



**DOMINICAN  
UNIVERSITY**  
*of* CALIFORNIA  
1890

**INSTITUTIONAL REVIEW BOARD FOR  
PROTECTION OF HUMAN SUBJECTS**

**HANDBOOK**

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## **DOMINICAN UNIVERSITY of CALIFORNIA**

### **INSTITUTIONAL REVIEW BOARD FOR PROTECTION OF HUMAN SUBJECTS**

#### **Introduction**

Dominican University of California has established the Institutional Review Board for Protection of Human Subjects (IRBPHS) with the mandate to protect the rights and welfare of human subjects recruited to participate in research conducted under the authority of Dominican University of California.

As an institution using human beings as research subjects, Dominican is required to provide an assurance to the Federal government that include a statement of principles governing the institution in the discharge of its responsibility for protecting the rights and welfare of human subjects or research conducted at, or sponsored by the institution, whether the research is subject to Federal regulation or not (45 CFR 46.103.b.1).

In 1991, the U.S. Department of Health and Human Services issued a set of revised regulations known as the Common Rule that constitute the core regulatory structure for research that involves human subjects. The Institutional Review Board for the Protection of Human Subjects of Dominican University of California complies with the Common Rule.

The IRBPHS was developed in accordance with the federal policy, Title 34, Code of Federal Regulations, Part 97, Protection of Human Subjects (Updated 4/2/02) [www.ed.gov/offices/OCFO/humansub/overview.html](http://www.ed.gov/offices/OCFO/humansub/overview.html), and Title 45 Public Welfare, Department of Health and Human Services National Institutes of Health, Office for Protection from Research risks, Part 46, Protection of Human Subjects (Revised 11/13/2002) [ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm). Additionally material from the federal government's Office of Protection from Research Risks (OPRR) 1993 publication, "Protecting Human Subjects: Institutional Review Board Guidebook," [ohrp.sophs.dhhs.gov/irb/irb\\_chapter2.htm](http://ohrp.sophs.dhhs.gov/irb/irb_chapter2.htm) was used as well as the American Association of University Professor's publication, "Protecting Human Beings: Institutional Review Boards and Social Science Research (May, 2000) <http://www.aaup.org/statements/Redbook/repirb.htm>

California's legislature enacted several laws that set legal requirements requiring the addition of an Experimental Subjects Bill of Rights when students or faculty are conducting medical research (California Health and Safety Code Section 24173(a) [www.rgs.uci.edu/hs/cacode.htm](http://www.rgs.uci.edu/hs/cacode.htm)

These documents are to be cited when appropriate in the text below. Some of the material in Dominican's IRBPHS Handbook was modeled after the University of San Francisco Institutional Review Board for the Protection of Human Subjects Manual 2001 (permission for use: Dr. James Wisner, Provost, 6/20/02).

## **Definition of Research and Human Subjects**

In determining whether a research proposal falls under the IRBPHS approval process it is important to establish whether the projects constitutes research and, secondly, whether the protocol uses human subjects in the manner defined by the Common Rule.

### **Research**

Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge. Research contributing to general knowledge includes following a deliberate plan to conduct an exploratory study or collect data to test a hypothesis. (34CFR97.102d) Most of the research conducted in the social sciences, clinical, and biomedical specialties would fall within the definition of “systematic investigation.”

#### **1. Student Projects**

Student research conducted by both undergraduate and graduate student students falls into three basic categories:

##### **Research Practica**

Research practica are classroom research projects, which provide research training. This would include practical application of studied theories of research methods and supervised by the course instructor. Often these practica involve individuals outside of the practica class that are interviewed, observed, or otherwise serve as participants. The object of the practica is to train students in the practice of research methods. Since these activities seldom contribute to generalized knowledge and are not designed to do so, the IRB does not consider Research practica research under the definition of Common Rule. Board review and approval is not required so long as the subjects are no identifiable by name or description. Projects must not require subjects to discuss personal issues or behaviors that might place them at risk by virtue of their participation.

##### **Research Projects**

Research Projects are either directed or independent activities, which require the student to *collect data* using a clearly defined and systematic protocol with the intent to disseminate for general knowledge. Any student initiated or conducted research outside of the definition of Research Practica using human subjects as participants with the intent to contribute to general knowledge requires review and approval. This includes undergraduate and graduate thesis and dissertation research projects. (Note: theses and dissertations are considered research publications.)

##### **Research Involving Sensitive or Vulnerable Populations**

These research projects identify the human subject. Identification might be from any of the following:

- results of responses to specific questions or specific behaviors
- small sample sizes involving questions of age, ethnicity, or sex
- selection of subjects from vulnerable populations (children, prisoners, homosexuals) for projects concerning behavior or opinion regarding sensitive topics such as: HIV/AIDS, rape or incest, substance abuse/use, mental health,

eating disorders, sexual abuse, sexual orientation, contraception and/or abortion issues, religious views. These research projects are subject to IRBPHS expedited or full board review.

## 2. Oral History

Oral History research consists of the research conducting a series of taped interviews with individuals who have information concerning a particular period or a particular historical event. It is not unusual for the tapes to become public at some future date to record and validate historical insight. Oral histories may concern an individual's personal and subjective perceptions or may be historical recollections of a personality or an institution. Oral history research projects may or may not be considered human subjects research. Research considerations that are crucial regarding oral history projects include conditions of use of the recording and advance approval of subject, effective consent to interview, and means of assuring privacy of anyone named in the interview. Oral history projects should be submitted to the IRB to determine appropriate level of review.

## 3. Other Types of Projects May or May not Require Review

Research involving program evaluations or questionnaires related to quality assurance may or may not fall under the IRB. If the project contributes to the general knowledge it should be submitted for review. If it is for internal use and not for publication or wider distribution it need not be submitted.

Projects that result in accumulation of information from a variety of sources or development of handbooks of information for distribution to particular populations to be used as resource guides do not constitute research and do not have to come before the IRB for review. Example: Development of booklets that address various issues that would help in the self-education process of diabetes patients and distribution of these completed booklets to a community care facility with request for an evaluation by users.

## **Human Subject**

Human subject is defined as “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.” (34CFR97.102f,2). (Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private communication includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public, e.g. school transcripts.

## **Ethical Principles Underlying Protection of Human Subjects**

The Department of Health, Education, and Welfare published the ethical principles upon which the regulations concerning human subjects research is based in 1979. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects Research (National Commission for the Protection of Human Subjects of Biomedical and

Behavioral Research, [www.ed.gov/offices/OCFO/humansub.html](http://www.ed.gov/offices/OCFO/humansub.html)) provides an analytical framework, through the basic principles of respect for persons, beneficence, and justice, that guides resolution of ethical problems arising from research involving human subjects.

1. **Respect for Persons:** Individuals must be respected as autonomous beings capable of deliberation regarding their actions and consequences of those actions. In the context of human subjects research clear and complete information regarding the research and clear indications that the subject enters the research voluntarily. Respect for persons also implies protecting individuals with diminished autonomy. The extent of protection depends upon the risk of harm and the likelihood of benefit.
2. **Beneficence:** Research on human subjects must be conducted with forethought to the maximization of benefits and the reduction of risk that might accompany the research investigation. If risk to the subject is involved, the benefits should so far outweigh the risk in long-term benefit to society that the research warrants exposing persons to possible harm.
3. **Justice:** All individuals must be treated equally with regard to their selection as human research subjects. Care should be taken to make sure that vulnerable populations (e.g. welfare patients, children, particular racial and ethnic minorities, or persons confined to institutions) are not singled out as human subjects. Justice also demands that benefits arising from the research are distributed fairly and equitably among all subjects.

