

RESEARCH WITH HUMAN SUBJECTS

INVESTIGATOR'S MANUAL



UNIVERSITY OF THE PACIFIC

**Institutional Review Board
Research & Graduate Studies**

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Forms are available from the Research & Graduate Studies website,

<http://web.pacific.edu/x19709.xml>

or by contacting the IRB Administrator at 209.946.7367

I. APPLICATION DEADLINES

Each academic year the IRB will publish deadlines for submission of research protocols and meeting dates.

In general, protocol that fit into the Exempt or Expedited categories can be submitted at any time. Protocol that require Full Review must be submitted two weeks before scheduled IRB meetings. This will allow for distribution to, and review by, the entire IRB.

Researchers should plan well in advance to allow time for the approval process. All submissions will be processed in as expeditious a manner as possible; however, a minimum of two weeks should be allowed before an initial response can be expected. It is the responsibility of the primary investigator to ensure that the submission is presented to the IRB in a timely manner.

II. DEFINITIONS and ABBREVIATIONS

As they Relate to the Design and Review of Research Involving Human Subjects

Abbreviations

IRB	The University of the Pacific's Institutional Review Board, established in accordance with federal regulations governing the protection of human subjects in research for the purpose of review and approval of such research.
RGS	Office of Research & Graduate Studies. All IRB materials are maintained here, and investigators should contact this office for information regarding procedures.
DHHS	U.S. Department of Health and Human Services, the federal agency which enters into agreement with institutions through a signed assurance of compliance for the protection of human subjects in biomedical or behavioral research. DHHS requires compliance with 45 CFR 46 Code of Federal Regulations implementing Public Law 93-348 establishing institutional review boards and an ethics guidance program.
Pacific	The University of the Pacific

Definitions

1. Research: "Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. The general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects. For example, some demonstration and service programs may include research activities.
2. Human subject: "Human subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between investigator and subject, e.g., surveys, interviews, and observations.
3. Minimal risk: The risk to the subject is said to be minimal when the probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Minimal risk is to be determined with regard to the state of vulnerability of the particular subject or subjects, especially if special populations are used as subjects. Refer to Section VIII for additional guidance in determining minimal risk.
4. Subject at risk: Any individual who is exposed to the probability of injury, physical or psychological, as a consequence of participation as a subject in a research procedure or related activity which departs from the application of those established and accepted methods necessary to meet his/her needs, or which increase the ordinary risks of daily life, is at risk. Thus, one may conclude that a

subject is beyond minimal risk when participating in a research endeavor in which the risks of harm are greater, considering either probability or magnitude, than those risks encountered in daily life. Refer to Section VIII for additional information on risk.

a) Physical risk: *Any strenuous and/or unusual physical activity or procedure required of a subject, use of compounds which might alter the subject's biochemical milieu, exposure to strong stimulation, or placement in a situation which could lead to violence.* The investigator is responsible for anticipating circumstances which might endanger the subject's physical well-being and for bringing these circumstances to the attention of the IRB.

b) Psychological risk: *Any experimental condition that induces personality change or intense changes in a subject's feelings or motivations, or that may induce such changes which extend beyond the experimental or debriefing period. This includes, but is not limited to, exposing the subjects to deceit, to demeaning, dehumanizing and/or embarrassing conditions.* The investigator has the responsibility to eliminate or minimize the effects of psychological risks to subjects and to bring these matters to the attention of the IRB.

c) Confidentiality: *Right of privacy and of non-release of disclosed personal information.* The investigator must protect subjects against invasion of privacy and loss of confidentiality. Lack of secure handling of completed personality tests, questionnaires, interview protocols or data, and recorded materials, augments risk and must be avoided.

5. Informed consent: *Informed consent means "knowing consent, the exercise of a free power of choice without undue inducement, force, fraud, deceit, duress, or other form of constraint or coercion."* If the subjects are minors, or are not capable of giving consent, then parental, guardian or other legal representative consent is required (refer to Section X). Use of a written consent form that includes all the basic elements of informed consent must be documented by a signature of the subject or legally authorized representative.

6. Anonymity: *Anonymity exists when there are no identifiers whatsoever on project materials which could link the data with individual subjects.*

7. Protocol: *A protocol is the researcher's plan of a scientific experiment or treatment.* A protocol to be reviewed by the IRB consists of a completed Human Subjects Activity Review Form, sample informed consent forms, and other pertinent information such as a sample survey instrument or questionnaire, grant proposal, thesis or dissertation, or prospectus, so as to provide complete information regarding activities involving human subjects.

8. Actions taken by the IRB

a.) Approved: The proposal is unconditionally approved. The investigator may proceed with data collection without further communication with the IRB, aside from the annual renewal. If problems develop relative to the safety of any subjects, the investigator must notify the IRB immediately.

b.) Conditional Approval: The proposal is not approved as submitted. The principal investigator must respond to the lists of minor modifications requested by the IRB prior to beginning data collection. Once the investigator has satisfied the IRB's

- request for modification, the investigator will receive approval from the IRB. The investigator may proceed with data.
- c.) Disapproved: The proposal is not approved as submitted. The principal investigator must respond to the lists of major concerns and/or modifications requested by the IRB prior to beginning data collection. Once the investigator has satisfied the IRB's request for modification, the investigator will receive notification of approval from the IRB. The investigator may proceed with data collection.
- 9.) Student: a person who is receiving academic credit for performing a research project. A student must have an academic advisor who is responsible for overseeing the research.
- 10.) Unit: This may be a school or department at Pacific, depending upon the needs of the individual groups on campus.
- 11.) Review Categories:
- a.) Exempt: This term refers to proposals that meet very specific criteria established by the U.S. Department of Health and Human Services. Those criteria can be found in Section VII of this manual. An investigator submitting a proposal that meets the criteria for Exempt status must file all of the documents required for the IRB to review the proposal. The investigator must also submit a "cover letter" stating the basis for the Exempt status (see sample in Section VII). The IRB committee makes the determination of whether the proposal meets the criteria for Exempt status. The term does not mean that the investigator is exempt from filing the documentation necessary for the IRB to review the proposal.
- b.) Expedited: This term refers to proposals that meet very specific criteria established by the U.S. Department of Health and Human Services. Those criteria can be found in Section VII of this manual. An investigator submitting a proposal that meets the criteria for Expedited status must file all of the documentation required for the IRB to review the proposal. An IRB subcommittee reviews Expedited proposals and makes the determination of whether the proposal meets the criteria for that status. The findings of the subcommittee are forwarded to the IRB administrator and Chair for action.
- c.) Full: This term refers to proposals that do not meet the criteria for Exempt or Expedited proposals. Those criteria can be found in Section VII of this manual. An investigator submitting a proposal for Full review must file all of the documentation required for the IRB to review the proposal. An IRB subcommittee reviews proposals for Full review. The IRB subcommittee findings are forwarded to the IRB administrator, Chair and all committee members, for action by the entire IRB committee.

Other definitions may be found throughout the manual in appropriate sections.

III. INSTITUTIONAL REVIEW BOARD

Charge and Membership

The Pacific Institutional Review Board (IRB) is responsible for holding all research projects involving human subjects to the standards set out in the Code of Federal Regulations, 45 CFR 46. The IRB committee reviews, examines and evaluates proposals for experimentation using human subjects in accordance with guidelines supplied by the Office for Human Research Protections (OHRP) of the Department of Health and Human Services.

The Committee is charged with determining:

1. risks to human subjects;
2. benefits to subjects and/or society;
3. specific nature of subjects participation including;
 - a. recruitment of subjects,
 - b. voluntary nature of subject participation,
 - c. informed consent,
 - d. remuneration (if any) to subject,
 - e. specific procedures to be followed.

The IRB committee must have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. Appointment to the IRB committee shall be made by the Associate Provost for Research. The IRB can have as many members as necessary for it to perform its duties effectively.

To promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects, the IRB must be sufficiently qualified through the experience and expertise of its members and the diversity of their backgrounds, including considerations of their racial and cultural heritage and their sensitivity to issues such as community attitudes. In addition to possessing the professional competence necessary to review specific research activities, the IRB must be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB must therefore include persons knowledgeable in these areas. The IRB may not consist entirely of members of one profession.

The IRB must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. The IRB committee must also include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. The IRB must make every nondiscriminatory effort to ensure that it does not consist entirely of men or entirely of women. Selections must not, however, be made on the basis of gender. An IRB may, in its discretion, invite individuals (adjunct members) with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These adjunct members may not vote.

The nonaffiliated member(s) of the IRB will be drawn from the local community-at-large. Ministers, teachers, attorneys, businesspersons, or homemakers are possible candidates. The

person(s) selected should be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration will be given to the type of community from which the institution may draw its research subjects. The nonaffiliated member(s) should not be vulnerable to intimidation by the professionals on the IRB, and their services should be fully utilized by the IRB.

Federal regulations require that no IRB member may participate in the initial or continuing review of a project in which the member has a conflicting interest, except to provide information requested by the IRB. Except when requested by the IRB to be present to provide information, IRB members should absent themselves from the meeting room when the IRB reviews research in which they have a conflicting interest, and such will be noted in the IRB minutes.

IV. OVERVIEW OF PROCESS

In accordance with federal regulations, Pacific assumes the responsibility for the protection of the rights and welfare of human subjects who participate in research and other projects conducted by, or under the supervision of, University of the faculty, staff or students. In addition, the IRB is responsible for reviewing protocols for projects to be conducted on any of the three campuses by outside individuals.

To conduct this responsibility effectively, the University maintains an Institutional Review Board (IRB) competent to review research, training and other activity protocols involving human subjects and to evaluate both risk and protection against risk for those subjects.

The function of the IRB is to:

1. determine and certify that all projects conducted at or sponsored by Pacific conform to the regulations and policies set forth by the DHHS and FDA regarding the health, welfare, safety, rights and privileges of human subjects; and,
2. assist the investigator in complying with DHHS regulations in a way that permits accomplishment of the research activity.

The IRB aims to provide a service to the University and the public by facilitating ethical treatment of research subjects while at the same time supporting the investigator's endeavor to advance knowledge. This manual is intended to assist investigators in their efforts to perform research and to protect the rights and welfare of human participants.

