



Saint Martin's University

Institutional Review Board: Protection of Human Subjects In Research and Investigational Activities

Policy and Standards

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Protection Of Human Subjects In Research And Investigational Activities

I. Statement of Policy

Background

Saint Martin's University recognizes, and affirms, the need for academic freedom in the conduct of research, and the value of well-designed, responsible activities which involve human subjects. At the same time, the University recognizes, and accepts, its responsibility to assure the protection of any human subjects so involved. The use of human subjects in research or investigational activities imposes both ethical and legal responsibilities upon the institution, the project director, and the investigator(s), for assuring that the rights and welfare of those subjects are adequately protected. Saint Martin's University thus requires that the project director, the investigator(s) and the institution utilize these policies, and their associated procedures, to monitor activities to insure that such protection occurs.

These University policies, with their associated guidelines, forms, and procedures, have been prepared to help project directors and investigators meet individual and institutional obligations with respect to human subjects. They have been developed in accordance with Federal requirements (45 CFR 46, and 21 CFR 56), policies of Saint Martin's University, ethical codes of the various professional organizations, and the ethical principles embodied in a respect for the rights and well-being of persons who may be subjects of research. These basic ethical principles include: respect for persons (acknowledging autonomy and protecting those with diminished autonomy); beneficence (doing no harm, or maximizing possible benefits while minimizing possible harms); and justice (sharing equitably the burdens and benefits in the population).

Current law places the burden of liability for negligence and harm directly on the researcher and the institution. These guidelines are formulated to help protect the University, the researcher, and in the case of students, the faculty advisor, from liability through imposition of minimum standards for research and developed procedures for careful review of projects. Failure to follow these guidelines may cause individuals to incur personal liability for negligence and harm. Failure to follow these guidelines may also cause the University to lose federal funding, prevent individuals from applying for or receiving federal research funds, and prevent the University from engaging in research which falls under Federal Food and Drug Administration rules. In addition, failure to follow these guidelines will be viewed by the University as violation of University Policies and Procedures which will result in appropriate administrative action.

General Policy

Saint Martin's University Institutional Review Board (IRB) has institutional responsibility for all use of human subjects under the auspices of, or utilizing the students, personnel or facilities of, Saint Martin's University. At its discretion, the IRB may delegate specific responsibility for minimal risk projects (as defined below). However, all projects must be accomplished in accord with this policy, and all projects covered by this policy may be undertaken only after appropriate approval and may be continued only so long as that approval remains in effect. Changes in a project, or continuation of the project following adverse occurrences during the project, are also subject to review and approval.

It is the responsibility of the principal investigator to refer his or her project to the IRB whenever humans are subjects, even if the investigator does not consider the subjects to be "at risk." It is the sole responsibility of the IRB, or those specifically delegated by the IRB, not the project director, investigator, or any University official, to determine the exemption of a project from review. Each project not specifically exempted by this policy must thus be submitted for review, **and human subjects may not be utilized until the project is approved.**

Basic Principles

Investigations conducted while at Saint Martin's University are expected to embody the following basic principles (each of which is explained in more detail in the following pages):

1. Participation of human beings as subjects must be voluntary: i.e., must occur as a result of free choice, without compulsion or obligation, based upon full disclosure of relevant information in a comprehensible way.
2. Adequate standards of informed consent must always be utilized.
3. Adequate provisions must be made to protect the privacy of subjects and maintain the confidentiality of information.
4. The selection of subjects must be based upon fair procedures and not overburden, overutilize, or unfairly favor, or discriminate against, any particular subject pool.
5. Any risks to the subject must be carefully minimized, and adequately balanced against potential benefits. Proper precaution should be taken and plans made to deal with emergencies that may develop in the course of even seemingly routine activities.

Applicability

This policy, and its associated procedures, apply to **all situations and activities** where human beings are participating as subjects of research or research related activities. It applies to all such projects, regardless of their source of funding.

For purposes of review, the term research means any systematic investigation designed to develop or contribute to generalizable knowledge (45 CFR 46.102). In particular, an investigation will count as research involving human subjects if it involves living individuals about whom an investigator obtains (1) data through intervention (direct data collection, such as through interview or questionnaire) and non-intervention (indirect data collection, such as observing subjects through one-way glass, or reviewing records), or (2) identifiable private information.