The IRBPHS is responsible in providing assurance of compliance for human subject research that the above ethical principles are maintained. The IRBPHS must ensure risks to subjects are minimized, risks to subjects are reasonable in relation to anticipated benefits, and the selection of subjects is equitable (34CFR97.111). Researcher should examine their projects in light of these principles prior to seeking IRBPHS approval.

Dominican University of California expects students and faculty conducting research using human subjects to conform to basic ethical responsibilities as outlined by the Belmont Report. The task of the IRBPHS is to insure that the researcher and his/her project meet these responsibilities.

The scientific researcher at Dominican University of California must exhibit the following basic ethical responsibilities:

1. scientific competences;
2. open and honest behavior with participants and loyalty to all promises and commitments made to them;
3. concern about the welfare, dignity, privacy and self-determination (i.e., right to refuse) of research decisions;
4. sensitivity to issues of ethics and values;
5. responsible behaviors relative to his/her decisions, actions, and their effects;

6. concerns about the future uses of the knowledge gained in research and accepting personal responsibility for decisions bearing on them;
7. high standard of scientific objectivity and confidentiality;
8. honesty and accuracy in reporting results without omissions that would seriously affect interpretation;
9. commitment to developing a methodology to advance knowledge and truth and not simply support a predetermined position.

**Note on Confidentiality:**

All researchers should be aware that the confidentiality of information collected from subjects cannot always be guaranteed. In most cases, information obtained in confidence as part of a research study has constitutional protection. However, while the likelihood of a request for disclosure is generally remote, *disclosure of some information may be mandated by statute or ordered by the court.*

A more detailed discussion under various headings of these basic responsibilities and their corollaries is meant to serve as a reference document for the scientific researcher and members of the IRBPHS. (These guidelines are based upon a study by E. Diener and R. Crandall, *Ethics in Social and Behavioral Research*, U. of Chicago, Chicago & London, 1978, and upon the codes of ethics of the American Psychological and the American Sociological Associations.)

**Objectivity and Competence**

Complete scientific objectivity is an ideal that cannot be realized in practice, but the researcher should strive to be as objective as possible in conducting research. Biases should never be deliberately introduced into the design or reporting of studies. Since poor research based on faulty methodology and design does not advance knowledge and wastes valuable resources, all researchers have a responsibility to do the best research of which they are capable. Results should be reported accurately and honestly, without omissions that would seriously affect their interpretation. Although values may influence the topic of research, the methodology should be designed to advance truth and not simply support a predetermined position.

**Sensitivity and Responsibility**

The ethical researcher is concerned about the well-being of research participants and about the future uses of the knowledge, and s/he accepts personal responsibility for decisions bearing on them. The basic ethical imperatives are that the researcher be concerned about the welfare of subjects, be knowledgeable about issues of ethics and values, and consider these when making research decisions and actions.

**Precautions to Safeguard Participants**

It is the researcher's responsibility to protect participants from physical or mental discomfort, harm, or danger. In research exposing subjects to possible discomfort, harm or danger, safety must be insured by stringent safeguards, including carefully selecting subjects and checking afterward for harmful effects. The investigator has a positive obligation to correct any harm that does befall a participant.

### **Informed Consent**

If the participants will be deprived of rights or exposed to possible physical or mental discomfort, harm, or danger, they should be informed of this and allowed to withdraw from the research. Subjects should always be informed beforehand about aspects of the study that would affect their decision on whether to participate. They have the right to withdraw at any time, and coercive pressure must not be used to gain cooperation

### **The Less Powerful**

Special care must be taken to protect the rights and interest of the less powerful participants in research such as children, the poor, minorities, prisoners, and patients.

### **Privacy**

Information about participants may be collected only with their consent. All research information on individuals should be strictly confidential and published only in summary form unless participants agree that they may be named in the report.

### **Deception**

Research deceptions should never be practiced until an ethical analysis of the situation has been made. Are there other ways to obtain the knowledge? What will be the negative effects of the deception? Can safeguards such as forewarning and debriefing be used? Deceptions vary from mild to blatant, and though many mild deceptions may be justifiable, large deceptions often are not. In addition to the ethical questions, deception research often suffers from methodological problems.

### **Review By Others**

If the investigator is unsure about the ethics of her/his research, s/he should seek the opinions of others, in this case especially the Institutional Review Board for the Protection of Human Subjects. If subjects are to be exposed to risks or if the research raises serious value questions, it is wise to solicit the opinions of several reviewers. Disinterested persons may have a sounder ethical perspective than the scientist who is deeply involved with the research. It is often important to gain input from participants as well as from professional colleagues.

### **Experiments In Change**

The goal of research is to change individuals or a group, those who are the target of change should be consulted and their wishes and needs respected. Usually the target group can be involved in setting the goals of the change intervention. When various treatment groups are used in formal experiments, the researcher should carefully consider whether the various experimental manipulations are ethical. A group should not be placed at a serious disadvantage unless subjects have accepted this possibility or resources are sufficient to offer the most desirable treatment to all persons.

### **Uses of Research Knowledge**

The researcher should examine the possible applications of scientific findings and endeavor to make these uses constructive. Before conducting a study the researcher must consider how the information will affect the people being studied.

## **Institutional Review Board for the Protection of Human Subjects**

The Institutional Review Board for Protection of Human Subjects reviews and approves all human subject research prior to the commencement of research activities. The Board may approve, request modification, or disapprove research projects. Long-term research projects must seek continuing review of the research activities once each year

The IRBPHS must have a minimum of five members with varying backgrounds and provide discipline expertise for proposals coming before the Board. The Vice President for Academic Affairs appoints the members for staggered three-year terms. If the IRBPHS is reviewing a proposal funded by a federal grant, one member not otherwise affiliated with Dominican University of California will be added to the Board. The five-member Committee includes the Associate Vice President for Academic Affairs who is the authorized institutional official with responsibility for the oversight of research and IRBPHS functions.

If the IRBPHS reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, handicapped or mentally disabled persons, consideration shall be given to the inclusion of an individual who is knowledgeable about and experienced in working with these subjects.

An investigator may be a member of the IRBPHS but may not participate in the review of proposals pertaining to research with which they are directly or indirectly involved except to provide information requested by the IRBPHS.

The IRBPHS may invite individuals with competence in special areas to assist in the review of particular research proposals. These individuals do not vote with the IRBPHS.

### **IRBPHS Meetings**

The IRBPHS meets monthly. The schedule of meetings will be announced at the beginning of the semester. **Proposals must be submitted to the IRB Office two weeks prior to an IRB meeting for the proposal to be considered.** In addition to ongoing review the IRBPHS may meet several times each semester to discuss policies, human subject's complaints, and to review controversial or sensitive applications. Due to the confidential nature of the items discussed at these meetings they are closed to non-IRBPHS members.

### **IRBPHS Functions and Operations**

Documentation of IRBPHS activities will be maintained, including copies of all research proposals reviewed, minutes of IRBPHS meetings, records of continuing review activities, copies of all correspondence between the IRBPHS and investigators, and statements of significant new findings provided to subjects.

Minutes of the meetings must include attendance at each meeting, actions taken, votes on actions taken (including the number of members voting for, against, and abstaining), changes required for approval, reasons for disapproval, and written summaries of controversial issues and their resolution.

Records will be maintained for three years after completion of the research. The date of graduation will be considered completion date for students.

Except for exempt and expedited review (see below), review of proposals requires a majority of members of the IRBPHS present, including one member whose primary concern is nonscientific areas. In order for the research to be approved, it must receive approval of a majority of the members present.

### **Exempt and Nonexempt Research**

Certain research is considered exempt from IRBPHS review. The word “exempt” may be misleading. It does not imply that the activity is not reviewed, only that the activity is not subject to further full Board review if exemption is granted. Applications for exempt status are reviewed by the Chair of the IRBPHS or a person from the Board appointed by the Chair.