Step 1 – Become Trained on Research with Human Subjects

It is Pacific policy that each individual conducting research with human subjects be trained in human subjects regulation history, ethical principles; federal, state and local regulations; and IRB procedures. Investigators must receive training before beginning any research with human subjects, regardless of investigator status or the category of research. Proof of training must be submitted to the IRB Administrator in the Research & Graduate Studies Office. At the time of this manual revision, investigators may receive the training by one of two ways: 1.) through periodic trainings conducted for campuses, schools, departments or specific courses; or 2.) by completing the tutorial found at: <http://phrp.nihtraining.com/users/login.php> Any updates to this policy or training sites will be available from the Research & Graduate Studies website.

Step 2 – Design Research

Although scientific concerns are important in the design of research involving human subjects, the rights of human subjects should be considered from the outset. The principles, policies and procedures set forth in this manual should be kept in mind throughout the design of any research project.

Step 3 – Determine Whether the Project Needs to be Reviewed

All research projects, whether funded or unfunded, directed or co-directed by the University's faculty, students or staff in which human subjects participate, are subject to the federal regulations governing such research, and to the policies and procedures outlined in this manual. Such projects include individual or collaborative research projects, as well as any

programmatic projects, class surveys or projects, and student government activities with a research component.

In addition, outside individuals wishing to conduct human research studies on any of the Pacific campuses are subject to these regulations. Such projects which may be subject to review by another institution's IRB must be reviewed by Pacific's IRB.

Classroom Research Projects:

Some projects assigned to students in a class may have a research component or constitute training in research methodology. *If such projects may contribute to a generalizable knowledge (e.g., through publication or dissemination of the findings), they are subject to the regulations and must undergo review.* Classroom research projects that are exclusively for instructional purposes, and meet the requirements for Exempt projects outlined in Section VII, should be registered with the Office of Sponsored Programs.

Instructors may register them by submitting a memorandum or letter outlining the nature of the research projects, and stating that they will insure that the projects conducted by students will meet the requirements for Exempt projects. If any of the student projects fit into the Expedited or Full categories, the individual students will need to submit a Human Subjects Activity Review Form.

The instructors also have the responsibility of making sure that any students that assist in or lead research projects for class credit receive appropriate training in Human Subjects Research, provided either online or through a workshop conducted by Sponsored Programs.

Instructors and students must follow federal and University regulations when designing and conducting class projects with human participants. It is the instructor's responsibility to review all classroom projects to ensure they meet the requirements for exemption.

Cooperative research:

Research between Pacific and other universities or research institutions will be reviewed by the lead institution's authorized Institutional Review Board. The lead institution is normally the primary grantee or contractor for funded projects and/or home institution of the principal investigator. Pacific will accept documented review and approval by another institution's IRB when appropriate. However, the investigator should complete the **Cooperative Research Agreement** for any research that has been approved by another Institutional Review Board other than Pacific's IRB.

Grant proposals lacking definite plans for involvement of human subjects, such as institutional block grants, training grants, or those projects in which the human subjects' involvement will depend upon completion of instruments, prior animal studies, etc., shall require the investigator to submit a protocol to the IRB once plans for activities involving human subjects are formulated. In the case of multiple projects, the investigator must agree to take the responsibility for seeing that each individual project involving human subjects will be submitted to the IRB for review.

If the investigator has any doubt as to whether or not the research is subject to the regulations, for the protection of both the human subjects and the University, the investigator should submit the protocol for review by the IRB. If there are any questions or need for clarification, the investigator is encouraged to consult with the administrator of the IRB in Research and Graduate Studies (RGS), 209 946-7367.

Step 4 – Complete and Submit the Protocol

The **Human Subjects Activity Review Form** provides the IRB with the information that it needs to approve the proposed research, and should be completed by the principal investigator of the research project. Copies of the Activity Review Form can be obtained from the unit to which the researcher belongs, or from the IRB Administrator in RGS.

Instructions for completing this form are found in Section V of this manual. As indicated in these instructions, a proposed Informed Consent Form must be attached to the Activity Review Form. For funded projects, and theses and dissertations, a copy of the proposal's methodology section must be attached. The material presented in the Activity Review Form must be complete in and of itself (i.e., do not refer to sections of the proposal to provide information to the IRB).

If the investigator believes that the research is exempt from the federal regulations, he or she should attach a cover letter to the Activity Review Form indicating the specific reason(s) for the exemption (see Section VII for categories of research that are exempt and a sample cover letter).

The investigator signs the Form, indicating that he or she will comply with the federal and University regulations outlined in the Investigator's Manual on Research with Human Subjects.

Step 5 – Review and Signature by Faculty Supervisor (Student Research Only)

All student-initiated research involving human subjects, whether dissertation, thesis, or other research projects, must be supervised by a University faculty member to insure that human subjects are protected. No less important is the opportunity for faculty to educate students about policies and procedures related to research with human subjects.

For thesis or dissertation research, the signature of the University faculty advisor is required unless there appears to be a conflict of interest (e.g., the advisor is also the unit reviewer). If the faculty advisor is unable to sign, another member of the student's committee may sign.

For student research other than thesis or dissertation projects, a faculty supervisor's signature is required and the student must be enrolled for at least one credit hour of research during that period of the project when human subjects are involved.

The faculty signature on student research attests that the research procedures comply with federal and University policies with regard to the protection of human subjects. The faculty supervisor is expected to monitor the research to insure that the approved protocol with human subjects is followed. When approved, the faculty member signs the cover sheet of the Activity Review Form in the appropriate place.

Step 6 – Review and Approval by Unit (For both faculty and student researchers)

When the investigator has completed and signed the Activity Review Form (and obtained faculty signature for student research), the Activity Review Form is submitted to the appropriate unit (department chair, or dean of the school/college) for review. The unit will either approve the protocol as described in the Activity Review Form or will consult and negotiate with the investigator until the protocol is acceptable.

The unit review plays a crucial role in the review process. By careful review of each protocol, the unit assures the investigator of a review by peers in their discipline, and also aids the IRB in expeditious processing. Units should review each protocol to determine whether the proposed research meets all accepted ethical standards as well as any more stringent criteria imposed by the unit.

Each college, department, institute, center or other University unit sponsoring research with human subjects must conduct a preliminary review of the research before submitting the protocol to the IRB. The signature of a designated reviewer within the unit is required for all projects submitted to the IRB for institutional review and approval.

Each unit must have established a review mechanism in accordance with University policy. The mechanism may consist of an already established review committee, a designated faculty member, an administrator, or some combination. A unit with five or fewer projects involving human subjects annually may request that the unit review be done by any member of the IRB prior to submission of the protocol to the IRB.

If the protocol as described in the Activity Review Form is acceptable, the designated representative of the unit signs the cover sheet of the Activity Review Form in the appropriate place. This signature indicates that the proposed project has been judged to be of sound methodology for the subject matter. Deans, department chairs and IRB Committee Members may serve as unit reviewers. The unit reviewer should not be the same as the faculty supervisor.

After the unit has approved the protocol, it is forwarded to the IRB for review as follows:

Step 7 – Determination of General Adequacy and Review Category

The proposed project is logged in at RGS by the administrator for the IRB. As needed, the administrator will perform a preliminary review of the protocol to determine whether: (a) the project is Exempt under the regulations or is to be reviewed under the Expedited or Full review process (see Section VII for a description of the review categories); (b) the protocol meets the general requirements for review under the regulations; and, (c) the informed consent form contains the required elements and is in satisfactory form for IRB review. The administrator will consult with the investigator (and/or faculty supervisor, if student research) by phone, e-mail and/or in person when the proposal does not meet the general requirements, the informed consent form is missing required elements, or additional information or clarification is needed to determine the review category.

Step 8 – Review and Approval by IRB

The administrator will send the Human Activity Review Form to reviewers, along with all supporting materials submitted by the investigator (including the Informed Consent forms). If the Administrator has requested revisions, the revised forms will be sent to the reviewers in place of the original documents.

If the protocol is determined to be Exempt under the federal regulations (refer to Section VII), the protocol is reviewed by the IRB administrator or one IRB committee member. If the protocol is satisfactory, the IRB chair signs in approval and sends an approval letter, indicating that the research may commence. The chair may delegate this step to the IRB administrator.

If the protocol is determined to require Expedited review (refer to Section VII), the Activity Review Form and supporting documents will be reviewed by two members of the IRB, who will have full authority to act on behalf of the IRB, except when the action is to disapprove a project. At the request of either reviewer, the protocol will be referred to the full IRB for consideration at their next meeting. If both reviewers approve the project, the chair of the IRB will sign the Activity Review Form and send an approval letter, indicating that the research may commence. The chair may delegate this step to the IRB administrator.

If the protocol is determined to require Full review, the Activity Review Form and supporting documents will be distributed to the entire IRB. It will be initially reviewed by two members of the IRB, who will make recommendations to the full IRB.

Therefore, the full IRB will meet to consider all protocols requiring Full review, as well as protocols in the Expedited category for which at least one of the reviewers determines that the procedures are unacceptable.

Minutes of the IRB meetings will include:

- Date, place and times (start, end) of the meeting.
- Attendees will be noted, as will absences.
- Approval of previous meeting minutes, old business, new business, as well as deliberations, actions, and votes for each protocol undergoing review by the convened IRB.
- If the IRB approves a procedure which does not include all of the required elements or varies from approved procedures, this *protocol-specific* approval will be noted and justified.
- Documentation of risk and approval period.
- Vote records will include the number of members voting for, against and abstaining in the following format: Total = #; Vote: For - #, Opposed - #, Abstained - #.

IRB Determination

The IRB can approve, conditionally approve, or disapprove the application. If the application is approved, the chair of the IRB signs the Activity Review Form, sends an approval letter, indicating that the research may commence. The chair may delegate this step to the IRB Administrator.

If there are correctable problems with the protocol, the administrator or the chair of the IRB will consult with the investigator(s) by phone, e-mail and/or in person to seek revisions in the protocol. This consultation may occur at several times in the review process (*viz.*, after review by the administrator, after review by two members of the IRB, or after a vote of the IRB).

Conditional approval indicates that problems with the protocol must be corrected before the research may commence; typically, determination of whether the changes made by the investigator satisfy the conditions set forth by the IRB can be made by the administrator or the chair, obviating further discussion of the protocol by IRB. When the conditions have been satisfied, the chair of the IRB will sign the cover sheet of the Activity Review Form, an approval letter and an approved Informed Consent document will be mailed to the investigator(s), and research may commence. The chair may delegate this step to the IRB Administrator.