This policy is therefore applicable to research involving human beings whose physical, emotional, or behavioral condition, responses, tissues, fluids, etc., are investigated for any purpose other than for the sole purpose of benefiting the subject as an individual. It is applicable to the use of interviews, tests, observations, and inquiries designed to elicit or obtain non-public information about individuals or groups.

This policy is applicable whether the research is undertaken on a large or small scale, and involving faculty, staff, students or University facilities. Pilot projects, student dissertation projects, independent study projects, and course projects must follow this policy if they involve human subjects in research. (See section II.D. Instructional Projects Using Human Subjects, for detailed guidelines on course projects.)

Eligibility

Any research involving human subjects must be under the supervision of a qualified faculty member at or above the level of instructor, or qualified staff member of an equivalent level.

Responsibility

Review of research involving human subjects is part of University Policy and Procedures. The Institutional Review Board has sole responsibility for research review. Although other University authority may prohibit a project which is approved by the IRB, a project which is not approved by the IRB may not be approved by another authority. Similarly, the President or other University authority may impose stricter limitations on the conduct of research than the IRB, however, no limitation placed by the IRB may be relaxed or overruled (45 CFR 46.112).

The Institutional Review Board has the authority to suspend or terminate approval of research that is not being conducted in accordance with its requirements, or that has been associated with unexpected risk, or harm, to subjects (45 CFR 46.113).

Administration

The Vice President for Academic Affairs of the University will appoint the committee on an annual basis and shall name the chairperson of the committee. Appointment to the committee will be for three years, and may be renewed. The terms of members will be staggered so that the 1/3 of the members will be newly appointed (or reappointed) each year. The chair shall have, prior to appointment, at least two years experience on the committee (or a similar committee elsewhere), and thorough working knowledge of these policies, as well as appropriate federal, state and local regulations and laws.

The responsibility for administering these policies, and overseeing the operations of the IRB rests with the Vice President for Academic Affairs. All records, files and materials of the IRB will be maintained through the Office of Vice President for Academic Affairs, under the direction of the President or his designee. Administration of the IRB will originate in the Office of Vice President for Academic Affairs, as will submission of projects and all project follow-up.

Implementation

The general procedure for implementation of this policy will be the review of proposed uses of human subjects, by the Institutional Review Board, in accord with this policy, utilizing procedures established and published by the IRB. An official written notification from the IRB to the investigator will authorize the investigator to conduct the proposed research when and if all other University requirements are met.

IRB Membership

The IRB will consist of members with varying backgrounds and professional competencies, in accordance with Federal regulations. Membership will include (but not be limited to): (a) at least one member who is not associated with the University except for membership on IRB; (b) at least one member whose primary concerns are in no scientific areas; (c) both male and female members; (d) no more than one member from any academic discipline area. As appropriate for judgments of institutional commitments and regulations, applicable law, and standards of professional conduct and practice, the IRB will include persons knowledgeable in those areas. The membership of the Institutional Review Board will be reported to Federal agencies as required.

In addition to regular members, the chair will utilize outside experts as needed for adequate review of projects. These may vary, except: (a) for FDA related drug studies, two persons licensed to prescribe the drugs will be included in the review process; and (b) when a project involves a category of vulnerable subjects (e.g. prisoners, children or the mental incompetent) and those subjects will be at greater than minimal risk, a person will be included whose primary concern is the welfare of such subjects.

Quorum for Review

A simple majority (one half members plus one) of the membership will be considered a quorum.

Votes

Each member shall have only one vote, but absent members may not vote by proxy. At least a simple majority, positive vote of the members present (at least a quorum) is required for approval, suspension, or termination of a project.

Conflict of Interest

A person will have a conflict of interest if he or she: (a) is involved in the project (e.g., adviser, thesis or dissertation committee, co-investigator, etc.); or, (b) is a participant in a larger project which includes the review project as a sub-part, even if the individual is not involved in the sub-part. A person who has a conflict of interest cannot serve as the primary reviewer for a project, and cannot vote on the acceptance or rejection of the project, but may participate in the discussion of the project prior to any vote.

Project Review

Before a project involving human subjects may be undertaken, and, if funded, before funds may be received, the project must be submitted to the Institutional Review Board, through the Office of Vice President for Academic Affairs, utilizing the forms and procedures of the IRB. It is the investigator's responsibility to regard appropriate lead times for IRB actions (1 - 4 weeks, depending upon whether the project fits the criteria for expedited review. See the Expedited Review Criteria, available on IRB web site, for review criteria.)