Exemptions do not apply to research using vulnerable populations as subjects.

The exemptions are found in 34CFR 97.101(b), and for ease of access, excerpted below.

Research activities in which involvement of human subjects falls into the following categories are exempt:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless the information identifies the subjects and disclosure could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation. Subpart D amends this exemption, in part: If the subjects are children, research involving interview or survey procedures and research involving observations of public behavior in which the researcher(s) participate in the activities being observed are not exempt. However, research involving the use of educational tests and research involving observations of public behavior in which the researcher(s) do not participate in the activities being observed are exempt.
3. 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 a manner that subjects cannot be identified, directly or through identifiers linked to subjects.
4. Research involving survey or interview procedures, except where responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, and either:

- a. The subject's responses, if they become known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, or
  - b. The research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.
5. Research involving the observation (including the observation by participants) of public behavior, except where observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, and either:
- a. The subject's responses, if they become known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, or
  - b. The research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.
6. Research involving elected or appointed officials or candidates for public office.

Additional exempt categories are described in 34CRF 97.101b. These categories include: use of educational tests where research is designed to study public benefits or service programs; and taste and food quality evaluation and consumer acceptance studies. If research involves these areas please review federal regulations to determine exempt/nonexempt status.

The research listed above poses little or no risk of physical or mental harm to human subjects. Risk is for the IRBPHS to decide. Therefore, **THE RESEARCHER MUST SUBMIT DOCUMENTATION TO VERIFY THAT THE PROJECT IS INDEED EXEMPT FROM REVIEW USING THE SAME PROCEDURE AS FOR RESEARCH THAT IS NOT EXEMPT.**

### **Expedited Review Procedures**

The IRBPHS may use an expedited review when it is determined that the research involves no more than minimal risk and it falls into one of nine research which may be reviewed at the Web address below. The two categories that principally relate to the majority of research conducted at Dominican are:

- 1. Collection of data from voice, video, digital, or image recordings made for research purposes.
- 2. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Expedited review may also occur when minor changes in previously approved research is requested during the one-year period for which approval had been granted.

It is expected that expedited review will be prompt. Review is expedited not because there is a different application or procedure involved since the Common Rule specifies “the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review” but because fewer people are reviewing the documents. The chairperson of the IRBPHS, carries out an expedited review. Expedited review may not disapprove of the research. A research activity can only be disapproved after review by the entire IRBPHS in accordance with non-expedited procedures. For additional information regarding research categories (especially medical research categories) authorized for expedited review see 45CFR 46.110 and 21CFR 56.110 at <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/expedited98.htm>.

### **Full Review Criteria**

If research involves more than “minimal risk” to subjects the project will require a full board review. Full board review is required for any of the following:

- ❑ Minor subjects (children 17 years of age or younger)
- ❑ Special populations (prisoners, pregnant women, individuals with disabilities, specific ethnic groups)
- ❑ Use of video-or audiotape to record subjects
- ❑ Asking questions that may be embarrassing or compromising such as questions regarding sexual behavior, sexual orientation, alcohol consumption, illegal drug use, medical conditions, violation of the law, personal finances, problems in the workplace, etc.
- ❑ Exposing subjects to graphically violent or pornographic materials
- ❑ Inflicting physical pain upon, attaching electrodes to, or injecting any substance into subjects
- ❑ Creating high levels of stress, fear, discomfort, or tension
- ❑ Threatening subjects in any way
- ❑ Causing subjects to violate laws or official university regulations
- ❑ Providing some subjects with benefits denied to others (this includes payments or rewards for participation, e.g., offering extra credit to participants, etc.)
- ❑ Causing physical or mental exhaustion or engaging subjects in intense exercise
- ❑ Placing individuals in confining physical settings or attaching other devices
- ❑ Exposing subjects to extreme conditions (e.g., bright lights, loud noise, intense pressure, strong odors, complete darkness, extreme heat or cold, sudden movements, etc.)
- ❑ Leaving subjects alone for periods of longer than 20 minutes
- ❑ Taking hair samples or nail clippings for subjects
- ❑ Taking human tissue samples, drawing blood, or sampling any other bodily fluid

### **Required Review of Research Involving Human Subjects**

The Institutional Review Board must review ALL research involving human subjects. This means all research involving human subjects conducted by Dominican University of California undergraduate and graduate students under the supervision of Dominican faculty, by graduate students from other institutions using Dominican subjects, or by Dominican faculty. Students in Psychology, Nursing, Occupational Therapy, and Education generally submit research proposals. However, faculty supervising senior projects in other disciplines should note that project proposals from their students are

subject to review whenever the project involves direct contact with humans, as, for example, research involving oral histories. Proposals must be submitted to and approved by the IRBPHS before the student can conduct the research or project.

The over-riding issue, regardless of the scope of the project, is review of potential areas of ethical concern, particularly anonymity, confidentiality, and freedom from coercion to participate. While it is true that some research—for example anonymous surveys and interviews—are considered “exempt”, the IRB must make that “exempt” judgment after considering the parameters of the project under review.

### **Course Instructors**

Faculty members who teach courses that require students to conduct research with human subjects as a part of the activities of the course must act as an extension of the IRBPHS and insure that the research is used only for the requirements of the course and will not form the foundation of any further or future study. Any instructor overseeing a student course project involving human participation should review the following with the student before the project is underway:

- 1) Brief description of the project: does the project involve sensitive areas of human behavior or put the participant(s) at physical or psychological risk?
- 2) Participant anonymity: how do the participants’ identities remain unknown to the researcher, the instructor, and other students in the class?
- 3) Confidentiality: how will researchers ensure confidentiality?

In addition the instructor must insure that risk to human subjects is minimized, subjects are protected, and students act in an ethical manner at all times. Please see section on types of classroom research on page 4 of this document for clarification of the need for IRB review of classroom projects using human subjects.

Any time an instructor has concerns regarding the interpretation and/or application of ethical standards in research, the instructor should consult a member of the IRBPHS.

### **Faculty Advisors**

It is expected that faculty advisors supervising undergraduate or graduate students conducting research involving human subjects will educate the student on the ethical principles and protocols required by such research. The advisor must be active in development of research protocols that safeguard the rights of human subjects and are legitimate and appropriate scientific methods of inquiry. The IRBPHS is not responsible for editing research protocol and expects proposals to come for approval after the faculty advisor has approved research methodologies. Ultimately any harm that results to a human subject as a result of a research project conducted by a Dominican student is the responsibility of the student’s faculty advisor. The signature of the faculty advisor on the application for IRBPHS approval indicates s/he has carefully read the proposal and is aware of the procedures and protocol used in the research to safeguard the rights of human subjects.

### **Researchers**

It is expected that research scientists are familiar with the federal regulations that govern their particular area of research involving human subjects. The principle investigator is

responsible for any harm to human subjects that arise as a result of the research (unless the principle investigator is a student, see above under faculty advisor). It is the responsibility of the principle investigator to ensure that all research is conducted in an ethical manner and that the human subjects are treated so as to minimize harm and safeguard their rights.

### **Research in Foreign Countries**

When research involving human subjects takes place in foreign countries procedures normally followed in the foreign country to protect human subjects may differ from those set forth in this policy. (An example is a foreign institution that complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989). Researchers should consult 45CFR46.101(h) in developing their proposal.