If requested by the researcher, the IRB Administrator can affix to the Informed Consent document an approval and expiration date to stipulate that copies of these dated documents must be used in obtaining consent.

If the protocol is disapproved, the researcher may not conduct the research, and the IRB will provide in writing the reasons for its decision. Copies of this report will be given to the investigator, faculty advisor (if student research), unit reviewer and Dean of Research and Graduate Studies. The researcher will have the right to appeal the decision.

If the protocol is approved, and the investigator is a student, the outcome of the IRB will be sent to the student, and the faculty member supervising the research.

Step 9 – Research Commences or Decision is Appealed

Once the protocol is approved, research with human subjects may commence. It is the responsibility of the investigator (and faculty supervisor if investigator is a student) to monitor the research to insure that the approved procedures are being followed. Any adverse effects or harm to subjects should be reported to the IRB immediately.

The IRB will conduct continuing review of approved projects at intervals appropriate to the degree of risk, but not less than once per year (see Step 10). Furthermore, the IRB has the authority to observe or have a third party observe the consent process and the research.

The 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. Any such termination will include a statement of the reason for action and shall be reported promptly to the investigator, to the faculty advisor if the investigator is a student, to the appropriate University officials, and to the appropriate federal officials.

If an investigator is not satisfied with the decision of the IRB or the process by which a decision is rendered, the right to an appeal is maintained (refer to Section VI).

Step 10 – Changes in Approved Procedures

Any changes in previously approved research must be approved by the IRB. Minor changes may be submitted to the IRB with a memorandum describing those changes. Substantial change will necessitate a memorandum describing the changes as well as a revised Activity Review Form. Changes may not be initiated without IRB approval, except when necessary to eliminate apparent immediate hazards to the subject.

The number of reviewers for changes in procedures will correspond with the project type – i.e., the Administrator or one committee member for Exempt research, two committee members for Expedited research, and the entire IRB for Full Review projects. The administrator will send to reviewers the original and revised Activity Review Forms, as well as any new supporting documentation.

To ensure that changes are not made without prior IRB review and approval (except when necessary as described above), the IRB may randomly audit research records or observe research being conducted.

Step 11 – Continuing Projects and Termination of Projects

At regular intervals, the IRB will conduct continuing reviews of projects in progress. The interval for continuing review will be appropriate to the degree of risk, but not less than once per year. If the project is of high-risk, or has a high risk to potential benefit ratio, it may require review more frequently than once per year.

Approximately one month before the current expiration date, the investigator should complete a **Continuing Review/Final Report Form**. If there are no problems, adverse effects on subjects, or changes in activities by the investigator, the continuing review will be handled administratively. If any of these conditions are present, review of the project will be conducted by the IRB.

Additionally, the IRB may determine that a continuing project may need verification from sources other than investigators that no changes have occurred since the previous review. This determination may be based on location or timing of the research, or other factors including:

- a) randomly selected projects;
- b) high-risk projects;
- c) projects conducted by investigators who have previously failed to comply with IRB regulations;
- d) projects where concern has been raised during continuing review or by other sources.

When the project is terminated (i.e., procedures involving human subjects are completed), the investigator must complete the Continuing Review/Final Report Form and send it to the IRB. The investigator must keep all study records, including consent forms, for three years after the research is completed. Records are subject to audit at anytime during these three years. Audits may be conducted by Pacific's IRB, Pacific's internal auditor, the Department of Health & Human Services, the Food & Drug Administration, the National Science Foundation, external audit agencies, or other external entities.

The IRB Administrator will retain copies of the following for a period of three years after the research is completed:

- Human Subjects Review Form, and all supporting materials submitted during the review process
- All communications regarding the project, including e-mails and logs of phone calls
- Continuing Review/Final Report forms and supporting materials

At the end of the three years both the Investigator and the IRB Administrator will destroy all copies of the data, unless there are extenuating circumstances that require the data to be

retained for a longer period of time. Destruction of the data shall include: shredding of paper documents, erasure of computer files, and snipping and disposal of audio and/or visual tapes used in recording subject responses.

V. EXPLANATION OF REVIEW FORMS

The Human Subjects Activity Review Form, Continuing Review/Final Report Form, and Cooperative Research Agreement can be found in Section XII of this manual. Additional copies of these forms may be obtained from Research and Graduate Studies (RGS) website or any academic unit. Questions concerning the forms or procedures should be directed to the administrator for the IRB at 209 946 7367.

Human Subjects Activity Review Form

Research investigators are required to complete and submit the Human Subjects Activity Review Form for all studies involving human subjects for determination of exemption or review by the IRB.¹ Signatures of the investigator, faculty supervisor if the investigator is a student, and representative of the unit review are required prior to submission of the Activity Review Form to the IRB for review.

In brief, the answers to questions on the Activity Review Form should provide the IRB with a complete description of the following items:

- 1.) the purpose and objectives of the study;
- 2.) the human subjects involved in the project;
- 3.) the activities involving human subjects and their potential effects
- 4.) data collection and procedures to promote protection and confidentiality;
- 5.) the benefits to humanity and to the participants that might result from the study;
- 6.) the likely risks (physical, psychological, sociological, loss of confidentiality, criminal or civil liability, etc.) to subjects as a result of their participation;
- 7.) the safeguards to be used to eliminate or minimize each of the possible risks;
- 8.) what, if any, other compliance issues need to be addressed; and,
- 9.) how and when informed consent will be obtained, documented and maintained.

The Activity Review Form should be written in clear, jargon-free language, understandable to people outside the researcher's field. The form must be typed. It is preferred that applications be signed, scanned as PDF documents, and submitted by e-mail to the IRB Administrator. However, if paper copies are submitted, an original plus one clear copy (two total) should be submitted for Exempt projects; two clear copies (three total) should be submitted for Expedited proposals; twelve (one original and eleven clear copies) should be submitted for Full Review protocol.

The proposed informed consent forms must be attached to each copy of the Activity Review Form, along with other pertinent information such as samples of the survey instrument,

¹ One exception to this requirement is Exempt classroom projects that are supervised by an instructor. The instructor, though, may request that the students fill out this form as part of the instruction on responsible conduct of research.

questionnaire, or interview questions, and copies of the thesis/dissertation or grant proposal, if applicable.

The investigator must sign on the appropriate line. If the investigator is a student, the completed protocol is then referred to the faculty advisor or supervisor for review and signature. Then, the signature of the unit reviewer should be obtained. The unit reviewer may be a department chair, dean, or an IRB committee member who resides in the researcher's department/unit.

Once all signatures are obtained in approval of the protocol, the completed protocol is submitted to RGS for preliminary review, assignment to review categories, and distribution to reviewers. Once the IRB review is completed, and if the project is approved, the chair of the IRB signs in final approval of the protocol and a letter or notification is sent. This step may be designated to the IRB Administrator.

Sections I through VIII.

I. Purpose and objectives of the research: Provide a brief description, in lay terms, of the overall objectives of the research. Specific activities to be undertaken will be addressed later in the form.

II. Description of Subject Population

a) Description of the subject populations/recruitment:

Be as specific as possible in identifying each subject group in the study. Indicate if a subject group(s) includes special populations (*refer to II.e. below or Section X for information on special populations*). Indicate the age or age-ranges of each group. If students are subjects, indicate which school(s) will be contacted (including University classes). Indicate how recruitment will be handled (through instructors of classes, subject pools, other organizations, advertising, etc.). Refer to Section VIII for recruitment concerns.

b) Approximate number of subjects in each group:

Indicate the proposed number of subjects for each subject group to be involved in the project.

c) If advertising for subjects:

Include a copy of the advertisement. Investigators must follow the following guidelines, published by the Food and Drug Administration (FDA):

- i. information must not be misleading to subjects, especially when a study will involve vulnerable populations;
- ii. information should be limited to the name and address of the investigator, the purpose of the research and eligibility criteria for participation as subjects, a clear description of any benefits and risks of participating, and the location of the research and whom to contact for further information; and,
- iii. if a drug or device is to be used in the research, no claim should be made as to its superiority, safety or effectiveness.

d) Selection/Exclusion criteria:

Selection/exclusion criteria can include age, health status, gender, physical activity level, extent of disabilities, profession, social parameters, etc. Be as specific as possible in identifying criteria for subjects in this project.

e) Special populations:

Under the regulations, special populations are more likely to be vulnerable as subjects in research and must be accorded special considerations. Special populations include children, mentally handicapped individuals, pregnant women, fetuses, and prisoners (refer to Section X for information on special considerations for these groups).

III. Description of Methodologies

a. Activities involving human subjects:

Each activity of each group must be completely described, including the expected time involvement of participants and location for each activity. Additional pages may be attached as necessary.

b. Collection of data:

Check all data collection methods to be used and include materials as indicated.

IV. Data:

Provide complete information concerning plans for recording, maintaining and disposing of data (refer to Section IX for information on confidentiality). All forms of data – paper, electronic, videotape, etc. – should be destroyed three years after the study is completed.

V. Benefits/risks/costs:

The risk/benefit ratio is crucial in the IRB's review and approval of research with human subjects. Some research cannot be approved unless benefits to participants or humanity outweigh the risks to subjects (refer to Section X). Projects of more than minimal risk to subjects require special considerations and additional elements in informed consent (refer to Sections VIII and IX). Investigators should consider all risks that may result from the research and design safeguards against those risks. Payment to subjects may be considered a benefit, but the amount and payment schedule should be determined carefully so as to avoid problems of coercion or undue influence.

VI. Other compliance issues:

State and local laws may exist which govern the use of special populations, existing data or documents, or other activities in research. The FDA requires review or exemption certification for the use of a new drug or device in research. The University has other committees which must review protocols involving the use of animals, radiation and biological or chemical hazards.

VII. Informed consent:

Informed consent must be obtained from participants prior to their involvement in the research, unless specifically waived by the IRB. Special populations require additional considerations in obtaining informed consent (refer to Section IX and Section X).