Student Projects

Student research projects will be reviewed using the same criteria as for any other project. However, student projects must have a faculty advisor who takes responsibility for approval and

monitoring of the project. Thesis and dissertation projects must be approved by the appropriate faculty committee(s), as determined by departmental or University policies, before submission to the IRB for review. In addition, any other required approvals (e.g., departmental, divisional, or outside agency) should be secured prior to submission and copies of those approvals appended to the project description. At the University level, a thesis or dissertation involving human subjects is not considered approved until the IRB has given approval relative to the use of those subjects.

Basis for Review

The IRB review will cover three general areas: (a) the rights and welfare of the individual(s) involved as subjects, including the equitable selection of those subjects; (b) the appropriateness of the methods used to secure and document informed consent; (c) the determination of the costs (including time) and risks to the subjects, and the minimization of those costs and risks, and the relationship of the reasonableness of those costs and risks to the anticipated benefits to the subjects and the importance of the knowledge expected to be gained in the project; and, if necessary, consideration of whether project design puts the subjects at risk and, if so, how that risk fits the analysis of (c) above.

IRB Action

Following receipt and review of project documents, the IRB may take any one of several actions: 1) it may exempt a project from further review; 2) it may approve a project as presented, or subject to modifications; 3) it may disapprove a project; or 4) it may defer action on a project pending additional review. Exemption and approval may be expedited if the research fits specific categories (see Expedited Review Criteria, available on IRB web site). Otherwise, full IRB action is required.

IRB review will be based upon the documents submitted by the investigator, as well as meetings with the investigator, as appropriate. Students who appear before the IRB will be accompanied by their project advisor.

Notification

The IRB will notify the project director in writing when the project is approved. No use of human subjects is permitted before such approval. The IRB will send copies of the approval to the Office of Vice President for Academic Affairs and, if a student project, to the faculty advisor. Following approval, the project director is responsible for carrying out the project precisely as presented to the IRB. Any changes in the protocol, additional elements, or problems which arise in the course of the project, must be reported to and reviewed by the IRB before use of human subjects may continue.

Regular Review

The project director is responsible for submitting annual progress reports to the IRB, unless otherwise directed, until the project is completed. Projects are approved for a period of up to one year. To continue a project beyond one year, the project director must apply, in writing, for an extension, specifying the reasons for the additional time. Approval for projects for which an extension is not requested is automatically terminated at the end of the reporting period.

Final Reports

When a project is finished, the project director must submit a Certificate of Compliance (obtained from the IRB) and a brief summary report which includes the number of subjects involved, the duration of subject usage, and a summary of the project results. In addition, if a code book (or list) was utilized to protect confidentiality, it must be either destroyed or turned in to the chair of the IRB for archiving (see Project Records below).

Project Records

All project records are subject to audit by Saint Martin's University, and in some cases by Federal officials. The project director is responsible for maintaining complete records for a minimum period of three years, and making any records pertaining to the project available to the IRB or appropriate authorities at anytime they are requested.

If a code book (or list) utilized to maintain confidentiality cannot be destroyed at the end of a project, it will be turned in to the chair of the IRB for archiving. The chair will transfer the code book (or list) to the University Archivist who will ensure that each is kept in a sealed envelope, with access restricted to (1) the Principal Investigator and (2) the Vice President for Academic Affairs. In accordance with Federal regulations, the retention period for any code book (or list) will be three years. It will then be transferred, still sealed, to the Vice President for Academic Affairs who is responsible for its destruction. If it is necessary to keep the code book (or list) for a longer period of time, the researcher must explicitly request this at the time of transfer to the chair of the IRB, or within the three year period.

Communication with the IRB

Once applications are submitted, all communication with the IRB shall be through the Office of Vice President for Academic Affairs, directed to the chair of the Institutional Review Board. Researchers may not contact IRB members directly, and IRB members are not permitted to discuss project applications with any persons outside the IRB, even the project director. The IRB chair shall be responsible for all communication between the IRB and project directors. Also, the Chairperson of the IRB should be contacted to answer any further questions or provide clarification concerning the policies or their implementation, by phone or e-mail irb@stmartin.edu. Forms for submission should be obtained from and returned to the Chairperson of IRB. The IRB world wide web site (<http://www.stmartin.edu/irb/>) will also provide policy statements and forms for submission.

IRB Files

The IRB maintains a permanent file of complete records on all projects, and annually at the end of academic year, presents a summary report to the Office of Vice President for Academic Affairs and the Faculty Senate of Saint Martin's University. Records of the IRB will be maintained in the Office of Vice President for Academic Affairs.

II. Statement of General Standards

A. Risk

Types of Risk

Different types of research impose various types and degrees of risk upon the subjects. These risks may be physical, psychological, social or ethical. They may entail a risk of bodily harm, alteration of psychological states, or subjection to deceit, public embarrassments, humiliation or emotional stress. They may also entail a violation of privacy and compromise of confidentiality.

Degree of Risk

Two classifications of risk will be utilized to determine standards of review. A subject is at minimal risk when the potential for harm is not greater, considering the probability and magnitude, than ordinarily encountered in daily life, or during the performance of routine physical or psychological examinations and tests, as determined for the general population. For exercise testing, minimal risk is defined at less than 60% of age corrected maximum effort in a healthy individual with no contraindications to the exercise.

A subject is at significant risk when the potential for harm is greater, considering the probability and magnitude, than ordinarily encountered in daily life, or during the performance of routine physical or psychological examinations and tests, as determined for the general population. For exercise testing, significant risk is defined at greater than 60% of age-corrected maximum effort in a healthy individual with no contraindications to the exercise. Administration of drugs is also defined as placing subjects at significant risk.

Subjects are considered not at risk only when the research does not include any identifiable subjects: e.g., data from which all identifying information has been removed before being seen by the researcher. If the researcher must remove the identifying information, the subjects are at least at minimum risk.

Risk Safeguards

1. For activities involving no more than minimal risk:
 - a. Participation must be voluntary, but signed consent may not be necessary (see B. Informed Consent)
 - b. Subjects should be able to state that they have no disorder which would preclude their participation in the project.
 - c. The project must be supervised by a qualified faculty or staff member who assumes responsibility for the protection of human subjects.
2. For activities involving significant risk:

- a. Participation must be voluntary and a signed, written consent is required unless an alternative method for obtaining consent is specifically approved by the IRB.
- b. A written record of the research, including copies of all signed consent forms, a detailed description of the procedures, and a report of the results obtained, will be maintained, and accessible, for at least 3 years following completion of the project.
- c. The project must be supervised by a qualified faculty or staff member who assumes responsibility for the protection of human subjects.
- d. The investigator, and the IRB must determine the following:
 - Whether it will be necessary for the subjects' physical or mental condition to be evaluated by a licensed physician who is acquainted with the possible hazards of the proposed investigations.
 - Whether supervision or ready availability of a physician, or other individuals appropriately qualified to handle an emergency, is necessary for the project.
 - Whether any special monitoring (EKG, oximetry, etc.) is necessary for the project.
- e. Use of radioactive material requires authorization of the person responsible to the University for the oversight of radioactive materials.

B. Informed Consent

Consent Policy

The University requires that all investigators secure consent for participation from either the subject or the subject's representative. This consent is to be secured under conditions which give the subject sufficient opportunity to make a considered judgment whether to participate or not, and which minimize the possibility of coercion or undue influence.

In all instances where a signed consent is utilized, a signed copy of the consent will be given to the subject, and another copy will be maintained as part of the permanent records for the project.

It is recognized that on rare occasions fully informed consent may have an injurious effect on the subject, or may invalidate the research. Such research may only be done by specific approval of the IRB and only if the following conditions are met:

- a. Incomplete disclosure is truly necessary for the research or to protect the subject; and
- b. There are no undisclosed risks to the subjects which are significant risks (as defined above); and
- c. Where appropriate, there is an adequate plan for debriefing subjects and disseminating research results to them.

The investigator always has the burden of proof when a project incorporates less than fully informed consent.

General Information

A sample of this form can also be found at the following address:
http://www.stmartin.edu/irb/application_info.htm.

At the top of the form, the following should be listed for all projects

Saint Martin's University
Informed Consent for Research

Title of the Project:

Name of Project Director (or advisor):

Investigator(s):

Department:

Phone # (of the investigator(s):

Types of Consent

All projects involving human subjects require voluntary participation. The voluntariness of participation is indicated in part by the subjects' consent. For some projects, a signed consent form is not appropriate, because that form will be the only identifying link between the subject and the data. Such projects may utilize an 'implied' consent paragraph. All other projects require written consent.

Consent Requirements

Five requirements must be met by all consent documents:

1. The consent may not include any exculpatory language through which the subject is made to waive, or appears to waive, any of his or her legal rights, including any release of the institution or its agents from liability or negligence.
2. The consent must comply with applicable federal, state, and local laws or regulations requiring additional information to be disclosed.
3. The consent cannot place limits on the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state and local laws.
4. When children, incompetent adults, prisoners, or wards of the state are to be subjects, the consent requirements of federal regulations 45 CFR 46 must be met. In addition, any subjects capable of assent (agreeing to participate) must be given the option to assent, despite permission of the parent or guardian. (A person may not be forced to participate.)
5. Where participation as human subjects are of students enrolled in a course of instruction at Saint Martin's University and, it forms an integral part of the conduct of the course, the

official University bulletins and timetables, as well as the course syllabus, shall state that fact in the description of the course. If the student's grade will be directly affected by participation in the projects, that must be explained as well, with a description of how the grade is affected, and whether alternative means are available to obtain the same grade effect.

Implied Consent

Many research projects utilize surveys or questionnaires as their data source. In most cases, it is not necessary to record the data in such a way that respondents may be identified, because data are only reported in composite. The use of a signed consent form will, in these cases, be the only means of identifying a person as participating in a project, and will thus be the only potential basis for the risk of violating confidentiality and privacy. At the same time, persons have the right to be informed, and the right to refuse participation in a research project. In order to maintain these rights, and avoid the risk of violating these rights, the following paragraph should be used in conjunction with all non-identified survey or questionnaire research:

Consent Paragraph

You are invited to participate in a research project being done for (*Name of Class or purpose of the project, e.g. thesis*). To participate you will only need to fill out the attached questionnaire. There will be complete privacy of the information you supply, because your name will never be used or associated with the project. You are free to choose to participate or not participate, and you may stop your participation at any time. Whether you participate or not will have no detrimental effect on ('your performance in the course or' use this phrase with students only) your relationship with the University. By completing this questionnaire you are giving your consent to participate in the project and you are certifying that you are over 18 years old.

With such a paragraph there is no signature and the names of those who participate cannot be known or associated with the data. If names must be used for some reason, then appropriate signed consent forms will need to be used.

Consent Form

The signed, written consent form consists of two sections. The first section constitutes the 'informed' part of the form, that is, a brief statement of the nature of the project, its objectives, its potential benefits in general and possibly to the subject individually. In addition, there must be a complete description of the nature of participation by the subject. This means exactly what the subject will do and what (if anything) will be done to the subject. This section need not be longer than one to several paragraphs but should be complete enough to stand alone as having informed the subject about the nature of the project and what participation means. It should also be written without the use of technical terms, so that a lay person may easily understand.

The second section should include the material in items 1 through 10 below:

1. A statement by which the subject indicates willingness to participate in the project, this participation is completely voluntary and that he or she may withdraw from the project at any time without explanation or penalty.

2. A statement through which the subject indicates that he or she has received a complete explanation of the nature of the project and the latter is completely understood.
3. A complete, detailed listing of any and all known or foreseeable risks associated with this participation, both immediate and long range. A complete listing of any and all benefits associated with this participation, including payments, gifts, extra credit for a course grade, etc.
4. If any illness or injury, ranging from discomfort to significant side effects should occur, a description of the medical measures to be available to the subject both immediately and beyond participation until the undesirable effects are eliminated. It should be made clear whether such medical care for side effects will be with or without cost to the subject. The following is recommended wording for such a paragraph:

In the unlikely event of injury or other problem which occurs during or as a result of participation in this project, you should understand that emergency treatment may be arranged but that the costs of such treatment, or any subsequent medical care, will be your responsibility. Financial compensation is not available from Saint Martin's University, administration, faculty, staff, representatives, or the investigators.

5. A statement indicating that the project director may discontinue the participation of any subject at any time. The conditions under which this action may be taken by the project director may be detailed or stated simply as, 'At the discretion of the project director.'
6. A listing or description of qualifications and disqualifications for participation by any subject in the project.
7. A statement indicating that all data collected will be kept confidential in that specific data will never be divulged in connection with the name (or other identification) of a specific participant. If there are exceptions to this confidentiality statement, they should be described in detail (e.g., to the sponsor of the research, a governmental agency like the Food and Drug Administration, etc.).
8. A statement to the effect that any questions relevant to the project asked by the subject will be answered, and the name and phone number of the person to contact for information.
9. In projects involving administration of medication, there should be detailed description of the protocols for the administration of the medication, diagnostic procedures to be used to establish eligibility of a subject for participation, complete enumeration of the side effects from the medication including possible severity and risk to health as well as medical services to be available to the subject until the side effects have disappeared. Conditions which would contraindicate the administration of the medication involved should also be described.
10. A statement to be followed by the subject's signature indicating that the signature means that the subject understands the project, the nature of his or her participation, the possible risks

involved and the other information on the sheet. A statement that the subject is 18 years of age or older, or if not that consent is being given by a parent/guardian for a minor.

C. Confidentiality of Data

Scope

Confidentiality of data is presumed in all research involving human subjects, and must be maintained unless the investigator obtains, via the consent form, specific permission of the subject to release the information.

The University recognizes the rights of subjects to be protected against injury or illegal invasions of their privacy and their interests as members of a free society in preserving their dignity. The more sensitive the material, the greater the care that must be exercised in obtaining, handling, and storing data.

Requirements

1. Questionnaires, inventories, interview schedules, and other data gathering instruments and procedures should be carefully designed to limit the personal information acquired to that which is absolutely necessary for the study. If at all possible, the data should be gathered without the use of any individual identifiers (items which would permit the linking of specific data with a specific individual).
2. Data that include information which would reveal a subject's identity would be stored in files accessible only to the project investigator, or if necessary, a very limited number of authorized staff representatives.
3. As early as possible, the data should be handled in coded form, with the subject's name and identifying information (such as social security number) removed. If a subject-code link must be maintained through a code book (or list), that book (or list) must be kept in a secure location, with access restricted to the investigator. Plans for destruction, or permanent security of, the code book must be explicit in the project proposal (see Part 1, Project Records for details).
4. The identity of subjects cannot be released except with their express permission, obtained via the consent form or a document specifically intended to authorize such a release (e.g., a photo release form).
5. For use of stored data or information, such as student records, counseling files, financial aid files, etc., which was originally obtained for different purposes, and which involves identifiable data, the IRB must determine whether the new use is within the scope of the original consent or whether obtaining additional consent is necessary and feasible. Also, access to student records is generally prohibited by the Federal Education Rights and Privacy Act, without specific permission from the student.

D. Instructional Projects Using Human Subjects

Scope

Saint Martin's University recognizes the need for diverse instructional projects utilizing human beings. However, the University makes no exception to the principle that there is always an underlying responsibility for the protection of people's privacy, dignity, and welfare. When comparing instructional projects and research projects, the difference lies not in the principles of sound and ethical practice, but in the focus of responsibility for monitoring compliance with those concerns.

Applicability

In a number of departments across various colleges, it is customary for undergraduate courses to incorporate small projects which have many of the characteristics of research, and involve using other persons as project resources. These projects, however, have as their usual purpose the provision of student opportunity for developing familiarity with means of investigation customary to the various disciplines. The process of such projects aims not at the collection of data for its own sake, but instead at the development of student knowledge and skills independent of those data. To the extent that regular courses involve projects with this intention, which would not later be used as part of a research project, and which do not put persons at risk, such projects do not need to be submitted to the Institutional Review Board for approval. Instead, the IRB delegates to the University, department and faculty responsibility for assuring that such projects are carried out in the spirit of the principles noted above. In particular, the IRB delegates to these persons responsibility for assuring that participation in such projects is voluntary and based upon appropriate informed consent.

Limitations

Not exempt from IRB review are internships, research practica, independent study, independent research, honors projects, thesis, dissertation, and other formal research projects of undergraduate students, graduate students, faculty and staff. In addition, course projects which are classified by Federal Regulations 45 CFR 46 as requiring IRB review (i.e., those not listed as for exemption in Instructional Exemptions Criteria, available on IRB web site) must also be reviewed by the IRB.

Non-Exempt Courses

Should a course project not be exempt according to the above description, instead of submitting individual projects, the faculty member may request a general approval for the course as a whole, either for a term or for an academic year. To obtain approval the faculty member should submit the following information to the IRB:

- 1) Class Information:
 - a. Semester(s), Year
 - b. Class Title, identifying number, and sections
 - c. Instructor(s) name(s)
 - d. Student level (Fr., So., Jr., Sr., Grad)
 - e. Approximate number of students involved

2) Project Information:

- a. Brief description of project(s)
- b. Brief description of subject activities
- c. Description of subjects (e.g., University students, over 18, etc.)
- d. Approximate number of subjects to be used
- e. Method of recruiting the subjects
- f. Description or consent procedure to be used