### **Initial Proposal Submission Process**

It is the responsibility of the researcher to submit the required documents to the IRBPHS members. Two copies of the research proposal, all relevant attachments and instruments, cover sheet (Appendix A) and proposal checklist (Appendix B) must be forwarded to the IRBPHS Office. Upon receipt the proposal will be date-stamped and given an IRBPHS review number. Five copies of the research proposal, all relevant attachments and instruments, etc. must be submitted for proposals that require full Board review. The IRBPHS will not make copies of any proposal. It is suggested that students keep copies of the materials submitted to the IRBPHS for their personal reference. Handwritten applications will not be accepted. Faxed or email applications will not be accepted. Incomplete applications will be returned to the researcher. Applicants may expect notification from IRBPHS 4-6 weeks following date forwarded to IRBPHS members. If the application is incomplete in some way, such as submitted with insufficient copies, missing measurement instruments, unclear or inadequate descriptions of subjects or of research protocol, or missing signature of faculty advisor, the review may take longer. Applications should be submitted in accordance with their particular department deadlines.

Applications will be reviewed in the order received. **Requests for “quick review” will not be honored.** Review is more rapid if all materials are complete, the research protocol is clear and scientifically sound, and all supporting materials are clear regarding protection of the human subjects to be recruited for the research.

The faculty advisor and departmental committee, if applicable, prior to submission to the IRBPHS, review each application. See the flowchart on page 16 which diagrams the review procedure. When the advisor and committee are satisfied that potential risks to human subjects have been addressed and minimized and that all relevant requirements have been met, s/he submits the application to the IRBPHS Office with a recommendation for an exempt, expedited or full review.

For both exempt and expedited reviews the Chair of the IRBPHS reviews the application and addresses any concerns with the advisor and the applicant, seeking expert consultancy if necessary. In a full review the entire IRBPHS membership reviews the

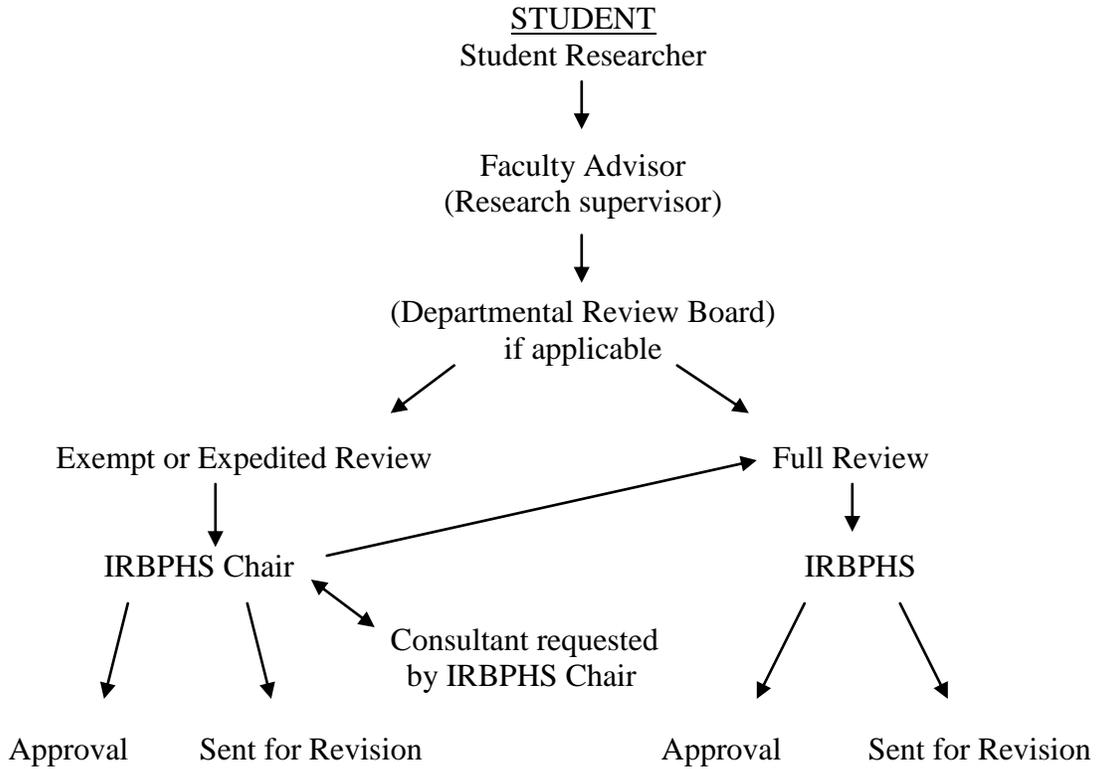
proposal and recommends approval/non-approval. When all concerns have been addressed the Chair of the IRBPHS will inform the researcher, and the faculty advisor, if the researcher is a student, of its decision. In cases where there are questions that may be answered by the faculty member, that faculty member may be invited to speak to the Board regarding those questions.

### **Renewal Application Submission Process**

Initial approval of research involving human subjects is granted for a period of one year. Researchers must obtain IRBPHS approval for continuation of the research before the year of initial approval has lapsed. Renewal approval must be obtained for students as well as faculty researchers whose research extends beyond the 12-month approval period. The procedures for review of a Renewal Application are the same as those of the Initial Application.

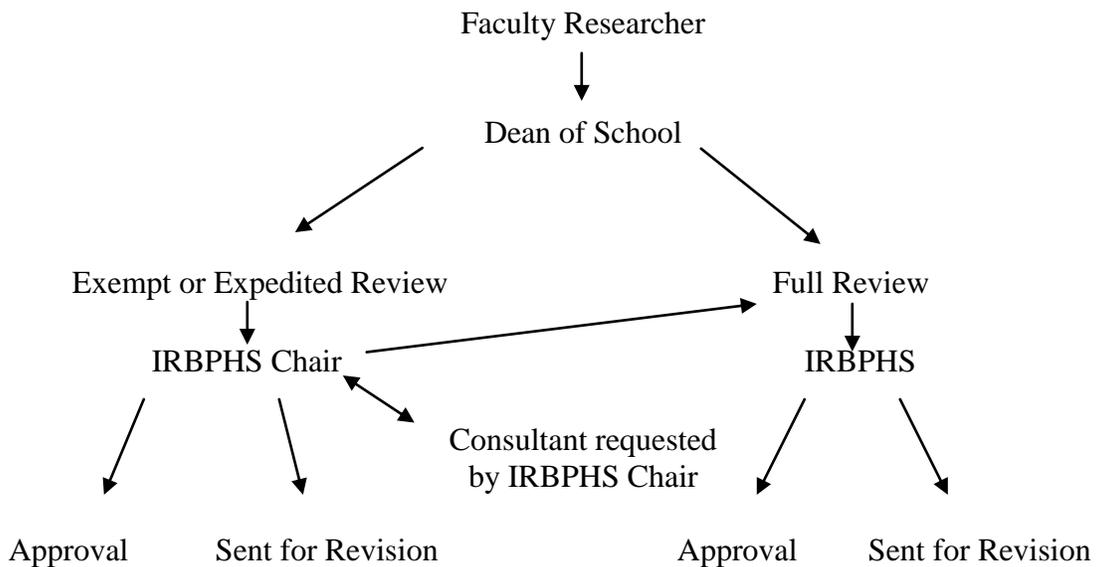
It is the responsibility of the researcher to initiate a Renewal Application, allowing sufficient time for review and approval prior to expiration of the initial approval. If research continues after the expiration date without renewal approval, the research is out of compliance with federal regulations and university policy. In the case of an emergency preventing a researcher from completing the renewal procedures, the Chair of the IRBPHS may grant an extension for up to one month. Request for extension must be made in writing to the IRBPHS Office and will be granted only for substantive reasons for failure to complete a timely Renewal Application.

**IRBPHS Approval Process Flowchart**



\*\*\*\*\*

**FACULTY MEMBER**



### **Modification Application Submission Process**

The IRBPHS approval is based on the document submitted with the Initial Application and/or Renewal Application. If the researcher desired any change in protocol, including changing subjects, timelines, procedures, wording of documents, or instruments, it must be summarized in an IRBPHS Modification Application. Approval of the Modification Application must occur prior to implementation of changes. Procedures for review of Modifications Application are the same as review of the Initial Application. Approval of the Modifications Application extends only until the expiration date of the Initial Application. If research is to continue beyond this date the researcher needs to submit a Renewal Application prior to the expiration date.