VIII. Fill out this section ONLY if you are requesting Exemption Category #4.

Continuing Review/Final Report of Research With Human Subjects

At least annually, and more often if the risk to subjects warrants it, the IRB will conduct continuing review of projects in progress. Approximately one month prior to expiration of the current approval period the Continuing Review/Final Report Form must be completed and submitted to RGS for review, along with a sample of the informed consent form in use. If there are no problems, changes in or identification of new possible adverse effects on subjects, or changes in activities indicated by the investigator, continuing review will be handled administratively. If any of these conditions are present, investigators should also submit a revised Activity Review Form for review by the IRB.

When the project is terminated (procedures involving human subjects are completed), the Continuing Review/Final Report Form must be completed and submitted to RGS for the project file.

Cooperative Research Agreements

In order to avoid duplication of effort, cooperative research between Pacific and other universities or institutions will be reviewed by the lead institution's authorized Institutional Review Board. The lead institution is normally the primary grantee or contractor for funded projects and/or home institution of the principal investigator. Pacific will accept documented review and approval by another institution's IRB when appropriate. The investigator should complete the Cooperative Research Agreement, available from RGS for any research that has been approved by another IRB. A copy of the signed agreement will be kept on file in RGS.

VI. CRITERIA FOR APPROVAL

IRB Review and Approval

The IRB may approve research when the following conditions are satisfied:

1. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and, whenever appropriate, by using procedures already being performed on subjects for diagnostic or treatment purpose;
2. Risks to subjects are reasonable in relation to anticipated benefits, and/or the importance of the knowledge that may reasonably be expected to result (the IRB will consider only those risks and benefits that may result from the research);
3. Selection of subjects is equitable (the IRB will consider the purposes of the research, the setting in which the research will be conducted, and the population from which subjects will be recruited);
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative and will be appropriately documented, unless informed consent or documentation is specifically waived by the IRB (refer to Section IX);
5. The research plan makes adequate provision for monitoring the data collected to insure the safety of subjects where appropriate;
6. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data where appropriate;
7. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as students or persons with severe physical or mental disabilities or illness, appropriate safeguards have been included in the study to protect the rights and welfare of these subjects.

The IRB may establish subcommittees as deemed practical to utilize a specific member's expertise, and may consult with individuals outside the IRB having competence in special areas to assist in the evaluation of complex issues.

As specified in the federal regulations, only the IRB or a quorum of its of officially appointed membership may give final review and approval to a project involving human subjects. Certification of approval will be issued by Research and Graduate Studies stating that the requirements of the Institution's federal assurance and federal regulations have been met.

The IRB may:

- 1) approve the protocols without question;

- 2) approve the protocol on condition (the basis for the conditional approval will be recorded in the minutes of the IRB meeting and forwarded to the investigator); or,
- 3) not approve the protocol (the basis for not approving the protocol will be recorded in the minutes of the IRB meeting and forwarded to the investigator).

Institutional approval must be granted prior to the commencement of the project. Projects that are not yet approved by the IRB prior to receipt of funds by the University will not be allowed use of the funds until such approval is granted. The chair of the IRB has the responsibility and authority to notify the business office to withhold all funds until such time as the project is approved by the IRB. Such notification responsibility may be delegated to RGS at the direction of the chair.

Compliance with, or exemption from, the regulations will not in itself constitute approval by the institution for conduct of the research. RGS and the IRB shall, therefore, review all research involving human subjects to determine whether this institution shall support or sponsor such research.

Appeal Process

In the event that a protocol is not approved by the IRB, the appeal process is as follows:

- 1) The investigator submits the grievance in writing to RGS for forwarding to the chair of the IRB;
- 2) The chair discusses the grievance with members of the IRB in an attempt to provide resolution;
- 3) If the grievance cannot be resolved at step 2, the investigator may request a meeting with the IRB, and may be accompanied by counsel or other persons with expertise or knowledge of research related to the procedures in question;
- 4) The IRB may invite a faculty member who is not a member of the IRB to act as an observer to the process; and,
- 5) Based on the findings of the IRB, a final decision regarding the grievance will be made by a majority vote of the IRB.

Review of Investigational Drugs/Devices

The Food and Drug Administration regulations governing the use of investigational drugs and devices in research with human subjects require the review of such research by the IRB. The IRB determines whether the drug or device is of significant risk or non-significant risk (significant risk devices are considered to support or sustain life or of substantial importance in diagnosing, curing or treating disease, such as artificial hearts, intrauterine devices, or hemodialysis systems).

Protocol submitted for studies on investigational drugs must include the investigators brochure. This will permit the reviewers (and subjects) to properly evaluate summaries of previous animal and human studies.

When an investigational device is being studied, the investigator must supply the name, address and contact information of the study sponsor. The FDA requires direct communication between sponsors and IRBs for certain studies of medical devices, and when the informed consent has been waived.

An "investigational device exemption" (IDE) exempts sponsors or investigators temporarily during the period of investigation from certain parts of the regulations.

RGS will make the appropriate certification to funding agencies when an investigational new drug or device is proposed in the research. Consult with the IRB administrator (209.946.7367) for further information.

VII. REVIEW CATEGORIES

There are three levels of review under which a protocol may be assigned: Exempt, Expedited and Full.

The three levels of review are:

- 1) "Exempt" research involves only minimal risk. The protocol should be evaluated by the investigator and a determination made concerning whether or not one of the exemption categories applies. A cover letter citing the applicable category or categories (a sample letter can be found later in this Section) should accompany the Activity Review Form.

Requests for exemption will be approved or disapproved by the IRB administrator, in consultation with the chair of the IRB as necessary. The protocol will then be reviewed by either the Administrator or one committee member.

Full review of Exempted protocols on a random basis may be performed by the IRB and/or by a federal committee.

- 2) "Expedited Review" is used for some research of minimal risk, and for minor changes in previously approved research during the period for which approval is authorized. Expedited protocols will be reviewed by two members of the IRB, who may approve the protocol, request changes, or refer it to the full IRB.
- 3) "Full Review" is given to all protocols involving greater than minimal risk and not eligible for Exempt or Expedited review. Two members of the IRB will review the protocol and make recommendations to the full IRB, which has the authority to approve, require revisions, or disapprove the protocol.

EXEMPTION CATEGORIES

For projects which Investigators deem to be exempt, they are required to submit a "Human Subjects Activity Review" form, and write a cover letter defending their reason for requesting this category. A sample cover letter follows this Section.

Paperwork for Exempt projects must contain the same detail of information as protocols of non-Exempt projects, as well as a cover letter citing the federal exemption category or categories under which the project falls (see sample letter is found in Section VII).

To help in deciding whether research is Exempt, the investigator should be aware of the the following criteria (taken from the Code of Federal Regulations, 45 CFR 46). The following categories of research are Exempt if the subjects are eighteen years of age or older:

- 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 if: i) information taken from these sources is recorded in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects, and ii) any disclosure of subjects responses outside the research could not 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 procedures, interview procedures or observation (including observation by participants) of public behavior, that is not exempt under (2) of this Section if: i) the subjects are elected or appointed public officials or candidates for public office; or, ii) 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 the information is recorded by the investigator 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 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 or 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 and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

The following categories of research are Exempt if the subjects are less than eighteen years of age or mentally handicapped and require a conservator:

- 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 instructional techniques, curricula, or classroom management methods.
- 2.) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

- 3.) Research involving observation of public behavior where the following conditions exist: i) observations are recorded in such a manner that the human subjects cannot be identified, directly or through identifiers linked to the subjects; ii) the observations recorded about the individual, if they became known outside the research, would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; iii) the research does not deal with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol; and iv) the investigator(s) does not participate in the activities being observed.
- 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 in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.
- 5.) Unless specifically required by statute, research and demonstration projects which are conducted by or subject to the approval of the Department of Health and Human Services, and which are designed to study, evaluate or otherwise examine:
 - i. programs under the Social Security Act, or other public benefit or service programs;
 - ii. procedures for obtaining benefits or services under those programs;
 - iii. possible changes in or alternatives to those programs or procedures; or
 - iv. possible changes in methods or levels of payment for benefits or services under those programs.

SAMPLE COVER LETTER FOR EXEMPT PROJECTS

Date:

To: Administrator, IRB
Research & Graduate Studies Office

FROM: (Investigator's name, department)

RE: (Title of project)

Based on DHHS policy regarding protection of human subjects, this project falls in exemption category #3 (refer to categories listed above). The research project proposed consists of a longitudinal survey of a volunteer sample of UOP students from the entering freshmen class of 1989. Subjects' stereotype beliefs about a variety of social groups are sampled at different points in time. The data are stored on computer by code number so that there is no way that an individual student's name can be associated with that student's responses. For purposes of contacting the subjects, there is a separate list of names without the corresponding code numbers that enables us to schedule subjects' participation. The master code list will be destroyed upon completion of the project. All subjects are volunteers, will be paid for each research session, and are free to drop out of the research at any time with no penalty or loss of benefits. The survey, attached, is nonsensitive in nature.

I am prepared to defend the exemption category I have cited to a federal agency if necessary.

EXPEDITED REVIEW CATEGORIES

For research activities of minimal risk in which the only involvement of human subjects will be in one or more of the following categories:

- 1) Collection of hair and nail clippings, in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.
- 2) Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.
- 3) Recording of data from subjects 18 years of age or older using non-invasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echocardiography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).
- 4) Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older, in good health and not pregnant.
- 5) Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
- 6) Voice, video, digital or any imaging recordings made for research purposes such as investigations of speech defects.
- 7) Moderate exercise by healthy volunteers.
- 8) The study of existing data, documents, records, pathological specimens, or diagnostic specimens that is not publicly available, or if subjects can be identified.
- 9) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.
- 10) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.
- 11) (Some research, that would be Exempt except that subjects are under 18, may be Expedited. See Section X.

FULL REVIEW: RESEARCH THAT REQUIRES APPROVAL AT A REGULAR COMMITTEE MEETING

Research which involves more than minimal risk, or is not covered by the categories listed previously, will require Full review.

Any research which involves fetuses, pregnant women, prisoners, or groups which may have diminished capacity to provide consent or who may be high risk must be provided Full review. Research where there is risk to children requires Full review.

VIII. RISK TO SUBJECTS

Pacific has an ethical and moral obligation to safeguard the rights and welfare of all subjects involved in research, training, educational development and other activities where subjects are exposed to a risk that could be detrimental to their health or well-being. In those cases where risk may exist, even with informed consent, approval of a research project will be made only if the risk to the individual is outweighed by a clear explanation of the potential benefit to the person (as in the case where an activity involves therapy, diagnosis, management, etc.). In evaluating risks and benefits, the IRB shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies the subjects would receive even if not participating in the research), and shall not consider long-range effects of applying knowledge gained in the research as among those risks that fall within the IRB's purview of responsibility.

The University shall be responsible for physical or psychological injury to human subjects attributable to university-sponsored research, development, and related activities, to the extent that the University may be found liable under federal and state laws. Therefore, the obligation of researchers to conduct activities in a manner and at such locations as will assure the proximity of adequate medical attention if warranted, and to provide appropriate referrals to subjects for adequate facilities and professional attention should subjects suffer physical, psychological or other injury, is of paramount importance when designing research involving human subjects.

The seriousness of a risk to subjects is a function of the magnitude of the harm and the probability of the harm. A risk may be serious or significant because it has a probability (even a low probability) of great harm (e.g., a low probability of death), or because it has a high probability of slight harm (e.g., a near certain probability of physical discomfort or psychological distress).

The risks of participation in research may be part of the research design or may be a consequence of the research procedures, or both (e.g., the risks of an adverse reaction to an investigational drug are part of the research design, while the risk of hematoma from blood drawn in the research is not part of the design but a consequence of the research procedures). Risks may be a consequence of the methods of recording, maintaining, or reporting data, and they may be a consequence of methods of obtaining informed consent.

Recruitment

Voluntariness begins with recruitment. Potential subjects must not feel that they have been coerced into participating, nor must they fear the loss of some benefit to which they are otherwise entitled if they choose not to participate (such as on-going support by a social agency).

Special care must be taken if the person doing the recruiting is a person who is in a position of authority (such as a teacher recruiting his or her own students) or makes decisions about the provision of services (such as a director of a training clinic). It is the investigator's responsibility

to ensure that a person's decision to participate or not will have no other effect on an existing relationship.

Research using classroom subjects:

Students at Pacific may be required to complete research projects for some courses. Instructors should ensure that several project options are available to the students, or alternative means are available for obtaining credit.

Students may be asked to participate as subjects in classroom research projects; however, it should not be a coercive requirement, and informed consent, if appropriate, must be obtained. Alternate means of receiving credit if a student chooses not to participate or chooses to withdraw during the course of the study should be provided.

The IRB recognizes that participating in research and receiving information about the research may be instructionally relevant. Studies for classroom purposes only (not for publication or presentation), and which meet the criteria for the "exemption" category are the sole responsibility of the instructor and their department chair. The instructor should advise the IRB at the beginning of the semester, by submitting a memo or e-mail, that such research will take place. It is the responsibility of the instructor and chair to ensure that the project meets the requirements for an Exempt proposal, that all procedures for informed consent are adhered to, and that copies of the protocol and forms along with justification for the exemption are kept on file in the department office for three years after the end of the semester's activities.

Recruitment of subjects who are clients of social service or other types of institutions:

The researcher shall not ask institutions to directly identify potential subjects for a research study. Rather, the investigator shall ask an intermediary (doctor, case worker, school administrator) to first approach potential subjects (or their guardians, as appropriate) and inform them about the research. If a potential subject agrees to participate, the intermediary should provide her/him with the information necessary to contact the researcher, in such a way that the institution is unaware whether the subject chooses to participate in the research.

The researcher shall not ask institutions to release records or anecdotal information either for the purposes of identifying subjects, or for examination by the investigator, unless this information is public. An investigator wishing to examine records must first obtain permission of the subject via an intermediary. If a potential subject agrees to release his or her records, the intermediary should provide the information necessary to contact the researcher.

Inclusion of Women and Minorities in Research:

All research that is supported by the NIH will provide information on the age ranges, gender, racial/ethnic composition and health status of the subject population. If this information is not included in the Activity Review Form, the investigators must provide a clear rationale for exclusion of this information.

Types of risks

The risks to subjects may be physical, psychological, sociological, or legal, among others:

1. Physical risks include physical discomfort, pain, injury, illness or disease brought about by the methods and procedures of the research. A physical risk may result from the

involvement of physical stimuli such as noise, electric shock, heat, cold, electromagnetic or gravitational fields, etc. Engaging a subject in a social situation which could involve violence may also create a physical risk.

2. Psychological risks include the production of negative affective states such as anxiety, depression, guilt, shock and loss of self-esteem and altered behavior. Sensory deprivation, sleep deprivation, use of hypnosis, deception or mental stresses are examples of psychological risks.
3. Sociological risks include alterations in relationships with others that are to the disadvantage of the subject, including embarrassment, loss of respect of others, labeling a subject in a way that will have negative consequences, or in some way diminishing those opportunities and powers a person has by virtue of relationships with others.
4. Economic risks include payment by subjects for procedures not otherwise required, loss of wages or other income and any other financial costs, such as damage to a subject's employability, as a consequence of participation in the research.
5. Loss of Confidentiality: In all research involving human subjects, confidentiality of identifiable information is presumed and must be maintained unless the investigator obtains the express permission of the subject to do otherwise. Subjects have the right to be protected against injury, illegal invasions of privacy and to preservation of personal dignity. The more sensitive the research material the greater the care that must be exercised in obtaining, handling, and storing data.

Investigators should be cognizant of the following guidelines to ensure confidentiality:

- a. acquiring of personal information should be limited to that which is absolutely essential to the activity;
- b. data should be securely stored and accessible only to the investigator and authorized staff;
- c. data should be coded as early in the activity as possible, and plans for the ultimate disposition of the data should be made;
- d. identities of individuals should not be released without express permission of the individual;
- e. use of stored data which was originally obtained for different purposes and which involves identifiable subjects, requires examination of the risk involved, a determination of whether the new use is within the scope of the original consent or whether obtaining additional consent or IRB approval is necessary and feasible, and provision made for the preservation of anonymity of the subjects.

If an investigator will have access to identifiers linking a subject to their medical information, HIPAA regulations must be followed (See page 42 of this manual for a list of the 18 identifiers that can be linked to the subject including name, identification code, date of birth, zip code [in some circumstances] or reference that could be used to identify an individual outside of the context of the research setting). In this instance, the

investigator should provide the IRB with the Pacific HIPAA Privacy Rule Questionnaire, and provide a copy of the HIPAA Authorization Form that will be used in the study.

An identifier that links a subject to identifiers kept elsewhere can also lead to loss of confidentiality. If records are linked to a second set of records (e.g, test scores linked to school grades) and the second set of records is identified, then the first set would also be identified. Privacy may also be invaded by being identified as a qualified participant for a study (e.g., membership in Alcoholics Anonymous). The investigator should decide whether the information or data could be traced back to an individual subject, and make appropriate safeguards to ensure that confidentiality will be maintained (refer to Section IX). Please also refer to the Recruitment section earlier in this chapter for information on accessing subjects' records.

6. Criminal or civil risks exist when the research methods are such that the subject or others will be liable for a violation of the law, either by revealing that the subject or others have or will engage in conduct for which they may be criminally or civilly liable, or by requiring activities for which the subject or others may be criminally or civilly liable.
7. Deception: Occasionally, some degree of deception is involved in a research study. Minor deception, such as failing to tell the subject what the specific points of interest are in an attempt to prevent biasing the results, can be acceptable provided the subject is fully debriefed after participating. Risks stemming from major deceptions, such as leading a subject to believe that he/she has committed a crime or has a disease, must be clearly counterbalanced by the benefits of the research. Withholding information cannot be used as a means to secure the participation of subjects in research.

The use of deception imposes special responsibilities on the investigator. One of these responsibilities is to provide appropriate debriefing to the subjects. In each case, the IRB will require information as to why deception is needed, how the potential benefits justify its use, and how debriefing will be done.

If information was temporarily withheld from the subject during the study, or if deception was employed, a separate debriefing statement should be presented at the end of the procedure. This statement should clearly indicate why information was withheld during the study, and/or the purpose of the deception.

8. Economic: Economic risk can include missed work or lost benefits. These should be explained to the potential subjects, even if they are being compensated for their participation.

Minimal Risk

Defining "minimal risk" in research involving human subjects is useful for both the investigator and the IRB, in that research involving more than minimal risk requires additional elements in the informed consent documents, including a liability clause, and possibly Full review by the IRB. Projects with minimal risk may be reviewed through the Exempt or Expedited process.

The federal regulations governing research with human subjects define minimal risk as follows: "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

In broad terms, a project may be determined as involving minimal risk if:

1. the participant experiences no pain or physical danger beyond the levels normally to be expected in their everyday life;
2. the participant experiences no emotional arousal or psychological stress beyond the levels normally to be expected in their everyday life;
3. the project neither induces nor attempts to induce long-term significant change in the participant's behaviors (including attitudes toward self and others);
4. the data would not embarrass or socially disadvantage the participant, were confidentiality to be violated; or,
5. any concealment on the part of, or misinformation provided by, the investigator with regard to the specific purpose of the project is such that there is no basis for believing the participant would choose not to participate in the research had the true state of affairs been made known to him or her.

Additional considerations for making this determination might include whether the project provides a novel environment for the subject, or whether the subject will be exposed to situations which would not be considered a risk for the general public but might be risky for a special population such as disabled, young or elderly subjects.

The IRB will make the final determination as to the project's level of risk and the safeguards required to minimize risks for subjects.

IX. INFORMED CONSENT

Investigators shall be responsible for ensuring that informed consent is documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative, unless this requirement is specifically waived by the IRB.

Investigators shall insure that each person signing the written consent form is given a copy of that form.

Informed consent is the knowing consent of an individual, or his/her legally authorized representative, which is obtained without undue inducement or element of force, fraud, deceit, duress, or other forms of constraint or coercion. A *consent form* confirms informed consent and is designed to protect the investigator and the institution against legal liability.

One of the most common reasons for delay of approval of a protocol is an inadequate consent form. The consent form should be a statement addressed to the subject and should read as such. Ordinarily, it is best worded in the second person. It must be in language the subject can understand (avoid or define technical terminology, adjust for educational background and ages, provide translations in other languages when subjects do not understand English). Separate forms may be required for different subject groups (parents, children, UOP students, etc.). If subjects are children, assent forms are used for the subjects, and consent forms for their parents or guardians.

Templates for informed consent forms for adults and assent forms for children can be found at the end of this Section. Researchers need not copy this language verbatim, so long as all required elements are included in the informed consent form.

If required, the IRB Chair or Administrator can affix to the Informed Consent document an approval and expiration date.

Obtaining Informed Consent

Research investigators are responsible for obtaining informed consent and for insuring that no human subjects will be involved in the research prior to obtaining their consent. In obtaining informed consent, investigators must avoid the possibility of coercion or undue influence.

Investigators may not delegate the responsibility of obtaining informed consent to another person without IRB approval. If an investigator does wish to delegate the responsibility, they should provide the name of the specific individual(s) that this duty is delegated to. Those individuals must also be trained on human subjects research.

Unless otherwise authorized by the IRB, investigators are responsible for insuring that legally effective informed consent:

1. is obtained from the subject or the subject's legally authorized representative;
2. is in language understandable to the subject or the representative;
3. is obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate; and

4. does not include exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the research investigator, the sponsor, the institution or its agents from liability for negligence.

A written consent form must include the following items. In addition, special provisions are required when subjects are from special populations (refer to Section X).

Required Elements for All Consent Forms

1. a statement that the study involves research;
2. an explanation of the purposes of the research;
3. a description of the procedures to be followed;
4. the expected duration of the subjects' participation;
5. a description of any reasonably foreseeable risks or discomforts to the subject;
6. a description of any benefits to the subject or to others which may reasonably be expected from the research;
7. a statement describing how confidentiality of records identifying the subject will be maintained;
8. an explanation of:
 - a) who the principal investigator is, their business phone number, (include faculty advisor name and phone number if appropriate) and what institution they represent.
 - b) whom to contact regarding research subjects' rights (RGS); and
9. statements that:
 - a) participation is voluntary,
 - b) refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled,
 - c) the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
 - d) the subject has been informed about the project and had an opportunity to ask, and have answered, any questions they have regarding their participation in the study.
10. a statement that the subject may keep a copy of the consent form; and,
11. a place for approval signature and date by a representative of the IRB.

Additional Elements if Appropriate

1. For research involving more than minimal risk, the consent form must include an explanation of compensation, available medical treatments (if necessary), who is responsible for payment of medical expenses incurred as a result of participation in the study, and where further information may be obtained. The following language is suggested: *You or your own insurer are responsible for any medical expenses resulting from injuries to you caused by your participation in this research project. If you are a University student or employee covered by a University medical plan, the terms of that plan may apply to such an injury.*

2. If subjects will be paid, all information concerning payment, including amount and schedule of payment.
3. a disclosure of any conflict of interest that may be present
4. A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.
5. Identification of any procedures that are experimental.
6. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
7. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
8. Any additional costs to the subject that may result from participation in the study.
9. The consequences of the subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
10. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue will be provided to the subject.
11. The approximate number of subjects involved in the study.
12. If the study falls under FDA regulations (i.e., an investigational drug or device), the informed consent document should state that the FDA may inspect research records. This inspection is not a waiver of the subject's legal right to privacy.

Forms of Consent Documents Acceptable

The consent form may be:

- 1) a written document that contains the required elements of informed consent, to be read by the subject or the subject's representative in which case a copy of the oral presentation will be provided to the IRB, or by the investigator to the subject; or
- 2) a short written form stating that the basic elements of informed consent have been presented orally to the subject or representative.

Waiver of Documentation of Informed Consent

Under certain conditions, the IRB may waive the requirement that the subject sign the consent form. However, waiver of documentation of informed consent does not constitute waiver of informed consent. The IRB may waive the requirement to obtain a signed consent form for some or all of the subjects if one of the following conditions exists:

1. The consent document is the only record linking the subject and the research and the principle risk would be potential harm resulting from a breach of confidentiality. Subjects will be asked whether or not they want documentation linking them to the research, and their wishes will prevail.
2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
3. For projects of minimal risk involving the use of questionnaires, the required elements of informed consent may be included in an introductory letter attached to the instrument,

which includes a statement that completion and return of the questionnaire will constitute consent to participate (a sample letter may be found at the end of this Section).

In cases where documentation is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Oral Consent

Only in special and/or unusual circumstances can the consent of the subjects be obtained orally. Waiver of prior written informed consent must be approved by the IRB. A waiver of prior written informed consent might be granted in the case where: a) the risk to the subject is minimal; b) use of primary procedures for obtaining consent would invalidate important research objectives; or c) alternative means would be less advantageous to the subjects.

Oral presentation of the elements of informed consent should be used only when it is the most appropriate means of conveying relevant information to the subject, thus adapting the presentation to the subject's capacities. The presentation may be made in either of two ways: 1) a written consent document that sets forth the required basic components of informed consent may be read to the subject or the subject's representative and the investigator will allow the subject or representative ample time to read and consider the document before it is signed; or 2) the IRB may approve a short written form describing the particulars of required informed consent that are to be presented orally to the subject or representative.

Where oral consent is allowable, investigators shall insure that:

1. a witness is present at the oral presentation;
2. the short form is signed by the subject or the representative;
3. the witness signs both the short form and a copy of the written summary of the oral presentation;
4. the person obtaining consent signs a copy of the summary;
5. a copy of both the short form and summary is given to the subject or representative; and,
6. the written summary of what is to be said to the subject or the representative receives prior approval of the IRB.

Waiver or Alteration of Informed Consent

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent, provided one of the following sets of conditions exists and is documented.

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine a) programs under the Social Security Act, or other public benefit or service programs; b) procedures for obtaining benefits or services under those programs; c) possible changes in or alternative to those programs or procedures; or d) possible changes in methods or levels of payment for benefits or services under those programs; the research could not practicably be carried out without the waiver or alteration.
2. The research involves no more than minimal risk to the subjects; the waiver or alteration will not adversely affect the rights and welfare of the subjects; the research could not

practicably be carried out without the waiver or alteration whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Retention of Signed Documents

Investigators are responsible for placing the consent documents signed by research subjects in a repository approved by the Research & Graduate Studies Office and for retaining signed consent forms for three years after termination of the project.

Confidentiality/Anonymity

Subjects in research, evaluation, and training projects give their informed consent to participate. In the informed consent procedure, subjects are often given assurances of protection against loss of confidentiality or for total anonymity. Despite the assurances and subsequent efforts, subjects may yet be identifiable, and it is recommended that the investigator does not assure anonymity.

Two legal conditions are at stake:

1. Loss of confidentiality can occur when a court requires that research files be submitted as evidence in a legal matter. The court decides who has access to the files and whose identity will be revealed.
2. Loss of confidentiality can occur under the so called "Freedom of Information Act." Under this Act, citizens can gain access to files of federal agencies, except as provided by law.

The University is obligated to protect subjects' identities when the promise of protection is made in obtaining their consent to participate. This obligation can be fulfilled in the following ways:

1. If the research files are arranged so that the investigators cannot know the identity of participants, then loss of confidentiality cannot occur by court order. This can be accomplished by routinely destroying master code lists. Confidentiality may not be preserved by locating the master code lists outside the jurisdiction of the court, i.e., in another country. Anonymity may be assured when there are no identifiers whatsoever on project materials which could link the data with individual subjects.

Investigators can be held in contempt of court for failing to submit the research files or for destroying the master code lists only because of knowledge of the intent of the court.

Investigators will not be held in contempt of court for not revealing the identity of the subjects, when they routinely take steps to keep the identity of subjects unknown to themselves (i.e., subject responses are anonymous).

2. If identifying information is not sent to a federal agency, then loss of confidentiality cannot occur under the Freedom of Information Act. Federal files are subject to the Act. University files are not subject to the Act. Participants should be informed if identifying information will be sent to a federal agency.

Refer to Section IX for additional information on confidentiality.

INFORMED CONSENT TEMPLATE
(TITLE of STUDY)

You are invited to participate in a research study which will involve (STUDY DESCRIPTION). My name is (YOUR NAME), and I am a (YOUR ROLE) at the University of the Pacific, (SCHOOL OR DEPARTMENT). You were selected as a possible participant in this study because of (REASONS FOR SELECTION).

The purpose of this research is to (PURPOSE). If you decide to participate, you will be asked to (PROCEDURES). Your participation in this study will last (DURATION).

There are some possible risks involved for participants. These are the (RISKS). There are some benefits to this research, particularly that (BENEFITS).

(If applicable, insert statement on ALTERNATIVES to this procedure.)

If you have any questions about the research at any time, please call me at (YOUR PHONE NUMBER), or (ADVISOR or ANOTHER CONTACT'S PHONE NUMBER). If you have any questions about your rights as a participant in a research project please call the IRB Administrator, Research & Graduate Studies Office, University of the Pacific (209) 946-7367.

(If applicable, insert statement on what steps should be taken in the case of research-related injury. See page 34 of Manual for suggested language.)

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission. Measures to insure your confidentiality are (CONFIDENTIALITY PROTECTIONS). The data obtained will be maintained in a safe, locked location and will be destroyed after a period of three years after the study is completed.

Your participation is entirely voluntary and your decision whether or not to participate will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to participate, you are free to discontinue participation at any time with out penalty or loss of benefits to which you are otherwise entitled.

Your signature below indicates that you have read and understand the information provided above, that you willingly agree to participate, that you may withdraw your consent at any time and discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled, that you will receive a copy of this form, and that you are not waiving any legal claims, rights or remedies.

(If applicable, give information on how to obtain the results of the study.)

You will be offered a copy of this signed form to keep.

Signature

Date

SAMPLE ASSENT FORM (children)

Child's Name:

We are interested in what attention is, so that one day we can try to help people who find it hard to concentrate on things, and we'd like you to help us. We'd like you to play a kind of game on a computer. All you'll have to do is press a button when some lights come on. It will take about an hour, but you can rest as much as you'd like, and you can stop the game whenever you want.

If you want to rest, or stop completely, just tell us--you won't get into any trouble! In fact, if you don't want to play the game at all, you don't have to. Just say so. Also, if you have any questions about what you'll be doing, or if you can't decide whether to do it or not, just ask us if there is any thing you'd like us to explain.

If you do want to try it, please sign your name on the line below. Your parent(s) have already told us that it is alright with them if you want to play the game. Remember, you don't have to, and once you start you can rest or stop whenever you like.

Signed:

Date:

SAMPLE CONSENT FOR FOR NONSENSITIVE QUESTIONNAIRES

Dear

We would greatly appreciate your assistance with this research project on vacations. We are studying people's experience with several popular tourist attractions. This research will help provide insight into why people travel to various destinations, and may provide some insights as to your own motives for traveling.

All you need to do is complete this short questionnaire, which should take about 10 minutes. Your participation is totally voluntary. If at any time you choose not to participate, you may discard the questionnaire. All responses are completely anonymous and confidential; your name will not appear anywhere on the survey. Completion and return of the questionnaire will constitute your consent to participate.

Please detach this letter and keep it for your records before you return the questionnaire. If you have any questions regarding the research project, feel free to contact one of us using the phone numbers listed below. Thanks again for your help.

Sincerely,

Informed Consent Checklist – Basic and Additional Elements

A statement that the study involves research
An explanation of the purposes of the research
The expected duration of the subject's participation
A description of the procedures to be followed
Identification of any procedures which are experimental
A description of any potential benefits to the subject, the subject population, or humanity.
A description of any reasonably foreseeable risks or discomforts to the subject.
A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. HIPAA regulations should be followed to protect identifiable medical information, if applicable.
For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained.
An explanation of whom to contact for answers to pertinent questions about: <ul style="list-style-type: none"> - the research (Investigator, and – if student – advisor) - the research subjects rights (Research & Graduate Studies) - whom to contact or where to go in the event of a research-related injury to the subject
Statements that explain that: <ul style="list-style-type: none"> Participation is voluntary, Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, Subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled. Subject may keep a copy of the form
A place for approval signature and date by a representative of the IRB.
Additional elements, as appropriate:
A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.
Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
Any additional costs to the subject that may result from participation in the research.
If the project involves more than minimal risk, insert a liability clause
An explanation of any conflict of interest that the investigator has in this study.

**HIPAA Regulations Regarding Identifiable Medical Information
18 Identifiers to Eliminate from Research Data**

- Names (individual, employer, relatives, etc.)
- Address (street, city, county, zip code – initial 3 digits if geographic unit contains less than 20K people, or any other geographical codes)
- Telephone/Fax Numbers
- Social Security Numbers
- Dates (except for years)
 - Birth Date
 - Admission Date
 - Discharge Date
 - Date of Death
 - Ages >89 and all elements of dates indicative of such age (except that such age and elements may be aggregated into a category “Age>90”)
- E-mail Addresses/URLs
- Medical Record Numbers
- Health Plan Beneficiary Numbers
- Account Numbers
- Certificate/License Numbers
- Vehicle Identifiers and Serial Numbers (e.g. VINs, License Plate Numbers)
- Device Identifiers and Serial Numbers
- Biometric Identifiers (e.g. finger or voice prints or full face photographic images)
- Any other unique identifying number, characteristic, or code

SAMPLE HIPAA Authorization for Use and Disclosure of Health Information in Connection with a Research Study

Why is this authorization required?

The US Government has issued a rule called the Privacy Rule. It became effective april 14, 2003. This rule requires all researchers with the University of the Pacific to safeguard your Protected Health Information.

What is Protected Health Information?

Protected Health Information includes information about you that could be used to link your identity to your health information. It also includethe information in your medical record. The purpose of this form is to explain to you how we propose to use your health information for the purpose of this study. None of your helath information will be used without your written permission.

Must I agree to this authorization to participate in the research?

To participate in this research study, you must agree to authorize the use of your health information as we describe below. If you do not approve of this use, you cannot participate in the study.

Why will my health information be used for this study?

The researchers will use your health information to conduct the study, monitor your health status, measure effecgts of procedures, determine research results, and develop new procedures. Your health information will not be disclosed outside of the University of the Pacific.

Who will use my information, and what is the purpose of this use?

If you sign this authorization, University of the Pacific researchers and their research team may use your health information. They will use your study research record and information from your medical record. This includes tests, interviews and both clinical and research observatioins made during your participation in the study. University of the Pacific researchers will not allow your health information to be seen by or sent to anyone outside the University of the Pacific. Your medical record may also be reviewed by authorized staff within the University of the Pacific to monitor this study, or others as otherwise required by law.

When will this authorization expire?

This authorization will expire at the end of the research study.

Can I withdraw this authorization?

Yes. At anytime during this study, you may decide that you no longer want to have your information used or disclosed as part of this study. If so, you must write a letter stating that you withdraw your authorization and send it to:

Researcher's name

Researcher's university address

And if student, the advisor's name and university address.

If you withdraw your authorization, you may be required to end your participation in the study. University of the Pacific researchers may continue to use your health information that was obtained before you withdrew your authorization. Even if you withdraw your authorization, the researchers are required by federal law to record and report anything that relates to your safety and the safety of others.

Will I get a copy of this authorization?

The researcher who is obtaining this authorization from you must give you a copy of this form after you sign it.

Authorization signature

My signature below indicates that this authorization has been explained to me, all of my questions have been answered, and I agree to allow the use and disclosure of my health information for the research as described above.

Signature of Participant

Signature of Personal Representative, if
participant cannot give authorization

Date

Date

Personal Representative's Authority (e.g., Power of
Attorney, Spouse, etc.):

X. SPECIAL SUBJECT POPULATIONS

DEFINITIONS

Child means any person younger than 18 years old unless he or she has been legally emancipated. A young person is legally emancipated if he or she is married or if a court has declared him or her emancipated. People younger than 18 who are living independently of their parents are not for this reason alone legally emancipated. However, college or university students 15-17 years of age may be considered adults for the purpose of participating in a research project with no more than minimal risk.

Parent means a child's biological or adoptive parent.

Guardian means a person who is authorized by law to consent on behalf of a child or handicapped individual to general medical care.

Permission means the agreement of the parent(s) or guardian to the participation of the child, handicapped individual, or ward in the research.

Assent means an affirmative agreement to participate in research; mere failure to object does not constitute assent.

A. CHILDREN

When research subjects are children, additional considerations must be met by the researcher. Two limitations are that 1) some research which would fall in the Exempt category if the subjects were all competent adults is not Exempt; and 2) some research involving more than minimal risk to the subjects is prohibited. Additional requirements pertain to informed consent.

1. Categories of Exempt research when the subjects are children

Category 1: involving research conducted in established or commonly accepted educational settings

Category 2: involving the use of educational tests

Category 4: involving observation of public behavior -- only if the researcher does not participate in the activities being observed.

Category 5: involving the collection or study of existing data

Category 6: involving the examination of public benefit programs

Categories of research that are not Exempt when the subjects are children

Category 3: involving survey or interview procedures

Category 4: involving observation of public behavior if the researcher does participate in the activities being observed.

All other research with children must undergo Expedited or Full review by the IRB. Research that includes children as subjects, that involves no more than minimal risk and that would be considered exempt if the subjects were adults may undergo review at the Expedited level. Please see the list of Expedited review categories (see Section VII).

In all cases, the assent of the children, and consent of parent(s) or guardian, must be obtained prior to conducting the STUDY.

2. Special considerations in research when subjects are children

a. Research that poses only minimal risk to the subjects

The only special consideration required for this type of research is that adequate provisions must be made for obtaining assent of the children and permission from their parent(s) or guardians, as described in Section 3 below. (Minimal risk is defined in Section VIII).

b. Research that poses more than minimal risk but which promises to benefit the individual child directly or involves a monitoring procedure likely to contribute to the child's well-being.

Such research will be permitted if:

- i. the risk is justified by the expected benefit to the child;
- ii. the relationship between the risk and benefit is at least as favorable to the child as that presented by other available approaches; and
- iii. adequate provisions are made for obtaining assent of the children and permission from their parents or guardians, as described in Section 3 below.

c. Research that poses more than minimal risk and does not promise to benefit the individual child directly. Ordinarily such research is permitted only if all of the following four conditions are met:

- i. the risk is only slightly greater than minimal;
- ii. the research will subject the child to experiences that are reasonably commensurate with those inherent in the child's actual or expected medical, dental, psychological, social or educational situation;
- iii. the research is likely to yield generalizable knowledge about the child's disorder or condition which is of vital importance to understanding or ameliorating the child's disorder or condition;
- iv. adequate provisions are made for obtaining assent of the children and permission from their parents or guardians, as described in Section 3.

In addition, if the child is a ward of the state or any other agency, institution, or entity, he or she may be a research subject only if the research is 1) related to his or her status as a ward or 2) conducted in a school camp, hospital, institution or similar setting in which the majority of the children involved as subjects are not wards. An advocate must be appointed for each child who is a ward. This advocate must be a person who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except as advocate or member of the IRB) with the research, the investigator or the guardian organization. The requirement for an advocate is in addition to the requirement that permission be obtained from any other person acting on behalf of the child as guardian or *in loco parentis*.

- d. Other research posing more than minimal risk:
Research not otherwise permitted that presents a reasonable opportunity to further understanding, prevention, or allocation of a serious problem affecting the health or welfare of children; and which is determined by an ethics committee convened by the Secretary, DHHS, to meet this criterion and sound ethical principles may still be approved by the IRB.

3. Informed Consent

- a. Assent of the children must be obtained from the child if the child is 7 years old or older. However, the IRB may waive the assent requirement if some or all of the children lack the capacity to give meaningful assent, or the research holds out the prospect of direct benefit that is important to the health or well-being of the children that is available only in the context of the research. The federal regulations do not set a minimum age at which a child's assent must be solicited but instead say that assent is required whenever, in the judgment of the IRB the children are capable of providing assent, taking into account their ages, maturity, and psychological state. In all cases the material provided to the child to obtain their assent must be written in language that is appropriate taking into account their age, maturity, and psychological state. The IRB has set this age at 7 years based on consultations with a child development expert on the Pacific faculty. Therefore, when research subjects are younger than 7, their assent does not have to be solicited, but the IRB encourages researchers to explain to younger children what they will be asked to do in the course of the research and to secure their agreement to participate if possible.
- b. Permission from parent(s) or guardian must be obtained from at least one of the child's parents, or the child's guardian. If the research involves only minimal risk, or it poses more than minimal risk but promises to benefit the child directly, permission.

If the research poses more than minimal risk and no direct benefit to the child, both parents or the child's guardian must give permission for the child to participate in the research. However, the permission of a parent who is deceased, unknown, or incompetent, or not reasonably available, or who does not have legal responsibility for the care and custody of the child is not required.

If a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the children (for example, neglected or abused children), the IRB may waive the requirement that parental permission be sought, provided that there is an appropriate alternative mechanism for protecting the children which is not inconsistent with the law. The choice of an appropriate alternative mechanism depends on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the children, and their age, maturity, status and condition. In such cases the researcher should propose an alternative mechanism

and explain how this alternative mechanism will protect the children. The IRB will then review the adequacy of this proposal.

- c. Information that must be provided in requests for assent and permission documentation of informed consent:

When parents or guardians are asked for permission and children are asked for assent, they must be given the same information that is generally required when informed consent for participation in research is sought, and their permission and assent must be documented in writing. The general requirements are discussed in Section IX, Informed Consent.

The assent form for children should, of course, be written in language appropriate to their age and understanding (a sample form for use with children can be found in Section IX). If the parents are not also research subjects themselves, it may be appropriate to have them sign the same form their children sign. If the parents are also research subjects, ordinarily a separate form should be drafted for them, addressing their own participation as well as that of their children.

B. MENTALLY HANDICAPPED INDIVIDUALS

The IRB has adopted special rules that apply when research subjects are mentally handicapped. Most of the general requirements for approving research with human subjects apply, but with some exceptions and additions.

The major exceptions are:

- 1) some research which would fall in the Exempt category if the subjects were all competent adults is not exempt, and
- 2) some research involving more than minimal risk to the subjects is prohibited. Additional requirements pertain to informed consent.

For the purpose of these requirements, a *mentally handicapped* person is defined as a person who, because of mental illness, mental retardation, emotional disturbance, senility, or for any other similar reason is incapable of giving informed consent.

Some individuals who have these conditions are also able to give informed consent, but the IRB cannot determine the capacity of persons with these conditions on the basis of labels alone. Therefore, whenever proposed research involves subjects who have been diagnosed with one of these conditions or who may have such a condition, the researcher should explicitly tell the IRB whether the subjects are able to give informed consent because of the condition. If the subjects are able to give informed consent, the special rules in this Section do not apply, and only the general requirements for research with human subjects must be satisfied.

1. Categories of Exempt research when the subjects are mentally handicapped
Category 1: conducted in established or commonly accepted educational settings (involving normal educational practices) is exempt only if the research

involves no changes in the content of instruction, location of instruction, or procedures used during instruction from those a subject would normally experience

Category 2: involving the use of educational tests

Category 4: involving observation of public behavior – only if the researcher does not participate in the activities being observed

Category 5: involving the collection or study of existing data

Category 6: involving the examination of public benefit programs

Categories of research that are not Exempt when the subjects are mentally handicapped

Category 1: conducted in established or commonly accepted educational settings involving normal educational practices – if the research involves changes in the content of instruction, location of instruction, or procedures used during instruction from those a subject would normally experience.

Category 3: involving survey or interview procedures

Category 4: involving observation of public behavior – if the researcher does participate in the activities being observed.

All other research with mentally handicapped individuals must undergo Expedited or Full review by the IRB. Research that includes mentally handicapped individuals as subjects, that involves no more than minimal risk and that would be considered Exempt if the subjects were competent adults may undergo review at the expedited level.

2. Special considerations in research when subjects are mentally handicapped

a. Research that poses only minimal risk to the subjects

No special limits are placed on this type of research, except that adequate provisions must be made for obtaining assent of the mentally handicapped subjects and permission from their representatives, as described in 3 below.

b. Research that poses more than minimal risk but which promises to benefit the individual subject directly

Such research will be permitted if:

1. the risk is justified by the expected benefit to the subject;
2. the relationship between the risk and benefit is at least as favorable to the subject as that presented by other available approaches; and
3. adequate provisions are made for obtaining assent of the mentally handicapped subjects and permission from their representatives, as described in item 3 that follows.

In addition, if the mentally handicapped subjects are wards of the state or any other agency, institution, or entity, they may be the subjects of research that poses more than minimal risk only if the research is 1) related to their status as

wards or 2) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of the subjects involved are not wards.

Furthermore, if the research poses more than minimal risk, an advocate must be appointed for each mentally handicapped person who is a ward. The advocate must be a person who has the background and experience to act in, and agrees to act in, the best interests of the mentally disabled person for the duration of the person's participation in the research. The advocate cannot be associated in any way with the research, the investigator(s) or the guardian organization. A person can be the advocate for more than one person. The requirement for an advocate is in addition to any other person acting on behalf of the mentally handicapped person as guardian.

- c. Research that poses more than minimal risk and does not promise to benefit the individual subject directly

Such research will be permitted if:

1. the risk is only slightly greater than minimal;
2. the research will expose the subject to experiences that are reasonably commensurate with those inherent in the subject's actual or expected medical, dental, psychological, social or educational situation;
3. the research is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance to understanding or ameliorating the subject's disorder or condition; and
4. adequate provisions are made for obtaining assent of the mentally handicapped subjects and permission from their representatives, as described in IX.B.3. below.
- 5.

In addition, if the mentally handicapped subjects are wards, the requirements described above in paragraph 2.b. apply.

3. Informed consent

- a. Assent of the subjects

Ordinarily, a mentally handicapped person may not be the subject of research unless the person gives assent. The IRB may waive the assent requirement if 1) the capability of some or all of the subjects is so limited that they cannot reasonably be consulted or 2) the intervention involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the subjects that is available only in the context of the research.

- b. Permission from competent adults acting on behalf of the subjects

Ordinarily, a mentally handicapped person may not be the subject of research unless permission is obtained from the person's guardian. For purposes of these

rules a guardian cannot be associated in any way with the research or the investigator(s). If the mentally handicapped person is a ward of the state or any other agency, institution or entity, a person associated with the entity cannot be a guardian for purposes of these rules.

The parent of a mentally handicapped person below the age of 18 is presumed to be the person's guardian. If the mentally handicapped person is older than 18, the parent is not automatically the guardian. If the subjects are mentally handicapped adults who have not formally had legal guardians appointed for them, the researcher should propose a procedure for securing permission from a competent adult acting solely in the interests of the mentally handicapped person. This procedure must be consistent with federal, state, and local law.

- c. Information that must be provided in requests for assent and permission and documentation of informed consent

Mentally handicapped subjects and the competent adults acting on their behalf must be given the same information that is generally required when informed consent for participation in research is sought, and their permission and assent must be documented in writing. The general requirements are described in Section IX. The assent form for the mentally handicapped subjects should, of course, be written in language appropriate to their level of understanding.

In circumstances in which the IRB may waive or alter the usual requirements for securing and documenting informed consent when the subjects are competent adults (refer to Section IX), the IRB may waive or alter the requirements for seeking permission and assent when subjects are mentally handicapped.

C. PREGNANT WOMEN AND FETUSES

Pregnancy encompasses the period of time from confirmation of implantation (as evidenced by missed menses or a medically acceptable test) until expulsion or extraction of the fetus. *Fetus* means the product of conception, from the time of implantation until a determination is made, following expulsion or extraction, that it is viable.

- 1) Activities Directed Toward Pregnant Women: No pregnant woman may be involved in a research activity unless a) the risk to the fetus is minimal, or b) the purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs.
- 2) Additional Consent Requirements--Research activity permitted above may be conducted only after fully informing the mother and father of any possible impact on the fetus and obtaining informed consent from the legally competent mother and father. Consent by the father need not be secured if:
 - a. the purpose of the study is to meet the health needs of the mother;

- b. the identity or whereabouts of the father cannot be reasonably ascertained;
- c. the father is not reasonably available;
- d. the pregnancy resulted from rape or incest.

3) Research Directly Involving Fetuses: Any research directly involving fetuses requires consultation with the IRB.

D. PRISONERS

Prisoner means any individual involuntarily confined or detained in a penal institution. The term applies to those sentenced to such an institution, those detained in other facilities as alternatives to prosecution, and those detained pending arraignment, trial, or sentencing.

Prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary decision whether or not to participate as subjects in research. Additional safeguards are required, therefore, when prisoners are proposed as subjects.

Prevailing state law(s) may prohibit research with prisoners.

IRB Membership Regarding Research with Prisoners

A majority of the IRB shall have no association with the prison(s) involved. At least one member of the IRB shall be a prisoner or prisoner representative, with appropriate background and experience. If the research is reviewed by more than one IRB, only one need have a prisoner representative.

Types of Research Permitted

When using prisoners as subjects, only the following types of research may be permissible, depending on prevailing state law:

- a. Study of possible causes, effects, or processes of incarceration or of criminal behavior;
- b. Study of prisons as institutional structures or of prisoners as incarcerated persons;
- c. Study of conditions particularly affecting prisoners as a class, including research on relevant social and psychological problems such as alcoholism, drug addiction, and sexual assault; and
- d. Study of practices, both innovative and accepted, that have the intent and reasonable probability of improving the health or well-being of the prisoner subjects.

In all cases, the research is to present no more than minimal risk and inconvenience to subjects. In cases c. and d. above, consultation with the IRB is necessary to determine possible need for approval by experts in penology, medicine and ethics. Any proposed biomedical research requires consultation with the IRB.

Additional Considerations

When using prisoners as subjects the following additional concerns must be addressed:

- a. Selection of subjects within the prison is to be fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless providing justification otherwise, control subjects must be selected randomly from an appropriate population of prisoners;
- b. Any advantages accruing a prisoner subject, when compared to standard prison conditions, are not to be of such magnitude as to impair the prisoner's ability to weigh appropriately the risks of research participation in the limited choice environment of prison;
- c. The risks involved should be commensurate with risks that would be accepted by non prisoner volunteers;
- d. Adequate evidence exists that parole boards will not take into account a prisoner's participation or non-participation in research and prisoners are informed in advance that participation or non-participation in the research will have no effect on parole decisions;
- e. Information is provided to prisoners in language they can understand, or if illiterate, the information must be read to the subject; and
- f. Where the IRB finds there may be a need for follow-up examination or care of subjects after participation, adequate provision is made, taking into account the lengths of subjects' sentences, and subjects are informed.

XI. References

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