead at 860-231-5213.

## **Saint Joseph College Institutional Review Board**

### **IRB Board Members**

Members of the IRB serve to protect the welfare of human subjects, therefore all members possess the professional competence necessary to review specific research activities and are qualified to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice [45 CFR 46. 107]. Membership of the Saint Joseph College IRB consists of 4 faculty members, including the chair, and 1 community member with no affiliation with the College.

## **IRB Members 20010 – 2011**

Richard Halstead (Chair)  
Department of Counseling and Family Therapy  
860-231-5213  
[rhalstead@sjc.edu](mailto:rhalstead@sjc.edu)

Tonya Rondinone  
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Connie Tait  
External Community Member  
860-832-2401  
[taitc@ccsu.edu](mailto:taitc@ccsu.edu)

## **IRB Information for Those Anticipating Conducting Research**

### ***Responsibility of Researchers***

IRB policies are intended to protect the rights of human subject participants. However, researchers have the primary day to day responsibility of assuring protection. In addition to the ethical principles governing human participant in research (See The Belmont Report), researchers must abide by guidelines summarized below, and they are encouraged to consult additional guidelines provided by their respective disciplinary groups. Specifically, investigators are responsible for all of the following components of the IRB protocol.

1. Compliance with all state and federal regulations.
2. Adhering to all applicable policies and procedures of Saint Joseph College and any cooperating institution.
3. Obtain informed consent from all participants.
4. Minimize the negative effects of participation by careful research design.
5. Maintain confidentiality of all information obtained in the research process.
6. Supervise and train all staff and students participating in the study.

7. Obtain permission to conduct the study by submitting an adequately prepared proposal and submission form to the IRB along with a description of the research complete with supporting documents (e.g. permission from cooperating institutions).
8. Immediately notify the IRB and departmental chairperson(s) of any injury, physical, psychological or social - suffered by a participant because of his/her participation.
9. Keeping all records, documents and informed consent forms for at least three years, or longer if requested by the IRB.
10. Submit a final report to the IRB at the completion of the project.
11. Include one copy of each researcher's certificate verifying completion of the Protecting Human Research Participants course offered by the National Institute of Health Office of Extramural Research with proposal submission. Access to the required NIH course can be found at the following URL:  
<http://phrp.nihtraining.com/users/login.php>.

## **Categories of Review**

Depending on the level of risk associated with the research as determined by the IRB, a protocol may be classified as exempt from review, eligible for expedited review, or require a full review. An expedited review will be conducted by the IRB Chairperson or by one or more experienced reviewers designated by the Chairperson from among the members of the IRB. When evaluating the proposal, the reviewer or Chairperson has all of the authority of the IRB except that of disapproving the research. A research activity may be disapproved only after a review of the full committee [45 CFR 46.110]. A full review requires a meeting of the entire IRB.

## **Criteria for Exempt Proposals [45 CFR 46.110(b)]**

### **Part A (all items must apply):**

1. The research does not involve as subjects prisoners, fetuses, pregnant women, or the seriously ill, or mentally or cognitively compromised adults, including economically or educationally disadvantaged persons.
2. The research does not involve the collection or recording of behavior which, if known outside of the research, could reasonably place subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.
3. The research does not involve the collection of information regarding sensitive aspects of subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).
4. The research does not involve subjects under the age of 18 (except as they are participating in projects that fall under categories 1, 3, 4, and/or 5 in Part B).

**Category B2** (see below) studies that include minors can be eligible for expedited review.

5. The research does not involve deception.

6. The procedures of this research are generally free of foreseeable risk to the subject.

**Part B (at least one item should apply after elements in Part A have been satisfied):**

1. Research conducted in established or commonly accepted educational settings, such as: research on regular and special education, instructional strategies, or cognitive processes, or research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, or (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.

3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

4. 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: Public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in, or alternatives to, those programs or procedures; possible changes in methods or levels of payment for payment for benefits or services under those programs.

5. Taste and food quality evaluation and consumer acceptance studies: if wholesome foods without chemical additives are consumed, or if a food is consumed that contains a food ingredient at or below the level of safety and for a use found to be safe, or agricultural chemical or environmental contaminant at or below a 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 [45 CFR 46. 101 (b)].

**Criteria for Expedited Review**

**Part A (all items must apply)**

1. The research does not involve as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults, including economically or educationally disadvantaged persons.

2. The research does not involve the collection or recording of behavior which, if known outside of the research, could reasonably place subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

3. The research does not involve the collection of information regarding sensitive aspects of subjects' behavior (e.g., drug or alcohol, use illegal conduct, sexual

behavior).

4. The procedures of this research present no more than minimal risk to the subject. (Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).

**Part B (at least one item should apply)**

1. Research that collects data from voice, video, digital, or image recordings;
2. Research on individual or group characteristics or behavior, including but not limited to survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodology as follows:
  - a. Involving adults, where (i) the research does not involve stress to subjects, and (ii) identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation;
  - b. Involving children where (i) the research involves neither stress to subjects nor sensitive information about themselves or their family; (ii) no alteration or waiver of regulatory requirements for parental permission has been proposed; and (iii) identification of the subjects and/or their responses would not reasonably place them or their family members at risk of criminal or civil liability or be damaging to the financial standing, employability, or reputation of themselves or their family members.
3. Continuations of projects previously approved by the IRB if (a) no new human subjects are enrolled in the study, all research-related interventions on human subjects have been completed, and the research remains active only for long-term follow-up of subjects; OR (b) no additional risks to subjects have been identified or the remaining research activities are limited to data analysis.
4. Certain classes of clinical studies of drugs or medical devices (i.e., clinical studies of drugs for which a new investigational drug application is not required; or research on medical devices for which an investigational device application is not required or the device is approved for marketing and is being used according to approved labeling).
5. Research involving existing identifiable data, documents, records, or biological specimens (including pathological or diagnostic specimens), where these materials, in their entirety, have been collected prior to the research for a purpose other than the proposed research. These sources are not publicly available and, although confidentiality will be strictly maintained, information will not be recorded anonymously (e.g., use will be made of audio or video tapes, names will be recorded, even if they are not directly associated with the data).
6. Collection of data through use of the following procedures: (a) non-invasive procedures routinely employed in clinical practice and not involving exposure to electromagnetic exposure or electromagnetic radiation outside the visible range (i.e., not involving x-rays, microwaves, etc.); (b) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (c) weighing, testing sensory acuity, electrocardiography, electroretinography, echography, sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, doppler blood flow, and echocardiography; (d) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing involving subjects; (e) collection of blood samples by finger stick or venipuncture.

7. Continuations of projects that do not fall into the above categories, and have been previously subject to the Full Review process by the IRB, which has determined that the research involved poses not more than minimal risk, and no additional risks have been identified [45 CFR 46. 110 (b)].

### **Criteria for Full Review**

If ANY of these apply:

1. The research involves as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults, including economically or educationally disadvantaged persons.
2. The research involves the collection or recording of behavior, which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. The research involves the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).
4. The procedures of the research involve more than minimal risk to the subject (where "more than minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the proposed research is greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).
5. Any research that does not fall into any of the categories explicitly identified as qualifying for exempt or expedited status [45 CFR 46].

### ***Student Research***

Students attending Saint Joseph College (both undergraduate and graduate) are bound by these procedures and policies. Moreover, no applications to the IRB from either an undergraduate or a graduate student will be reviewed unless sponsored by a faculty or staff member familiar with the student and the proposed activity. The faculty sponsor must be familiar with proposal protocol and accept responsibility to oversee the research. All bound theses must include a copy of the IRB approval.

Course-related research does not fall under the purview of IRB policies except when the research is not a routine procedure that is employed on a regular basis in the course, or the research involves more than minimal risk, or involves subjects outside the university. In these cases, the complete application form, description of the research must be submitted to the IRB. The IRB discourages the use of one's own students as participants in research projects.

### ***Review of Continuing Research***

IRB-approved research that is continuing or has been changed must be re-reviewed at least annually depending on the level of risk as determined by the IRB. Research that has greater than minimal risk will be reviewed on a time table determined by the IRB. Approximately one month prior to the year anniversary of the IRB approval date, the investigator is expected to complete the Review of Continuing Research form and submit it to the IRB Chair. Continuing review is required for all research activities that are conducted on a repeated basis. If the scope of the research changes or deviates from the description originally provided to the IRB, investigators must submit a memo to the IRB Chair describing such changes. The changes will

be reviewed under the exempt, expedited, or full review process. Failure to comply with the continuing review process can result in suspension or termination of IRB approval for the project. After a proposal is underway, investigators must promptly report to the IRB Chair any unanticipated problems or adverse events that pose risks to subjects or others.

## **How to Submit a Proposal**

### **Submitting a Proposal to the IRB**

All researchers conducting human subject research that gathers or creates data from sources outside the public domain are required to submit their proposal to the IRB. While studies of information in the public domain do not require IRB approval, researchers are still expected to make every effort to protect the well being of individuals.

A review and approval of research activities will be made by the IRB only for studies sponsored by members of the faculty, staff, or administration of Saint Joseph College. In those instances where individuals from another institution wish to conduct research on the College's campus, a faculty member of the College must sponsor the application. Faculty or staff members must sponsor the research of students.

Any individual intending to conduct research involving human subjects, whether or not the research is supported by a grant, contract, or fellowship from any public or private agency, has the responsibility to submit a research application in order to determine whether the activities proposed require formal IRB review. The IRB determines exemption status. If a grant or contract application is involved, this application should be sent directly to the IRB and sufficiently in advance of the due date of the application in order to allow time for the review process, should it be deemed necessary.

When reviewing research proposals, the IRB is primarily concerned with protecting the rights and ensuring the safety of human subjects. The IRB will examine the research design only to the extent that it affects the rights or the well being of human subjects. In analyzing the risk/benefit ratio of a research proposal, both the stated goals and the scientific merit of the research can be considered. Therefore the research must be described to the IRB in sufficient detail to allow for adequate review of all aspects of the research. This description must be submitted with the proposal submission form, consent form and other supporting materials. Investigators are strongly encouraged to utilize the Saint Joseph College IRB standardized templates for proposal submission and informed consent. The components of the research proposal should include:

- A purpose statement including rationale and aims
- A description of the participants, including sampling procedures
- A full description of all procedures and instruments (include copies of all questionnaires and surveys)
- Informed consent forms

Submit all required information to: Dr. Richard Halstead  
Chair, IRB  
Saint Joseph College  
1678 Asylum Avenue  
West Hartford, CT 06117  
[rhalstead@sjc.edu](mailto:rhalstead@sjc.edu)  
860-231-5213

**Saint Joseph College Institutional Review of Research Employing Human Participants  
Proposal Submission Forms**

This form should be completed by any principal investigator who is proposing to conduct a study with human subjects. It should be forwarded with five copies of the proposal to the IRB. The investigator should complete all and attach a copy of the submission form to each proposal as a cover sheet. One copy of each researcher's certificate verifying completion of the Protecting Human Research Participants course offered by the National Institute of Health Office of Extramural Research (<http://phrp.nihtraining.com/users/login.php>). Please allow 7-10 days for expedited review and up to 30 days for proposals requiring full board review. A letter providing the results of the review will be sent within 24 hours after the review has been conducted. Forward the copies of the proposal with the submission form attached to:

Dr. Richard Halstead  
Chair, Human Subjects Committee  
Saint Joseph College  
1678 Asylum Ave  
West Hartford, CT 06117.

**Part A**

Project Title: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_

Street Address:  
City, State, Zip Code  
Department:

Check one of the following:

\_\_\_\_ Saint Joseph College faculty member      \_\_\_\_ Saint Joseph College staff member  
\_\_\_\_ Saint Joseph College student              \_\_\_\_ Other: please explain

If you are a student conducting this research, provide the following information:

Major advisor:  
Campus Address:  
Campus Telephone

Has this research proposal been approved by the thesis or research committee of the department or division?      \_\_\_\_\_yes      \_\_\_\_\_no

- or -

Has this research proposal for an academic class been approved by the teaching faculty member?  
\_\_\_\_\_yes      \_\_\_\_\_no

**If this proposal has not yet been approved please do not submit it for IRB review. It will not be reviewed until this requirement has been met. Please have advisors sign below**

Advisor/Professor: \_\_\_\_\_ Date \_\_\_\_\_

All researchers must respond to the items below:

1. If this research involves the use of human subjects or data governed by other institutions, attach evidence of approval granted to you by the appropriate IRB or authority of that institution which permits your use of the subjects or data.
2. Does your research involve subjects younger than 18 years of age?  
yes (requires full committee review) no

On an attached page, provide information that addresses each of the following issues:

- a. Briefly describe the purpose of the proposed study.
- b. Provide a description of the sample that will be used in this study.
- c. Briefly describe of procedures, including sample selection, sample size and time commitment expectations.
- d. Provide a sample of your informed consent form or information sheet. See Informed Consent Form Criteria below. Be sure that each area is addressed prior to submission of you proposal materials.
- e. Provide an assessment of risk of harm to participants in your study. (Note: There is always some risk to a study participant. Even if risk levels are minimal be sure to provide a detail explanation. Do not submit a proposal stating, "There are no risks to participants.")
- f. Describe any benefits for the participants or others as a result of this study and/or the potential information/knowledge that it may reveal.
- g. Attach a copy of all surveys, measures, and/or questions intended for use in addressing variables and/or area(s) of interest in the study
- h. Indicate the type of proposal classification that you are requesting. Please check one of the categories below:  
 Exempt Review Status  
 Expedited Review Status  
 Full Committee Review

I attest that all information stated in the Proposal Submission Form is true:

\_\_\_\_\_ Date \_\_\_\_\_

Signature of Principal Investigator (PI)

**Note:** The PI of the study is the person who will actually be the person conducting the study.

## Consent Form for Participation in a Research Project Saint Joseph College

1. Name of Principal Investigator (or faculty sponsor)
2. Student Researcher (if applicable)
3. Study Title
4. Invitation to Participate (please be specific that this is a research study)
5. Purpose of the Study
6. Description of Procedures (be specific about any experimental procedures)
7. Risks and Inconveniences (include time commitment)
8. Benefits (this does not include compensation)
9. Confidentiality (include a statement in this paragraph that says “You should be aware that the Saint Joseph College Institutional Review Board may inspect study records as part of its mission to protect the safety of research participants”).
10. Voluntary Participation
11. Contacts for Additional Information (Note: Be sure to include the following two sentences in your form: “If you have any questions about your rights as a research participant, please contact the Saint Joseph College Institutional Review Board (IRB) at 860-231-5213. The IRB is a group of people that reviews research studies and protects the rights of individuals who agree to participate in research studies.”)
12. Authorization (include a statement that says “I have read this information and have had the study purposes, procedures, risks and benefits explained to my satisfaction. My signature indicates my informed consent to participate in the study. I acknowledge that I have received a copy of this consent form.”)

### Signatures

Name of Participant \_\_\_\_\_ Date \_\_\_\_\_

Participant or Parent \_\_\_\_\_ Date \_\_\_\_\_

Primary Investigator \_\_\_\_\_ Date \_\_\_\_\_

Faculty Advisor if Applicable \_\_\_\_\_ Date \_\_\_\_\_