### **Initial Application**

To obtain initial Institutional Review Board for Protection of Human Subjects approval for research with human subjects fill out the IRBPHS Initial Application.

The IRBPHS Initial Application is found in Appendix A and may be printed and photocopied or completed online then printed to be included with submission.

Type the requested information directly on the application form and respond to items 1-11 by typing in black ink using standard 12-point font printing only on one side of the paper. Please be concise and clear in your information. **NO HANDWRITTEN APPLICATIONS WILL BE ACCEPTED - APPLICATIONS THAT ARE HANDWRITTEN WILL BE RETURNED UNREAD.**

The following is a detailed description of the requirements for successfully completing the initial application form:

#### **Background and Rationale**

This is a summary of your research project. It is NOT a review of the literature. This section should focus on describing the nature of the research problem and purpose of current study. . It should be concise, and provide clear and compelling justification as to why the research is important. This section may be no more than 300 words

#### **Description of Sample**

The description of sample should include:

- detailed description of sample including age, gender, and ethnicity;
- special characteristics of subject population (e.g., prisoners, children, dependent adults);
- method researcher is using to obtain access to subjects (e.g., co-workers, students in classroom, mailing lists);
- if subjects are employees of a corporation, students in a particular school or some other type of captive audience (e.g. preschool students, prisoners,) provide a letter from appropriate member of the institutional management indicating awareness and support of the research project;

- if subjects are persons for whom English is not their primary language and/or who are not proficient in reading speaking, and writing English at the **8<sup>th</sup> grade level**, the applicant must provide documentation that written correspondence, consent documents, and measurement instruments will be provided to the subject in his or her preferred language (include copies of the translated documents as well as qualifications of the translator of the documents along with a signed statement from the translator that the non-English versions of the written documents are equivalent to the English versions);
- describe any dual relationships applicant has with the subjects or the institution in which the subjects work or attend school (e.g. Is applicant an employee or manager? Is applicant a member of the same community?) (See Appendices I, J, K for model letters)

### **Recruitment Procedure**

The recruitment procedure section should include how the researcher will solicit participation from subjects (e.g., face-to-face, phone contact, mail) and provide copies of memos, email messages, cover letters, flyers, etc. that will be used to recruit potential subjects.

### **Subject Consent Process**

#### Human Subjects' Rights

Individuals who agree to participate in a research study have certain rights. These rights are outlined in Appendix F. It is the responsibility of each researcher to ensure that every subject contacted and recruited to participate in a research project is guaranteed these rights. It should be concise, and provide clear and compelling justification as to why the research is important. A copy of the Research Subjects Bill of Rights must be provided at time of recruitment. For research that involves no more than minimal risk it is up to the researcher and her/his advisor to determine whether to provide a copy of the document to participants.

#### Informed Consent Forms Needed

Informed Consent Forms must be signed. Extra scrutiny will be paid to the consent process where the research involves

- subjects younger than 18 years of age, mentally disabled, or prison inmates or other institutionalized persons;
- face-to-face interviewing between researcher and subject or any videotaping of the subject;
- “moderate or high risk” involving sensitive or emotional issues or any possible physical risk to the participant;
- situations where subject is potentially identifiable on the basis of demographic information. (See sample letters Appendix G, H, I, J, K).

If subjects younger than 18 years of age (or unable to consent for themselves), describe the procedure for obtaining parental (guardian) consent. Include a copy of the Parental/Guardian Consent Form (see Appendix H).

- a. If project involves a survey or questionnaire that will be distributed and collected through mail or hand-delivered and hand-collected, submit a copy of the Consent Cover Letter that will accompany the survey or questionnaire.
- b. If project involves telephone interview provide a copy of the introductory letter sent to subjects and describe the verbal protocol used at the start of the telephone interview for purposes of obtaining informed consent.
- c. If project involves a survey or questionnaire given to a large group of people simultaneously (e.g. a classroom) provide a copy of the Consent Cover Letter that will accompany the survey or questionnaire or describe the verbal protocol used prior to distributing the survey or questionnaire.
- d. If it is not possible to obtain informed consent provide rationale for lack of informed consent and describe methods for ensuring voluntary participation of subjects (e.g. implied consent when one completes a questionnaire).
- e. An informed consent checklist may be found at:  
<http://ohrp.osophs.dhhs.gov/humansubjects/assurance/consentckls.htm>.

#### Informed Consent Forms Not Needed

Informed consent forms are not needed for survey research. This research poses minimal risk to subjects and a returned questionnaire is considered as evidence of implied consent. If informed consent forms are not required it must clearly be stated in the “Subject Consent” section of the application and questionnaires must be returned in a manner that no recognizable connection may be made between a questionnaire and a participant or be clear that subjects are identifiable and return is in a manner that will insure confidentiality.

#### **Procedures**

Describe in detail what your subjects will experience as a result of their participation in the research including all experimental activities or manipulations (e.g. treatments, exposure to music or film, stress tests), completion of surveys or questionnaires, telephone contacts, etc. Include copies of all written materials that subjects will see including surveys, questionnaires, interview questions, etc. If a researcher plans to use test scores or other data about human subjects that has been previously collected, the researcher should be aware that use of that individual’s standardized test scores or grades without a subject’s permission is prohibited by FERPA (Family Educational Rights and Privacy Act of 1974.) Research studies that use such data must include a signed consent document unless the person’s name is not included with the test score and it is anonymous and confidential.

#### **Potential Risks to Subjects**

All research projects involve some potential risks to subjects. Describe in detail all potential risks to subjects including such risks as emotional discomfort, boredom, frustration, loss of confidentiality, as well as any risks inherent in the particular research project. **This section must be addressed or the researcher will be asked to resubmit the proposal.**

### **Minimization of Potential Risk**

Describe the ways in which the potential risks described in the Potential Risks to Subjects section above will be minimized by the researcher and any debriefing procedure to be used with subjects who experience more than minimal risk.

### **Potential Benefits to Subjects**

Describe in detail all potential benefits to individual subjects. While you may include benefits of the research, the focus here is on the subject. If there are no benefits, state this fact but most research has some benefit to the subject and should be carefully considered.

### **Costs to the Subjects**

Describe any costs to subjects such as monetary fees, costs of treatment, medications, psychological testing, cost of transportation, as well as costs in terms of time and effort.

### **Reimbursement or Compensation to Subjects**

Describe completely and provide a rationale for any reimbursements or compensations to be made to subjects in response to their participation in the research.

### **Confidentiality of Records**

State whether the data will be anonymous or not anonymous. If data will not be anonymous, describe how the data will be kept confidential. Indicate how raw data and computerized data will be stored as well as a method for keeping subject's identity separate from subject's data. (Anonymous signifies the person's name is withheld. Confidential implies that information, in this case the name of the subject, is held privately and secretly).

### **Signatures**

Sign and date the application. When the applicant is a student, the faculty advisor must also sign and date the application. Each copy of the application must have both signatures but the second copy need not have the original signatures. If the proposal is reviewed by the department chair or a departmental committee prior to submission to the IRB, the chair of the department or committee must sign the application stating the review recommendation of the chair/committee, i.e. exempt, expedited or Full Board review.

### **The Proposal Checklist**

There is a proposal checklist included in Appendix B for convenience. Faculty advisors should encourage the student to use this checklist to make sure that the proposal is complete. Missing information will result in return of the proposal to the researcher with loss of time for approval.

### **Renewal Application**

All researchers who wish to have contact with human subjects past the date of expiration of initial approval from the Institutional Review Board for the Protection of Human Subjects will need to complete the IRBPHS Renewal Application.

IRBPHS Renewal Application is found in Appendix D, which may be photocopied for use.

Type or word process the requested personal and contact information directly onto the Renewal Application form. Respond to items 1-6 by typing in black ink using standard 12-point font on one side of separate, white paper, stapled to the application form. **No handwritten applications will be accepted.**

The Renewal Application must provide the following information:

1. **Subjects.** Number of subjects used last year in project, number who completed the study and number of subjects needed to complete the research study.
2. **Summary of Results to Date.** Concise (300 words or less) summary of results obtained thus far.
3. **Changes in Anticipated Risks.** Any changes in potential risk to human subjects due to changes in protocol. \*
4. **Changes in Anticipated Benefits.** Any change in potential benefits to human subjects such as the potential impact of any changes in research protocol, instruments, follow-up plans, etc. during past year. \*
5. **Discussion of Problems During the Past Year.** Summarize any adverse effects or problems experienced or encountered by human subjects during the past year. \*\*
6. **Explanation of Modifications in Protocol.** Summarize any modifications in the research protocol made during the past year (instruments, follow-up contacts, subject sample). \*\*

**Signatures:** Provide signature and date of signature of the applicant and, when the applicant is a student, the signature of the faculty advisor.

\*Any changes to the research study from that stated in the Initial Application must be submitted to the IRBPHS for approval on a Modification Application prior to implementation of the changes.

\*\* Any adverse effects experienced by a human subject must be reported to the Chair of the IRBPHS in writing within 10 working days of their occurrence. See Appendix M.

### **Modification Application**

All researchers who wish to make changes to the research protocol as described in the IRBPHS Initial Application must complete the IRBPHS Modification Application. Changes include subjects, timelines, procedures, wording of consent documents, instruments, correspondence, etc.

The IRBPHS Modification Application is found in Appendix E, which can be photocopied for use. It can also be obtained on-line at [inside.dominican.edu/academics](http://inside.dominican.edu/academics) or directly from the Office of the Associate Vice President for Academic Affairs, Ann Hathaway, Room 5.

Type the requested personal and contact information directly onto the Modification Application form. Respond to items 1-5 by typing in black ink using standard 12-point font on one side of separate, white paper, stapled to the application form. `

The Modification Application must provide the following information:

1. Description of Proposed Changes to Protocol: Describe any and all changes proposed to the original research study as approved in the IRBPHS Initial Application. Include a detailed summary of changes and attach copies of revised materials, including revised correspondence, consent forms, instruments or other research tools proposed.
2. Rationale for Proposed Changes: Provide detailed justification and rationale for the changes proposed above.
3. Impact on Potential Risks to Human Subjects: Describe any impact on the level of potential risk to human subjects resulting from the proposed change. The impact can be an increase or decrease; if no change, state clearly.
4. Minimization of Increased Potential Risk: If an increase in potential risk is described indicate how the researcher intends to minimize it.
5. Impact on Potential Benefits to Human Subjects: Describe anticipated benefit to human subjects resulting from the proposed change. Focus should be on individual subjects not on benefits to society in general. If no change, state clearly.
6. Signatures: Provide signature and date of signature of the applicant and, when the applicant is a student, the faculty advisor.

### **Informed Consent**

The informed consent process is at the heart of the ethical principal for the respect for human subjects. Human subjects must voluntarily consent to the participation in any research project and evidence of that consent is absolutely essential.

The process of obtaining informed consent must comply with the federal requirements of 45CFR46.116 and the California Health and Safety Code. The documentation must comply with 45CFR46.117 of the federal guidelines and Section 24173(a) for the State requirements. For further information please refer to the following documents: <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/ictips.htm>; [www.rgs.uci.edu/hs/cacode.htm](http://www.rgs.uci.edu/hs/cacode.htm)

If researchers are conducting experiments in states other than California they are expected to adhere to the laws of the state in which the research is being conducted as well as those of California.

Voluntary consent requires that the person has the legal capacity to give consent and be free to exercise choice without pressure or coercion. Information must be presented in such a way that an individual can clearly understand the nature of the research and any risk/benefits they may incur as a result of participation so that they can make a decision on whether or not they wish to participate. Researchers should not use scientific terminology in describing the research and it is best to use language at approximately the **8<sup>th</sup> grade reading level** to make sure that most people are able to understand the document. If changes occur during the research period that will affect the risk to the human subject, revised consent forms must be presented immediately to the research participants.

The consent document must include the following the purpose of the research, nature of the experiment, duration of the experiment, procedures to be used, risks, potential inconveniences and/or hazards, and benefits of the study, confidentiality of records, the subject's rights in participating in research, and the freedom to decline to participate without consequences. All consent forms MUST provide the name, institutional affiliation, and address of the person or persons actually performing and primarily responsible for the conduct of the experiment as well as the name, address, and phone number of the faculty advisor or another impartial third party, not associated with the experiment, to whom the subject may address complaints about the experiment. Questions about the research are usually best answered by the researcher but questions concerning rights as a research subject should be referred to the research supervisor, if the researcher is a student. The IRBPHS may also be listed as a contact for questions posed by the subject and as the contact for reporting the event of a research-related injury to the subject. (See Appendices F and G for sample forms)

It is important that research subjects be informed that they can withdraw from the research project at any time without penalty and that participation in the research is entirely voluntary. An informed consent checklist that can be used to develop the consent document can be found at:

<http://ohrp.osophs.dhhs.gov/humansubjects/assurance/consentckls.htm>.

The signed informed consent form must be provided as part of the documentation when seeking approval of the IRBPHS. A copy of the signed form must be given to the person signing the form (subject or subject's legal representative).

### **Waiver of Signed Consent**

The IRBPHS may waive the requirement for a signed consent form if the only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality, or where there is a possible risk to the subject entailed in signing the consent form (e.g. for immigrants who might be identified as being illegal aliens), or in a retrospective records review or analysis of previously collected data where the subjects need not be contacted as part of the study and appropriate precautions to protect confidentiality of the data are described, or that 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.

Informed consent forms are not needed for survey research. This research poses minimal risk to subjects and a returned questionnaire is considered as evidence of implied consent.

In cases where the signed consent is waived, the IRBPHS requires the researcher to provide subjects with a written statement regarding the research.

### **Proxy Consent for Subjects Unable to Give Consent for Themselves**

For studies involving subjects who cannot give signed or verbal consent for themselves (children under the age of 18, cognitively or emotionally impaired persons, unconscious patients, etc.) the IRBPHS may waive the consent requirement as stated above and require consent from a legally authorized representative, relative or subject advocate. (See Appendix H for sample Proxy Consent Form.).

## **Consent Document Standard Format**

The standard format for the Consent Form has been developed to satisfy federal and California State informed consent requirements and to encourage construction of a consent document that presents all necessary information to the prospective human subject in as clear and easily understandable a manner as possible.

**Understandable Reading Level:** It is recommended that the consent form be written at an **eighth-grade** reading level using everyday vocabulary and simple sentence structure.

**Lay Language:** Technical and/or scientific terminology should be replaced by lay language unless subjects are themselves professionals.

**Non-legalistic Language:** Use common language to ensure clear comprehension by the subject.

**Grammatical Person:** Form should be written in the first person (e.g. "I have been asked to participate."). If the subject is less than 18 years of age the third person should be used (e.g. "My child has been asked to participate.")

See sample Informed Consent Form in Appendix G. Additional sample information and consent forms are found in Appendices H, I, J, K.

## **Human Subject Incidents**

If any human subject incurs injuries or experiences adverse events associated with study procedures, or any problems involving the conduct of the study arise the IRBPHS must be notified. In addition, if any individual of the Dominican community becomes aware of possible breach of human subject protection in any research activity at Dominican University of California they should report the incident to the Institutional Review Board for the Protection of Human Subjects within ten working days. The Human Subject Incident Report Form is found in Appendix M.

The following problems having to do with human subject safety must be reported to the IRBPHS:

- adverse effects associated with study procedures.
- problems involving conduct of the study or participation of the human subjects such as recruitment and/or consent processes

Any serious or recurring problem, any anticipated side effect, any adverse effect reported to a study sponsor, and adverse effect requiring treatment or any side effect about which the human subject is concerned should be reported to the IRBPHS.

A report is not an admission of liability. For adverse effects, the researcher should determine whether changes should be made to the study procedures. While the IRBPHS does not actively monitor compliance with the guidelines set forth for research with human subjects, it is responsible for continuing review of research involving human subjects involved in the annual review process for on-going research.

Serious adverse effects or incidents are forwarded to the Dean of the researcher's school and to the Vice President for Academic Affairs. Failure to report adverse effects/incidents involving human subjects in research at Dominican is a breach of the conditions of approval and can result in suspension or revocation of IRBPHS approval.

In addition, the IRBPHS, in cooperation with the Office of the Vice President for Academic Affairs, will conduct an inquiry following any report of possible misconduct that may be reported by members of the campus community relative to research involving human subjects conducted at Dominican University of California. An inquiry will be made to the researcher conducting the study and if the investigator is a student, to the student's faculty advisor, maintaining requested anonymity of the individual submitting the report whenever possible. The IRBPHS will forward information about the incident to the Dean of the researcher's school and to the VPAA for appropriate resolution.

**APPENDIX A  
IRBPHS INITIAL APPLICATION**

**DOMINICAN UNIVERSITY OF CALIFORNIA**  
**INSTITUTIONAL REVIEW BOARD FOR  
THE PROTECTION OF HUMAN SUBJECTS**  
**INITIAL APPLICATION**

*All information must be typed. Handwritten applications will be returned to researcher.  
See IRB Forms for Word document.*

**Applicant Information:**

Name: \_\_\_\_\_

School: \_\_\_\_\_

Department: \_\_\_\_\_

Campus or Local Address: \_\_\_\_\_

Home Address: \_\_\_\_\_  
\_\_\_\_\_

If different from campus/local address please provide home address for contact during periods when you may not be living on campus or locally.

Local Phone: \_\_\_\_\_

Work Phone: \_\_\_\_\_

E-mail Address: \_\_\_\_\_

Note: All communication regarding your application will be by email so be sure you include a functional email address.

Name(s) of Co- Investigator(s): \_\_\_\_\_

**Faculty Advisor Information:**

Name: \_\_\_\_\_

Campus Phone: \_\_\_\_\_

E-mail Address: \_\_\_\_\_

Note: All communication regarding a student's application will be by email. Advisors will be copied on all correspondence so be sure to provide a functional email address.

**Project Information:**

Exact Title of Project: \_\_\_\_\_  
\_\_\_\_\_

Duration of Project (cannot exceed 1 year): \_\_\_\_\_

**Review Prior to Submission to IRBPHS:**

- Department Chair                      Signature: \_\_\_\_\_
- Department Committee              Signature of Committee Chair: \_\_\_\_\_
- Dean of School                          Signature: \_\_\_\_\_

Note: Review by Dean is required for faculty researchers but not for student investigators unless this is a procedure of the School within which the student is majoring.

**Category of Review:**

- Exempt (exempt category number from page 10)                      \_\_\_\_\_
- Expedited (expedited category number from page 11)                      \_\_\_\_\_
- Full Board

**Research Project Information:**

All requested information must be typed directly on the application form. Refer to pages 17-20 in the IRBPHS Handbook for aid in providing required information.

**Background and Rationale** (no more than 300 words). Describe nature of research problem and purpose of current study.

**Description of Sample.** Indicate by an X whether the following are involved and attach all required documents to this application.

- Patients as subjects
- Non-patient volunteers
- Students as subjects
- Minor subjects (less than 18 years)
- Subjects whose major language is not English (include copies of translated documents)
- Mentally disabled subjects
- Mentally retarded subjects
- Prisoners, parolees, or incarcerated subjects
- Other vulnerable or sensitive populations (gifted children, persons with alcoholism or drug addiction, homosexuals, etc.) Please identify \_\_\_\_\_
- Subjects studied at non-Dominican locations
- Filming, video-, or voice-recording of subjects
- Data banks, data archives and/or registration records

- There is a dual relationship between researcher and subject (explain)

**Recruitment Procedure.** Indicate how applicant will solicit participation (face-to-face, phone contact, mail, email, etc) along with copies of materials used to recruit subjects and permission letters if applicable

**Subject Consent Process.** Attach Informed Consent Forms to be used. If consent forms are not to be used explain why and provide copy of the Consent Cover Letter.

**Procedures:** Describe in detail what your subjects will experience and include copies of all written materials subjects will see including surveys, questionnaires, interview questions, etc.).

**Potential Risks to Subjects:** All research projects involve some potential risks to subjects. Describe all potential risks. Applications that do not address risks will be returned.

**Minimization of Potential Risk.** Describe ways the potential risks will be minimized by researcher.

**Potential Benefits to Subjects:** Describe in detail all potential benefits to the individual (focus is individual not society). There is always some benefit – why else do the study.

**Costs to the Subjects:** Describe any costs to subjects (transportation, time, effort, etc.).

**Reimbursement or Compensation to Subjects:** Describe and provide rationale for any reimbursement or compensation in response to participation in the research.

**Confidentiality of Records:**

- Data will be anonymous

How will anonymity be ensured?

- Data will not be anonymous

How will data be kept confidential? Who will see it?

How will raw data and computerized data be stored?

How will subject identity be kept separate from subject data?

(Note: all tapes and records should be destroyed after a period of one year following completion of the research project).

**Signatures:**

I acknowledge that all procedures will meet relevant local, state, and federal regulations regarding use of human subjects in research. I am familiar with and agree to adhere to the ethical principles in the conduct of research with human subjects as set forth by the Dominican University of California IRBPHS Handbook.

\_\_\_\_\_  
Signature of Applicant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Faculty Advisor\*

\_\_\_\_\_  
Date

\*Your signature indicates that you accept responsibility for the research described, including work by students under your supervision. It further attests that you are fully aware of all procedures to be followed, will monitor the research, and will notify the IRBPHS of any significant problems or changes.

Submit **2** copies of proposal for expedited or exempt review and **5** copies for full review.

**APPENDIX B  
PROPOSAL CHECKLIST**

**DOMINICAN UNIVERSITY of CALIFORNIA**

**IRBPHS PROPOSAL CHECKLIST**

This Checklist is provided to aid researchers and their advisors in preparation of the IRBPHS Application so that approval of the investigation may be accomplished as quickly as possible. Applications that are not submitted with all the necessary materials will be returned to the researcher and review will be postponed to next IRB review cycle.

1. \_\_\_\_ The proposed methodology is appropriate to the research question and the sample.
2. \_\_\_\_ Copies of **all** materials (letters of introduction, consent forms, demographic questions, surveys, and/or psychological measures) are attached to this proposal in an Appendix.
3. \_\_\_\_ Written permission has been obtained or requested (and a copy is attached) for the use or adaptation of any published tool, test, questionnaire, inventory, or survey.
4. \_\_\_\_ Written permission has been obtained or requested (and a copy is attached) from the appropriate institutional authority for the use of clients, students, patients, or employees of any institution as participants in the study.
5. \_\_\_\_ If human subjects are involved in the proposed project, participants understand:
  - (a) the purpose of the project, and how the results will be used and made available.
  - (b) what s/he is required to do as a participant.
  - (c) participation in the project is voluntary and that s/he may withdraw from the project at any time.
  - (d) that his/her identity will be revealed in any way in any subsequent written or oral reports describing the project.
  - (e) that participation/non-participation in the project will not affect the participant's care, grade, or status at the institution from which he or she was recruited if the subject is a student.
  - (f) that any risks/benefits to the participant are explained.
6. \_\_\_\_ Human subjects (and/or their parent or legal guardian) **must sign** an informed consent statement if **any** of the following conditions apply:
  - (a) face to face interviewing between the researcher and participant or any videotaping of the participant.
  - (b) the research is "moderate or high risk," involving sensitive or emotional issues or any possible physical risk to the participant.
  - (c) situations where the participant is potentially identifiable on the basis of demographic information.
  - (d) the participant is a minor, is mentally disabled, or is a prison inmate or member of any other at risk population.
7. \_\_\_\_ Ethical issues and values pertinent to the discipline in which the student is working have been considered in making decisions about the project's methodology and the application of results.
8. \_\_\_\_ The plan for reporting results to subjects, institutions, and the academic department reflects concern for accuracy, honesty, timeliness, and the welfare of the human subjects

**APPENDIX C**  
**CONFIRMATION OF RECEIPT OF APPLICATION**

**DOMINICAN UNIVERSITY of CALIFORNIA**

**CONFIRMATION OF RECEIPT OF COMPLETE IRBPHS APPLICATION**

Dominican University of California  
Institutional Review Board for Protection of Human Subjects

Date: \_\_\_\_\_

Dear: \_\_\_\_\_

Your application to the Institutional Review Board for the Protection of Human Subjects was received on \_\_\_\_\_ and has been given the following file number \_\_\_\_\_.

\_\_\_\_\_ Your application was complete when received.

\_\_\_\_\_ Your application was incomplete when received; it is now complete

Please allow 4-6 weeks from receipt of this notice for review.

You will be contacted if additional materials and/or clarification are needed.

Questions should be directed to IRBPHS office by phone at 415-257-0168. Please leave a number and electronic mail address where you can be reached or where a response message can be left.

IRBPHS Committee

**APPENDIX D  
RENEWAL APPLICATION**

**DOMINICAN UNIVERSITY of CALIFORNIA**

**INSTITUTIONAL REVIEW BOARD FOR  
THE PROTECTION OF HUMAN SUBJECTS**

**RENEWAL APPLICATION**

*All information must be typed. Handwritten applications will be returned to researcher.  
See IRB Forms for Word document.*

IRBPHS Number on Initial Application: \_\_\_\_\_

**Applicant Information**

Name of Applicant: \_\_\_\_\_

Department: \_\_\_\_\_

Local Address or Campus Address: \_\_\_\_\_  
\_\_\_\_\_

Home Address: \_\_\_\_\_  
\_\_\_\_\_

If different from campus/local address please provide home address for contact during periods when you may not be living on campus or locally.

Local Phone: \_\_\_\_\_

Work Phone: \_\_\_\_\_

E-mail Address: \_\_\_\_\_

Note: All communication regarding your application will be conducted by email so be sure you include a functional email address.

Name(s) of Co-investigators: \_\_\_\_\_

**Faculty Advisor Information:**

Name of Faculty Advisor: \_\_\_\_\_

Campus Phone: \_\_\_\_\_

Email Address: \_\_\_\_\_

Note: All communication regarding your application will be conducted by email so be sure you include a functional email address.

**Project Information:**

Exact Title of Project: \_\_\_\_\_

Duration of Project (note that renewal applications must be submitted each year): \_\_\_\_\_

**Review Prior to Submission to IRBPHS:**

- Department Chair                      Signature: \_\_\_\_\_
- Department Committee      Signature of Committee Chair: \_\_\_\_\_
- Dean of School                      Signature: \_\_\_\_\_

Note: Review by Dean is required for faculty researchers but not for student investigators unless this is a procedure of the School within which the student is majoring.

**Research Project Information:**

All requested information must be typed directly on the application form. Refer to page 20 in the IRBPHS Handbook for aid in providing required information.

**Subjects:**

- Number of subjects used last year in project \_\_\_\_\_
- Number of subjects who completed the study \_\_\_\_\_
- Number of subjects needed to complete the research study \_\_\_\_\_

**Summary of Results to Date** (limit to 300 words or less)

**Changes in Anticipated Risks.** Any changes in potential risk to human subjects due to changes in protocol.

**Changes in Anticipated Benefits.** Any change due to impact of changes in research protocol.

**Discussion of Problems:** Summarize any problems experienced or encountered by human subjects during past year.

**Explanation of Modification in Protocol:** Summarize any modifications in research protocol made during the past year.

**Signatures:**

I acknowledge that all procedures will meet relevant local, state, and federal regulations regarding use of human subjects in research. I am familiar with and agree to adhere to the ethical principles in the conduct of research with human subjects as set forth by the Dominican University of California IRBPHS Handbook.

\_\_\_\_\_  
Signature of Applicant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Faculty Advisor\*

\_\_\_\_\_  
Date

\*Your signature indicates that you accept responsibility for the research described, including work by students under your supervision. It further attests that you are fully aware of all procedures to be followed, will monitor the research, and will notify the IRBPHS of any significant problems or changes.

Submit **2** copies of proposal for expedited or exempt review and **5** copies for full review.

**APPENDIX E  
MODIFICATION APPLICATION**

**DOMINICAN UNIVERSITY of CALIFORNIA**

**INSTITUTIONAL REVIEW BOARD FOR  
THE PROTECTION OF HUMAN SUBJECTS**

**MODIFICATION APPLICATION**

*All information must be typed. Handwritten applications will be returned to researcher.  
See IRB Forms for Word document.*

IRBPHS Number on Initial Application: \_\_\_\_\_

**Applicant Information**

Name of Applicant: \_\_\_\_\_

Department: \_\_\_\_\_

Local Address or Campus Address: \_\_\_\_\_

Home Address: \_\_\_\_\_

\_\_\_\_\_

If different from campus/local address please provide home address for contact during periods when you may not be living on campus or locally.

Local Phone: \_\_\_\_\_

Work Phone: \_\_\_\_\_

E-mail Address: \_\_\_\_\_

Note: All communication regarding your application will be by email so be sure you include a functional email address.

Name(s) of Co-investigators:

**Faculty Advisor Information:**

Name of Faculty Advisor: \_\_\_\_\_

Campus Phone: \_\_\_\_\_

Email Address: \_\_\_\_\_

Note: All communication regarding your application will be by email so be sure you include a functional email address.

**Project Information:**

Exact Title of Project: \_\_\_\_\_

Duration of Project (renewal applications must be submitted each year for multi-year projects): \_\_\_\_\_

Briefly describe the modification for which you are seeking approval: \_\_\_\_\_

**Review Prior to Submission to IRBPHS:**

- Department Chair                      Signature: \_\_\_\_\_
- Department Committee              Signature of Committee Chair: \_\_\_\_\_
- Dean of School                      Signature: \_\_\_\_\_

Note: Review by Dean is required for faculty researchers but not for student investigators unless this is a procedure of the School within which the student is majoring.

**Research Project Information:**

All requested information must be typed directly on the application form. Refer to page 21 in the IRBPHS Handbook for aid in providing required information.

**Background and Rationale** (no more than 300 words). Describe nature of research problem and purpose of current study.

**Description of Sample.** Indicate by an X whether the following are involved and attach all required documents to this application.

- Patients as subjects
- Non-patient volunteers
- Students as subjects
- Minor subjects (less than 18 years)
- Subjects whose major language is not English (include copies of translated documents)
- Mentally disabled subjects
- Mentally retarded subjects
- Prisoners, parolees, or incarcerated subjects
- