IRB POLICIES AND PROCEDURES
Investigator Manual

Saint Joseph's University
Institutional Review Board for the Protection of Human Subjects in Research of Saint Joseph’s University
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INTRODUCTION

What is Human Subjects Research?

**Research** is defined by the regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." The regulations further specify "activities which meet this definition constitute research, whether or not they are conducted or supported under a program which is considered research for other purposes.

**Human Subject** is defined by applicable Federal regulations (45 CFR 46.102(f)) “as a living individual about whom an investigator conducting research obtains:

1. Data through intervention or interaction with the individual, or
2. Identifiable private information."

This manual provides the necessary procedures that must be followed and the forms that must be submitted to conduct human subjects’ research at Saint Joseph’s University. The information found in this manual is based on the principles found in the Belmont Report and the Code of Federal Regulations Title 45 part 46, Protection of Human Subjects. These regulations apply to all research involving human subjects conducted under the auspices of a department or institute within Saint Joseph’s University, regardless of funding status.

All research involving the use of human subjects must be approved or declared exempt from any further review by the University Institutional Review Board (IRB). To submit a project for review, the researcher must complete an IRB Protocol form and send the form with original signatures and all supporting materials to the IRB for review. Research involving the use of human subjects cannot commence until approval or exempt status is received from the IRB. **There are no exceptions to this rule.**

**Classroom Research Training Activities** Class assignments or projects may have a research component or constitute training in research methodology. Classroom projects that are used exclusively for instructional purposes need not undergo review by the IRB. However, instructors are encouraged to follow federal guidelines and University regulations when designing and conducting class projects with human participants.

If the data collected for a class assignment is collected outside of the classroom or may be used in future research activities, publications or presentations by the investigators, faculty, or staff at Saint Joseph’s University or by individuals in another institutional setting, an IRB review is required prior to data collection. The IRB Administrator is available for consultation regarding class projects should questions arise.

Overview

Human Subjects Research is subject to three categories of review: **Full IRB Review**, **Expedited** IRB Review and **Exempt** from further IRB Review.

A decision as to whether a proposal is Exempt from further IRB review, or is subject to Full or Expedited IRB review will be made by the IRB Chair and/or Administrator. The PI and/or the FA will be notified as soon as possible if there is a change in the initial decision on review level. If it is decided that Full board review is required, the PI will be responsible for providing an additional 14 copies to the Office of Research Services (ORS) for review by the IRB. The ORS is located at 215 City Avenue.
Protocols which undergo Full or Expedited review and receive IRB approval are subject to continuing review. This continuing review must be done at least annually to retain IRB approval. An Annual Renewal form must be submitted to the ORS before the one year expiration date which will be noted on the approval letter. Failure to submit an Annual Renewal can result in the study being stopped. If there is Grant Project funding, it is possible that funding may be lost. The SJU IRB has the authority to suspend or terminate approval of research which is not renewed annually. This action will include a statement of the reasons for the IRB’s action and shall be reported promptly to the investigator, appropriate institutional officials, and the Department or Agency head.

If IRB approval is necessary for a grant application, the PI should submit a protocol for review in time to report the decision of the IRB on the grant application. Some agencies for which IRB approval has not yet been received may continue submission of their grant application. Approval is generally required to be sent in writing to the funding agency prior to the start date of the research. Note: Not all funding agencies will allow this. Consult with the guidelines of the agencies or with the ORS for information.

**IRB Membership and Scheduled Meeting**

The composition of the IRB is governed by the federal regulations and the University’s Federal Wide Assurance. The Saint Joseph’s IRB consists of 15 members. Fourteen of the members are taken from the Saint Joseph’s faculty and staff. There is one non-institutional member on the board who serves as a community representative. The members of the IRB represent multiple professional, ethnic and gender backgrounds.

As of September 1, 2007, the SJU IRB members are:
- Philip Schatz – Psychology, IRB Chair
- Edward Balotsky– Management
- Kim Logio – Sociology
- Deirdre Guion – Management
- Melissa Logue - Sociology
- Jennifer Ewald – Foreign Language and Literature
- Jeffrey Hyson – History
- Josephine Shih – Psychology
- Andrew Payne, Philosophy
- Mark Reynolds – Chemistry
- Althier Lazar – Education
- Beth Hagovsky – Student Leadership
- Sally Black- Health Services
- Gary King – Non-affiliated member
- Jena Fioravanti Burkett - IRB Administrator

Meetings of the IRB are held in Post Hall 322, on the third Thursday of each month from 11:30 to 1:00.
APPLICATION GUIDELINES

Any questions about protocol submission and Human Subjects research should be directed to the IRB Administrator, Jena Fioravanti Burkett, Office of Research Services, at (610)660-1298, or via email at irb@sju.edu.

Required Materials for Submission

The initial review process is begun by the submission of an IRB Human Subjects Research Protocol Application Form, informed consent document, and any research instruments to the Office of Research Services. Proposals must be submitted for all research involving human subjects, where research is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (45 CFR 46.102(d)). (Neither pilot nor regular studies can be run until IRB approval or exemption by the IRB is received)

All persons involved with the research protocol must complete training in Human Subjects Research. The University uses the Collaborative Institutional Training Initiative (CITI) online program, which may be accessed at https://www.citiprogram.org/default.asp. Proof of completion should be included with application materials, for the file. The PI and FA must also provide the most recent copy of their Curriculum Vitae or resume to be added to the protocol file. If the research will involve data collection from an institution other than Saint Joseph’s University, a letter of support must be provided by that institution.

Below is a list of all items needed at the time of submission:

- Proof of Human Subjects Training for anyone involved with research protocol (Valid for only 2 years)
- Curriculum Vitae or Resume for anyone involved with the Research protocol (PI, FA, Co-Investigators)
- IRB Human Subjects Research Protocol Application Form with all questions answered, Signed by the PI, FA and Department Chair
- Informed Consent Document following the Template found on the ORS website.
- Research Instruments (Recruitment Flyers, Questionnaires, Interview Guides, etc....)
- Letters of support or approval from performance sites where data will be collected on appropriate letterhead (i.e., some research requires school district or organization permission).

Principal Investigator must submit the ORIGINAL COPY of the protocol form with the ORIGINAL SIGNATURES, Informed Consent Form, questionnaires and any other items relating to the protocol, to the IRB Administrator at the Office of Research Services, along with:

2 copies of complete proposal for EXEMPT or EXPEDITED Review.
14 copies of complete proposal for FULL IRB review.

The complete proposal includes the protocol application form, informed consent document, questionnaires and other documents necessary to conduct the research. Please submit by the 1st working day of the month in which the review results are needed. The IRB Administrator will contact the principal investigator if additional information or data is needed. The proposal will be retained in the Office of Research Services, 215 City Avenue, (610)660-1298.
Route of Submission

All research conducted at Saint Joseph’s must be associated with a department on campus. The Principal Investigator and the chair of the department endorsing the protocol must sign both the cover sheet and the investigator’s assurance.

If the Principal Investigator is a student, they must be sponsored by a Faculty Advisor. The FA also must sign both the cover sheet and the investigator’s assurance of the proposal regardless of the level of review. The FA is expected to work closely with the student, monitoring the procedures and progress of the research project. This individual is responsible for ensuring that the student researcher complies with all of the conditions of the approval, and must sign the assurance form certifying that the project is under his/her supervision. The FA will be included in all communications sent by the IRB and is expected to assist the student PI throughout the research project ensuring their compliance to the approved research protocol.

Ethical Principals

Regardless of the type or review a protocol undergoes, every researcher must read and agree to abide by the Standards of Research with Human Participants found at the front of this manual, as well as all principles and standards endorsed by the University. The signatures on the Investigator’s Assurance found on the last page of the Protocol form attest to the fact that all relevant personnel have read and agree to these standards.

As the Principal Investigator it is your responsibility to:

- Ensure that you, as well as anyone involved with the research project, have received human subjects training.
- Ensure that this research and the actions of all project personnel involved in conducting the study will conform with the IRB approved protocol, IRB requirements/policies, and all applicable HHS regulations.
- Ensure that valid informed consent/assent has been obtained from all research subjects or their legally authorized representatives. Also to ensure that all project personnel involved in the process of consent/assent are trained properly and are fully aware of their responsibilities relative to the obtaining of informed consent/assent according to the IRB guidelines and applicable federal regulations.
- Inform the IRB of any unanticipated adverse event or injury no later than two (2) business days following the time it becomes known that a SJU subject suffered an adverse event/injury.
- Refrain from initiating any change in protocol without IRB approval except when it is necessary to reduce or eliminate a risk to the subject, in which case the IRB will be notified as soon as possible.
- Maintain all required research records on file and recognize that the IRB is authorized to inspect these records.
- Inform the IRB immediately of any significant negative change in the risk/benefit relationship of the research as originally presented in the protocol and approved by the IRB.
- Understand that IRB approval is valid for a maximum period of one (1) year, unless Exempt from continuing IRB review, and that for Expedited and Full IRB approvals, review by the IRB is required at least annually in order to maintain approval status.
- Inform the IRB immediately if PI becomes aware of any violations of HHS regulations (45CFR46), or IRB requirements for the protection of human subjects.
- Understand that failure to comply with all applicable HHS regulations, IRB requirements/policies and the provisions of the protocol as approved by the IRB may result in suspension or termination of my research project.
Conflict of Interest

All Investigators must reveal on this application whether they or any other person involved in this research has a conflict of interest, which would reasonably appear to affect their conduct of this research project. Where any member of the IRB is personally involved in the research, that individual cannot participate in the review or approval of the research by the IRB (an alternate member should be appointed to act in their stead during the review process for the proposal involved.)

Training

Federal regulations require Principal Investigators submitting their first research protocol to receive training in the involvement of human subjects in research projects. To meet these requirements at Saint Joseph’s all Principal Investigators, Faculty Advisors, and others involved in the research process (not including participants) must provide evidence of having completed training in Human Subjects research.

The University utilizes the Collaborative Institutional Training Initiative’s (CITI) online program, which may be accessed at https://www.citiprogram.org/default.asp. It is designed to educate researchers so as to prevent abuses of persons volunteering in research. The basic course will require several hours to complete. Investigators are encouraged to use multiple sessions, as the username and password you create will allow you to log in and out of the training as needed. It is the responsibility of the PI to ensure that anyone involved with the research project in any way is identified to the IRB and has received Human Subjects Training. Training is valid for a 2 year period. If a PI has received Human Subjects training at another institution, they must provide documentation to the IRB Administrator. Research may not commence until documentation of Human Subjects training has been given to the IRB Administrator.

Protocol Approval Timeline

- Protocols submitted for Exempt Review will generally be processed within two (2) weeks.
- Protocols submitted for Expedited Review will generally be processed within two (2) weeks.
- Protocols submitted for Full Review must reach the Office of Research Services by the first working day of the month to be reviewed at the convened IRB meeting for that month. That meeting is held on the third Thursday of each month. The PI will be notified of the status of his/her protocol by following Monday.

* Please Note: Delays may be incurred if protocols are submitted incomplete.

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<thead>
<tr>
<th>Types of IRB Review</th>
<th># of copies needed</th>
<th>Review Duration</th>
<th>Renewal Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exempt</td>
<td>Original and 2 copies</td>
<td>2 weeks</td>
<td>No renewal needed</td>
</tr>
<tr>
<td>Expedited</td>
<td>Original and 3 copies</td>
<td>2 weeks</td>
<td>Annual Renewal/Final Report needed</td>
</tr>
<tr>
<td>*Full</td>
<td>Original and 14 copies</td>
<td>4-6 weeks</td>
<td>Annual Renewal/Final Report needed</td>
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*Must be submitted by the first working day of the month to be reviewed at the monthly IRB meeting.
**IRB FORMS AND SUBMISSION PROCEDURES**

The Research Protocol – Request for Approval Involving Human Subjects forms can be downloaded from the ORS Web site. [http://www.sju.edu/offices/research/](http://www.sju.edu/offices/research/) All forms are also available in the Office of Research Services, located at 215 City Avenue in Room 27. The IRB Administrator is available if any assistance is needed during the protocol submission process. The IRB Administrator can be contacted by telephone at (610)660-1298, or e-mailed at irb@sju.edu. **NOTE: ALL FORMS MUST BE TYPE WRITTEN. FORMS THAT ARE HAND WRITTEN WILL BE CONSIDERED INCOMPLETE AND SENT BACK TO THE PI/FA FOR COMPLETION.**

**Instructions for Preparing the Protocol Application Form**

Every request for review of research involving human subjects must be typed. Hand written applications will not be accepted for review. Every question on the Protocol Application must have a response. If any question does not apply to your research project, answer with NA for not applicable.

**Specific Items**

1. **Item 1.** Type the name of the Department the PI/FA reports to and the date of protocol submission.

2. **Item 2.** Type the contact information for the PI, the FA and any other personnel who will be involved with the protocol. Check off whether all persons involved have received Human Subjects training. Arrangements must be made with the IRB Administrator to receive training or to provide documentation of previous training. Provide a copy of a Curriculum Vitae or Resume.

3. **Item 3.** Type the complete title of the project. If the project is being funded by an outside sponsor you must provide the name and address of the agency who is planning or who has already provided funding for the project.

4. **Item 4.** Type the dates that you will conduct this research project. The dates should include both data collection and data analysis. The beginning date for your project cannot predate IRB approval.

The items in the gray box will be filled in by the IRB once the protocol has been reviewed.

5 – 12 on the Protocol Form

The responses to all of the items below should be concise and avoid technical jargon as much as possible. Keep in mind that the protocol will be read by individuals outside of your specialized field. Unless otherwise indicated, all questions must be answered for specific projects. Remember to answer questions that do not apply to your research, as not applicable (NA).

5. **Item 5. Project Purpose.** Summarily describe the project, the purpose of the research, and what you hope to learn or demonstrate. Indicate what subjects will be told, what will be done to them, and what they will have to do.

6. **Item 6. Characteristics of Potential Subjects.** Answer parts A – E of this section. Use NOT APPLICABLE (NA) when a response would not apply to a particular study. If the subjects are from a special population, such as children, prisoners, and the mentally or physically disabled, or are institutionalized, particular care is required to see that their participation is not coerced and their rights are protected. If advertisements will be used to recruit subjects, copies of the ads must be included with the proposal.

7. **Item 7. Experimental or Research Procedures.** Answer part A – F of this section. Use NOT APPLICABLE (NA) when a response would not apply to a particular study. This section provides a
comprehensive description of the research methodology including how results will be analyzed and how subjects may be affected by the research design. Append copies of all non-standard tests and all questionnaires. Provide citations to standardized materials.

Describe the nature of any illegal activities that may be involved.

If deception is involved, indicate its nature, why it is necessary, and the form that subsequent debriefing will take. When deception is involved the investigator incurs a special responsibility to protect the rights and welfare of the subjects. The use of deception in no way obviates or reduces the need for informed consent. Deception includes not only the presentation of false information to subjects, but also the intentional withholding of information in a manner destined to mislead subjects. Under no condition can deception involve the withholding or falsification of information likely to affect the willingness of subjects to participate in the research.

If monetary payment is used, it may be considered a benefit to the subject. However, neither the amount of payment nor the method of disbursement should present problems of coercion or undue influence. Such problems might occur, for example, if the entire payment were contingent upon completion of the study or if the payment were unduly large.

**Item 8. Consent Procedures.** Informed consent must be obtained from each subject who is legally, mentally, and physically able to provide it. The consent may be written or oral. A copy of the consent form must be included with the proposal submission. All PI’s must use the Informed Consent Template found on the ORS website.

Certain cases may allow the use of oral informed consent. PI’s must submit a copy of the written statement that will be given to participants.

For subjects not able to provide informed consent themselves, written informed consent must be obtained from others (e.g., parents, guardians, etc).

In all cases, describe how informed consent will be administered. If the subjects are children or mentally challenged, describe how their assent will be obtained. (Under certain conditions the IRB may waive the informed consent provision based on federal regulations).

**Item 9. Data Confidentiality.** Preserving subject anonymity and confidentiality is crucial to achieving compliance with the criteria under which consent is given. The PI should give details on how they plan to maintain data confidentiality or anonymity during the research and how they plan to destroy data, once the research is completed. If a researcher wants to retain data for further use, they must remove any identifying information from all data collected.

**Item 10. Risks/Discomforts to the Participants.** Subjects are at risk if exposed to the possibility of physical, mental, or social discomfort and or danger, or otherwise beyond minimal risk. “Minimal risk” means that the “probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.” (Title 45 Code of Federal Regulations 46.102(i))

If subjects will be placed at risk, describe all steps taken to minimize risk, and if necessary attach a justification for these procedures based on the scientific literature.
**Item 11. Benefits of the study.** List the possible benefits that can reasonably be expected to result from your research project. Examples of benefits can be those experienced directly by the participants or a contribution to the body of generalizeable knowledge in the area of your study.

**Item 12. Investigator’s Assurance/ Signatures.** This section highlights the responsibilities of the PI and the FA. The Investigator, Faculty Advisor and Department Chair must read and sign the Investigator’s Assurance.

**Submission Procedures for Class Projects**

A class project refers to research studies involving human subjects to be conducted by a classroom full of students in fulfillment of a course requirement, where multiple students are conducting similar studies.

If the data collected for a class assignment/project may be used in future research activities of the investigators, faculty, or staff at Saint Joseph’s University or by individuals in another institutional setting, an IRB review is required prior to data collection. The IRB Administrator is available for consultation regarding class projects should questions arise.

1. The Faculty Advisor (FA) will prepare and endorse a Research Protocol – **Class Projects** acting as Principal Investigator (PI) for groups of similar studies assigned as a class project.

2. Each student conducting a research study under the protocol, will prepare and attach a one page summary of his or her study, including a description of the study, the research design, and sequence of activities. A copy of the consent form, questionnaires, or other interview materials must also be included.

3. The FA will assign a study number to each student project. (Student Project 1, Student Project 2 etc...)

The FA will complete all remaining protocol questions, and append student project descriptions, consent forms, and other materials before submitting to the Office of Research Services for distribution to the IRB.

**Protocol Amendments/Consent Form Changes**

The Principal Investigator is responsible for reporting to the IRB and all changes that may occur to the approved research protocol. This can be done by submitting a Protocol Amendment/Consent Form Change to the Office of Research Services. This form should be submitted along with a copy of the original protocol with tracked changes, as well as copies of new consent forms and/or other documents that have been revised.

Minor amendments or modifications can be made to previously approved research protocols. The PI must submit any proposed modifications of a research project to the IRB Administrator.

The IRB may use expedited review procedures to review minor changes in ongoing, previously full IRB approved research during the period for which approval is authorized. The IRB Administrator or chair will perform an expedited review of the submitted changes.

When a proposed change in research study is not minor, (e.g., procedure involving increased risk or discomfort are to be added) then the IRB must review and approve the proposed change at a convened meeting before the change can be implemented. The only exception is a change necessary to eliminate apparent immediate hazards to the research volunteers. In such a case, the IRB should be promptly
informed of the change following its implementation and should review the change to determine that it is consistent with ensuring the subject’s continued welfare.

Any proposed change must be approved by the IRB before it can be implemented into the procedures of the research project.

**Adverse Events and Other Unanticipated Problems**

The IRB is charged with the responsibility of reviewing reported unanticipated problems involving risks to subjects and adverse events in accordance with federal policy. Investigators are responsible for informing the IRB of any adverse event and/or unanticipated problem involving risks to subjects in accordance with federal regulations.

A PI must report any adverse event or unanticipated problem resulting during research to the IRB as soon as they are aware of any problem. Call the IRB administrator at (610) 660-1298 to begin the reporting process. This contact information should also be given to any participant who reports adverse reaction during the project.

An **Adverse Event/Unanticipated Problem** form must be submitted immediately after an Adverse Event is experienced. An additional attachment may be included, if necessary, to provide details of the unanticipated problem that has occurred.

This form should be used to report single adverse events. The PI should complete all information on the form. The PI should include an attachment which elaborates on the nature of the adverse event involving the conduct of the study or subject participation. These events may include problems with the recruitment and/or consent processes and any deviations from the approved protocol in a letter attached with this form.

The SJU IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB requirements or that has been associated with unexpected serious harm to subjects. Not reporting an Adverse Event to the IRB could result in suspension or termination of the IRB approval for your protocol. If the IRB decides to suspend or terminate approval of a project, the IRB shall report its decision promptly to the investigator, appropriate institutional officials and federal department or agency head (if federally funded). The IRB report must include a statement of the reasons for suspension or termination.

**Annual Renewal/Progress Report**

**Annual Renewal/Progress Report** refers to the annually required renewal of IRB approval of research still in progress. The report should provide a summary of the status of the data collection, and of any problems encountered in collecting the data.

An **Annual Renewal/Progress Report** form will be sent by the IRB Administrator to the PI and the FA, if the PI is a student, approximately 60 days prior to the expiration of IRB approval of each specific project or protocol change.

Periodic review of research activities is necessary to determine whether IRB approval should be continued or withdrawn. The IRB will determine the intervals between review periods based on the level of risk involved with the research. All research must be reviewed at least annually.

An annual renewal is required for all continuing projects that received Full or Expedited review, but is not necessary for research projects that have been exempted from further review. If a protocol received Full review at the initial review, it will most likely require a Full review for Annual Renewal.
All items listed on the **Annual Renewal/Progress Report** Form should be completed by the PI and/or FA.

An IRB re-approval allows the research project to continue for another year. In order to facilitate IRB continuing review of your project and to avoid unnecessary delays, please ensure that each applicable section of the Application form in completed according to the instructions. Information must be provided in sufficient detail to allow the IRB to perform the required review. Failure to provide all necessary information may delay IRB re-approval of your protocol and could result in a suspension if there is not sufficient time for the IRB to complete its review before the 12 month expiration of approval. Federal Regulations prohibit the IRB from granting extensions on a temporary approval. Should suspension occur, all subject accrual must cease as of the date of suspension. In addition, research related procedures can no longer be performed on human subjects who are currently enrolled in the study for follow-up or other reasons unless this restriction represents a health hazard to the subjects. In this case, the IRB will grant an exception upon receipt of a written justification.

The PI should submit the signed, original of the IRB Application for Annual Renewal and attach a copy of the most recently approved protocol, informed consent form and research instruments that are being used. All signed consent forms collected up to this point in the research should be submitted at this time as well. Annual Renewals should be submitted on the First of the month which IRB approval is due to expire.

**Final Report/Study Completion**

Upon completion of data collection and data analysis, all PI’s must submit a **Final Report** for the research study.

The PI must complete all information on the Final Report form. At this time, all signed Informed Consent forms should be returned to the IRB office. The PI should also submit a copy of the research paper or presentation that has resulted from the study.

The Final Report asks for demographic information for the subjects involved in the study and the occurrence of any adverse events during the research study.
INFORMED CONSENT

Informed consent must be obtained from each subject who is legally, mentally, and physically able to provide it. There is an Informed Consent template that should be used for all protocols. This template can be found on the ORS website. The consent form must be in written form and signed by the subject (or his/her authorized representative) unless the IRB determines either Oral Consent or a Waiver of Documentation may be used. There are certain situations where a waiver of consent documentation may be requested. Refer to item B below, Waiver of Consent Documentation for more information.

For subjects such as minors, mentally challenged persons, prisoners etc... who are not able to provide informed consent themselves, written informed consent must be obtained from the subject’s legal representative. In most of these cases assent will also be sought from the actual participants. There is an assent template on the ORS website to be used as a guide for this purpose.

Written Consent

The essential elements that must be included in a written consent form are provided below. A written consent form should include the elements below and it should relate to a specific study. It should not be a standard form. It must be written in simple language, free of technical jargon, so as to easily be understood by persons who have no medical, social science, or scientific background. If the primary language of your subject is other than English the consent form must be translated so the subject can understand what they are being asked to consent to. A general rule is that potential subjects must be given all information that might reasonably be expected to influence their willingness to participate. The PI should provide two copies of the consent form; one for the subject or parent/guardian to sign and return to the PI and the other for the subject to keep. All signed consent forms with original signature must be sent to the Office of Research Services for audit and storage once the study is completed.

The Office for Human Research Protection (OHRP) has suggested that investigators avoid writing the consent forms in the first person language (“I understand that...”). Consent form templates can be found beginning on page 27 of this manual and on the ORS website. Consent forms should resemble these examples, but should be re-typed with the information that pertains to each individual protocol.

A written consent form must include the following:

1. A simple descriptive title of the research project.
2. Name and telephone number of the Principal Investigator (PI) and Faculty Advisor (FA) if the PI is a student.
3. A statement that the study involves research.
4. An explanation of the general purpose of the research. If the research involves an experimental treatment for a problem or disorder, that treatments should be identified and any alternative treatment that may be advantageous to the subject.
5. An explanation of any procedures concerning the treatment.
6. A statement concerning the approximate number of subjects involved in the study.
7. A description of all discomforts and risks to be reasonably expected.
8. A description of benefits to subjects that can be reasonably be expected.
9. A statement concerning the expected duration of the subject’s participation in the research. Any undue traveling should also be stated.

10. A statement, if applicable, about any monetary or other inducements for participation and how and when they will be paid.

11. A statement describing how confidentiality will be maintained and who will have access to the data.

12. A statement that the subject is free to refuse to participate or to withdraw from the research activity at any time without fear of any repercussions.

13. A statement that the Principal Investigator or Faculty Advisor, if the PI is a student, may be contacted if the subject has further questions or would like to voice a concern about the research.

14. A paragraph containing information about the IRB similar to the following below:

   You may contact the Saint Joseph’s University’s Institutional Review Board at the following address and telephone number at any time during this study if you have question or concerns about your right as a research subject: IRB Administrator, Jena Fioravanti Burkett, 610-660-1298, Office of Research Services, Saint Joseph’s University, 5600 City Avenue, Philadelphia, PA 19131; and/or IRB Chairperson, Philip Schatz, 610-660-1804, 222 Post Hall, Saint Joseph’s University, 5600 City Avenue, Philadelphia, PA 19131

15. Signature of the subject indicating consent. The signature of a parent/guardian if the subject is underage or cannot represent himself.

16. When appropriate, a simply worded assent form for children who can read and write should be prepared for their signature. This is in addition to the consent form signed by the parent or guardian.

17. For research involving greater than minimum risk to subjects, a statement specifying whether any compensation, medical treatments, or counseling services are available if injury occurs and where further information may be obtained.

Waiver of Consent Documentation

There are certain occasions when documentation of consent may be waived. An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either;

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; or

2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which consent is normally required outside the research context.

In cases in which the documentation requirement is waived, the IRB requires the investigator to provide subject with a written statement regarding the research. This statement must be submitted along with the research protocol for IRB approval. This document should be written using the same elements as a written consent form.
CHILDREN AS RESEARCH SUBJECTS

According the document 45 CFR 46.406, children are permitted to be research subjects, if:

1. There is no greater than minimal risk.
2. An intervention or procedure holds out the prospect of direct benefit for the individual subject, or a monitoring procedure is likely to contribute to the subject’s well being.
3. There is only a minor increase over minimal risk and the intervention or procedure is likely to yield generalizable knowledge about the subject’s disorder or condition which is of vital importance for the understanding or amelioration of the subjects disorder or condition, and intervention procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.

A. Consent by Parents or Guardians
   a. According to the federal regulations on the Protection of Subjects, for research falling under categories #1 and #2 above, the permission of one parent is sufficient.
   b. Permission from both parents is required for category #3 above unless one parent is deceased, unknown, incompetent or not reasonably available, or when only one parent had legal responsibility for the care and custody of the child.
   c. The IRB requires parental consent to be written.

B. Children’s Assent

In addition to parental permission, federal regulations require in most instances that a child who is sufficiently mature to comprehend his/her participation in the research project be offered the opportunity to give assent. Generally speaking, the federal government has interpreted this rule as requiring assent of children seven years of age or older, and encourages assent of younger children if there is reason to believe it would be meaningful. “Assent” means a child's affirmative agreement to participate in research. Mere failure to object to involvement in the research should not be construed as assent. Affirmative agreement is necessary. Under some circumstances verbal assent may be appropriate, but generally written assent is preferred. When a written form is used it should contain a simple explanation of the research project, including possible benefits, risks and safeguards. A copy of the assent form should be included in the IRB proposal. There is a sample of an Assent document on the ORS website which should be used as a guide.
LEVELS OF IRB REVIEW AND POSSIBLE ACTIONS

It is the IRB’s responsibility to ensure that researchers follow the guidelines established in 45 CFR 46. Therefore, before a proposal is approved, the IRB may request additional information about the proposal, and/or may require changes in the consent form, subject recruitment methods, or other aspects of the procedure.

It is important to understand that any research that involves the use of human subjects, even though it may be exempt, must go to the IRB for review. A general rule of thumb is if a person is being used as part of the research you must submit a protocol. Please contact the IRB Administrator in the ORS for further clarification.

Research Exempt from Further IRB Review

Research is exempt from further IRB review if the research entails no more than “minimal risk” and falls in one or more of the following categories. (Title 45 Code of Federal Regulations 46.101 (b).)

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies or (ii) 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: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) 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 use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedure, interview procedures, or observation of public behavior that is not exempt under paragraph 2 of this section, if: (i) the human subjects are elected or appointed by public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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 or the primary source of data in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of Governmental Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency of the Food Safety and Inspection Service of the U.S. Department of Agriculture.
Please note: Research involving children, although designated a “vulnerable population,” can be classified as Exempt from Review only if the study involves observational research when the principal investigator does not participate in the activities being observed.

Receiving Exempt status does not supersede any State or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

Research Eligible for Expedited IRB Review

Certain research projects may qualify for an Expedited review. Research activities that present no more than minimal risk to human subjects, and involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. There are four categories under which research may be reviewed through the Expedited procedure at Saint Joseph’s University.

Expedited Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.
   b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
   a. hair and nail clippings in a nondisfiguring manner;
   b. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
   c. permanent teeth if routine patient care indicates a need for extraction;
   d. excreta and external secretions (including sweat);
   e. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
   f. placenta removed at delivery;
(g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

(h) supra- and sub gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;

(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

(j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples:

(a) 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;

(b) weighing or testing sensory acuity;

(c) magnetic resonance imaging;

(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;

(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.
(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

An Expedited Review will be carried out by two experienced IRB members designated by the IRB administrator or IRB chairperson. In reviewing the research, the reviewers may exercise all of the authorities of the IRB, except that the reviewers may not disapprove the research. If either reviewer determines the protocol does not qualify for Expedited Review, the PI will be notified and it will be sent to Full Review at the monthly meeting. The PI will be responsible for supplying 12 additional copies of the protocol to facilitate the Full Review.

Criteria for Approval of Research Requiring Full IRB Review

The Full committee review category is used for research that does not qualify for Exempt or Expedited review. Full review of protocols takes place at the monthly IRB meetings, held on the third Tuesday of each month. All PI’s and FA’s are encouraged to be available at the time the meeting is held to answer any questions the IRB may have about their protocols.

When reviewing research for approval, the IRB must determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized: (i) by using procedures that do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic, treatment or educational purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits (if any) to subjects, and to the importance of the knowledge that may reasonably be expected to result.
3. Subjects will be recruited in an honest, non-coercive, and equitable fashion.
4. Informed consent will be sought from each prospective subject and/or the subject’s legally authorized representative.
5. Informed consent will be documented except when specifically waived by the IRB.
6. In cases of oral informed consent a written statement that describes the study will be provided to participants.
7. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
8. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
9. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included to protect the rights and welfare of these subjects. Additional precautions are sometimes indicated (and required by federal regulations) when some or all of the subjects are pregnant women.

The IRB has the authority to approve, require modifications, or disapprove all research activities that involve Human Subjects. The decisions and requirements for modifications by the IRB will be promptly conveyed to investigators in writing by the IRB Administrator. Written notification from the IRB of decisions to disapprove a protocol will be accompanied by the IRB Committee’s reasons for the decision and an invitation for an opportunity for reply by the investigator, either in person or in writing.
Criteria for Continuing IRB Review

The IRB conducts continuing review of all research projects which it has approved at intervals appropriate to the degree of risk, but not less than once per year. “Not less than once per year” means that the research must be reviewed on or before the one-year anniversary of the previous IRB review date, even though the research activity may not have begun until some time after the IRB gave its approval. The anniversary date for an approved protocol will be the date of the IRB meeting at which it was reviewed. Investigators are required to submit an Annual Renewal/Progress Report prior to the expiration of the study or as specified by the IRB. The report should normally be filed 30 days before the study approval period ends. The IRB Administrator will send an Annual Renewal form to the investigator 60 days before the study approval period ends.

There is no grace period extending the conduct of the research beyond the expiration date of IRB approval. Extensions beyond the expiration date will not be granted. If Annual Renewal/Progress Report forms and any other requested progress reports are not received as scheduled, the Investigator must suspend the study and study enrollment until reports are reviewed and approved.

Studies that initially went through a convened meeting of the IRB will most likely require a Full-board review at the time of the Annual Renewal. However, an expedited review may be conducted for protocols which initially underwent Full Review in the following circumstances:

(a) Where:

(i) The research is permanently closed to the enrollment of new subjects;

(ii) All subjects have completed all research-related interventions; and

(iii) The research remains active only for long-term follow-up of subjects; or

(b) Where no subjects have been enrolled and no additional risks have been identified; or

(c) Where the remaining research activities are limited to data analysis.

Under the expedited review procedure, the review may be carried out by the IRB chairperson or by an experienced reviewer designated by the IRB administrator or IRB chairperson.

If the research project will not last longer than one year, the PI must submit a Final Report form at the completion of the research study to the IRB.

Possible Actions Following IRB Review

There are several actions that the IRB can take when reviewing human subjects research. The level of IRB involvement in a research project often depends upon the attention to detail that the PI applies when preparing the research project. The possible actions of the IRB following review are:

- **Final approval** - There are no changes needed in the study and the investigator can proceed with the research without further delay;

- **Conditional approval** - There are minor revisions that need to be made, but full review is not required by the IRB. After the revisions are completed, the study can be reviewed and signed by the Chair of the Board giving final approval;

- **Tabled** - There are major problems or concerns with the study that impact the protection of the human subjects to be involved, and the study must be reviewed again by the IRB at a subsequent meeting after the investigator has addressed all the reviewers’ concerns;
• **Not approved** - There are severe problems or concerns. Specific reasons for disapproving research will be communicated to the investigator. The study may not be resubmitted unless completely revised.

• **Exempt** - Certain minimal risk protocols are given exempt status by the IRB.

• **Exempt with conditions** - The IRB will require that certain revisions are made and submitted to the Office of Research Services before exempt status is given. *(see page 3 for exempt criteria)*

The IRB will communicate the decisions made on protocols to the PI, and the FA if applicable, with instructions on how to proceed.
AUDIT AND MONITORING OF APPROVED IRB PROTOCOLS

In order to help ensure compliance with federal regulations and local IRB policies regarding research with human subjects, and to ensure that human subjects are adequately protected, the IRB Administrator may conduct routine, targeted or random audits of approved research protocol files. In addition, the IRB may request monitoring of approved projects that may take the form of routine, targeted, or random audits. These activities may include, but are not limited to the following:

a. Request progress reports from investigators at specified intervals;
b. Collect signed Informed Consent Documents;
c. Examine research records;
d. Contact research subjects;
e. Verify from sources other than investigators that no material changes in the study have occurred;
f. Audit advertisements and other recruiting materials to confirm proper IRB approval;
g. Review projects to verify from sources other than the investigator(s) that no material changes have occurred since previous IRB review; and/or
h. Other monitoring or auditing activities deemed appropriate by the IRB.

The results of any audit by will be reported to the full IRB on the agenda of the next regularly scheduled meeting. However, if the information gained during the monitoring or auditing process indicates that human subjects may be exposed to unexpected serious harm, the IRB may suspend or terminate approval of the research prior to the next regularly scheduled IRB meeting.

Investigations Regarding Possible Non-Compliance

Research investigators are the most frequent source of noncompliance with human subjects regulations. The most common lapses in investigator compliance include unreported changes in the IRB approved protocol or consent documents, misuse or non-use of the IRB approved informed consent documents, lapse in approval for continuing review, and failure to obtain IRB approval prior to starting research activities. When unapproved research is discovered, the IRB and the University will act promptly to halt the research, assure remedial action regarding compliance with federal, local, and institutional human subject protection requirements, and address the question of the investigator's fitness to conduct human subject research. Any serious or continuing noncompliance with Department of Health and Human Services (DHHS) human subjects regulations or the determinations of the IRB must be promptly reported to the Office for Human Research Protections (OHRP) and possibly the funding department or agency head.

Reporting of Suspensions, Terminations for Non-Compliance

As soon as possible, but no later than within 10 days of determination by the convened IRB, suspensions, terminations and non-compliance findings will be reported in writing to the Institutional Official, Associate Provost, Paul DeVito, Ph.D. The Institutional Official must also notify in writing the relevant Department Head, any applicable regulatory body and OHRP (for federally-funded research) of any suspensions, terminations, and/or serious or continuing non-compliance.
APPENDIX

Standards for Research with Human Participants (Copyright APA 1992)

Planning Research
a. Investigators design, conduct, and report research in accordance with recognized standards of scientific competence and ethical research.

b. Investigators plan their research so as to minimize the possibility that results will be misleading.

c. In planning research, investigators consider its ethical acceptability under the Ethics Code. If an ethical issue is unclear, investigators seek to resolve the issue through consultation with institutional review boards.

d. Investigators take reasonable steps to implement appropriate protections for the rights and welfare of human participants and other persons affected by the research.

Responsibility
a. Investigators conduct research competently and with due concern for the dignity and welfare of the participants.

b. Investigators are responsible for the ethical conduct of research conducted by them or by others under their supervision or control.

c. Researchers and assistants are permitted to perform only those tasks for which they are appropriately trained and prepared.

d. As part of the process of development and implementation or research projects, investigators consult those with expertise concerning any special population under investigation or most likely to be affected.

Compliance with Law and Standards
Investigators plan and conduct research in a manner consistent with federal and state law and regulations, as well as professional standards governing the conduct of research, and particularly those standards governing research with human participants.

Institutional Approval
Investigators obtain from host institutions or organizations appropriate approval prior to conducting research, and they provide accurate information about their research proposals. They conduct the research in accordance with the approved research protocol.

Research Responsibilities
Prior to conducting research (except research involving only anonymous surveys, naturalistic observations, or similar research), investigators enter into an agreement with participants that clarifies the nature of the research and the responsibilities of each party.

Informed Consent to Research
a. Investigators use language that is reasonably understandable to research participants in obtaining their appropriate informed consent (except as provided under the standard labeled “Dispensing with Informed Consent”). Such informed consent is appropriately documented.
b. Using language that is reasonably understandable to participants, investigators inform participants of the nature of the research; they inform participants that they are free to participate or to decline to participate or to withdraw from the research; they explain the foreseeable consequences of declining or withdrawing; they inform participants of significant factors that may be expected to influence their willingness to participate (such as risks, discomfort, adverse effects, or limitations on confidentiality, except as provided under the Standard labeled "Deception in Research"); and they explain the aspects about which the prospective participants inquire.

c. When investigators conduct research with individuals such as students or subordinates, investigators take special care to protect the prospective participants from adverse consequences of declining or withdrawing from participation.

d. When research participation is a course requirement or opportunity for extra credit, the prospective participant is given the choice of equitable alternative activities.

e. For persons who are legally incapable of giving informed consent, investigators nevertheless:
   1. provide an appropriate explanation,
   2. obtain the participant’s assent, and
   3. obtain appropriate permission from a legally authorized person, if such substitute consent is permitted by law.

Dispensing with Informed Consent
Before determining that planned research (such as research involving only anonymous questionnaires, naturalistic observations, or certain kinds of archival research) does not require the informed consent of research participants, investigators consider applicable regulations and institutional review board requirements, and they consult with colleagues as appropriate.

Informed Consent in Research Filming or Recording
Investigators obtain consent from research participants prior to filming or recording them in any form (i.e. photographs, tapes, etc.) unless the research involves simply naturalistic observations in public places and it is not anticipated that the recording will be used in a manner that could cause personal identification or harm.

Offering Inducements for Research Participants
a. In offering professional services as an inducement to obtain research participants, investigators make clear the nature of the services, as well as the risks, obligations, and limitations.

b. Investigators do not offer excessive or inappropriate financial or other inducements to obtain research participants, particularly when it might tend to coerce participation.
Deception in Research
a. Investigators do not conduct a study involving deception unless they have determined that the use of deceptive techniques is justified by the study’s prospective scientific, educational, or applied value and that equally effective alternative procedures that do not use deception are not feasible.

b. Investigators never deceive research participants about significant aspects that would affect their willingness to participate, such as physical risks, discomfort, or unpleasant emotional experiences.

c. Any other deception that is an integral feature of the design and conduct of an experiment must be explained to Participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the research. (See also the Standard labeled "Providing Participants with Information about the Study.")

Sharing and Utilizing Data
Investigators inform research participants of their anticipated sharing or further use of personally identifiable research data and of the possibility of unanticipated future uses.

Minimizing Invasiveness
In conducting research, investigators interfere with the participants or milieu from which data are collected only in a manner that is warranted by an appropriate research design and that is consistent with investigators’ roles as scientific investigators.

Providing Participants with Information about the Study
a. Investigators provide a prompt opportunity for participants to obtain appropriate information about the nature, results, and conclusions of the research, and investigators attempt to correct any misconceptions that participants may have.

b. If scientific or humane values justify delaying or withholding this information, investigators take reasonable measures to reduce the risk of harm.

Honoring Commitments
Investigators take reasonable measures to honor all commitments they have made to research participants.
CONFIDENTIAL

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of Study: The Relationship Between Use of Alcohol and Depression in a Sample of College Students

Principal Investigator: John E. Doe, Ph.D.
Department of Psychology
101 Science Center
Saint Joseph’s University
Philadelphia, PA 19131
Telephone: (610) 555-1212

Co-Investigator: Mary D. Doe, Ph.D.
Department of Psychology
111 Science Center
Saint Joseph’s University
Philadelphia, PA 19131
Telephone: (610) 555-1212

You are being asked to take part in a research study under the direction of Dr. John E. Doe and Mary D. Doe. Research assistants who work with Drs. John and Mary Doe may assist or act for them in conducting this study. Approximately 200 subjects will participate in this research.

Purpose:
The purpose of this research is to examine the relationship between use of alcohol and levels of depression in a sample of college students.

Duration and Location:
Participation in this study will occur over a one day period in the First Summer Session, 1997, in a classroom here at Saint Joseph’s University. Participation will last for approximately one (1) hour.

Procedure:
In this study you will be asked to complete a questionnaire regarding your alcohol use, and the Beck Depression Inventory (BDI) which measures level of depression.

During the course of study the following will occur. One of the investigators or research assistants will give you a date, time and location to come and complete the alcohol use questionnaire and BDI. The questionnaire and BDI will be administered by the investigators or research assistants in a group setting of about 40 to 50 students.

Inclusion and Exclusion Criteria:
Participants for this study are being recruited from undergraduate classes at Saint Joseph’s University.

You should not participate in this study if you are under the age of 18.

Risks and Discomforts:
The risks and discomforts involved in this study are believed to be minimal in that subject’s may experience some discomfort in answering questions about one’s alcohol use and mental health.

As with any study, you should be aware that unforeseen problems may occur, however, the likelihood of any serious problem is believed to be low. Your participation is voluntary, and you may refuse to participate or stop your participation at any time for any reason without penalty.

Subjects will be instructed NOT to put their name on the questionnaires such that anonymity can be protected (that is, the information will be collected in a manner in which a subject’s individual responses cannot be linked to that subject).

**Right to Refuse or Withdraw from the Study:**
Subject’s participation in this study is voluntary. You may refuse to participate, or may discontinue your participation at any time without penalty or loss of benefits which you would be otherwise entitled.

Drs. John and Mary Doe have the right to stop your participation in the study at any time.

**Use of Research Results:**
The data obtained in this study will assist current investigators in understanding the relationship between alcohol use and depression in college students. Such an understanding will be helpful as future investigators conduct research on the cause and treatment of alcohol use and depression. Data may be used in publications or for teaching purposes.

**Benefits and Payment:**
In addition, participants will receive ten dollars total payment upon completion of both the alcohol use questionnaire and BDI. This study does NOT provide funding to participants for treatment services nor for any reason other than the $10 provided for completion of both questionnaires.

**Confidentiality:**
In order to ensure confidentiality, participants will be instructed NOT to put identifying information on the questionnaire and BDI. All data collected will be coded and not have the participant’s name on it. Upon completion of the questionnaire and BDI the participants will place the material in a slot in a closed box such that the investigators and research assistants will not be able to identify the individual responses of a given participant.

To ensure confidentiality, the signed consent forms will be stored in a locked file in Dr. John E. Doe’s office.

No subject will be identified in any report or publication of the study or its results.

**Institutional Review Board Approval:**
This research study has been approved by the Saint Joseph’s University Institutional Review Board (IRB) for the Protection of Human Subjects in Research. If you believe that there is an infringement upon your rights as a participant in this research you may contact the IRB Administrator, Chris Meussner, Telephone (610) 660-1298, irb@sju.edu.

**Subject’s Agreement**
I have read the information provided above and voluntarily agree to participate in this research study. If I have any questions or concerns that arise in connection with my participation in this study, I should contact Dr. Phillip Schatz, 222 Post Hall, (610) 660-1804, pschatz@sju.edu

I understand that I will be given a copy of this consent form.

________________________________________________________________________
Name of Research Participant (Print)

________________________________________________________________________
Signature of Research Participant    Date

________________________________________________________________________
Signature of Investigator
Sample B. Cover Letter for Mailed Anonymous Questionnaire

Dear __________,

I am conducting a multi-organizational study of employee turnover. This research project is funded by the U.S. Department of Labor. The objective of this research project is to attempt to understand why people leave their jobs.

Enclosed with this letter is a brief questionnaire that asks a variety of questions about your attitudes toward your job with the University. I am asking you to look over the questionnaire and, if you choose to do so, complete the questionnaire and send it back to me. Do not write your name on the questionnaire. I do not need to know who you are. The results of this project will be summarized and appropriate people at the University will be given a summary report. I guarantee that your responses will not be identified with you personally. Nothing you do or say will in any way influence your present or future employment with the University. Also, this information will not affect your use of the University as a previous employer or any job references that you may list. I plan to compare the answers of people who have left with a group of people who are still employed with the University.

I hope you will take a few minutes to complete this questionnaire and to return it in the enclosed self-addressed and stamped envelope. Without the help of people like you, research on employees would not be conducted. Your participation is voluntary and there is no penalty if you do not participate. Regardless of whether you choose to participate, you can have a summary of our findings. To receive a summary, use the enclosed letter size self-addressed and stamped envelope and the address form. To preserve your anonymity, you can send this request by separate mail. In this way, I have no way of knowing who sent back a questionnaire and who requested a summary of the results.

Understanding why people quit their jobs is very important. Through your participation, I eventually hope to understand how best to satisfy the needs of organizations and the needs of employees.

Sincerely,

John E. Doe
Associate Professor
(610) 555-1212

You may contact the Saint Joseph’s University Institutional Review Board at the following address and telephone number at any time during this study if you have questions or concerns about your rights as a research subject.

Saint Joseph’s University Institutional Review Board
IRB Administrator
Jena Fioravanti Burkett
Saint Joseph’s University
Philadelphia, PA 19131
(610) 660-1298
Sample C. Minor Assent Letters (Used for Protocols Involving Minors)

Following are two sample assent forms. They are included as guides to you in construction of a child’s assent to be used in your project. Fill in the appropriate information and adjust to the specifics of your research. There is IRB contact information at the bottom which should be incorporated into the assent form which you select.

NOTE:
*Do not include a statement to the effect that “your parent has agreed to allow you to take part in the study”. This implies the possibility of parental pressure for the child’s participation. Instead use “your parent is aware of this project”.
*Make sure you use age appropriate language. For example, do not use the same language for a third grade student as you would a graduate student.

Example
Sample Minor Assent Document

Project Title:
Investigator:

*We are doing a research study about* purpose in simple language. *A research study is a way to learn more about people. If you decide that you want to be part of this study, you will be asked to description, including time involved.*

*There are some things about this study you should know. There are* procedures, things that take a long time, other risks, discomforts, etc.

*Not everyone who takes part in this study will benefit. A benefit means that something good happens to you. We think these benefits might be* description.

*If you do not want to be in this research study, we will tell you what other kinds of treatments there are for you.* This statement applies to research projects that offer treatment or intervention.

*When we are finished with this study we will write a report about what was learned. This report will not include your name or that you were in the study.*

*You do not have to be in this study if you do not want to be. If you decide to stop after we begin, that’s okay too.*

*If you decide you want to be in this study, please sign your name.*

*I, ____________________________, want to be in this research study.*

(Print your name here)

______________________________________

______________________________________

______________________________________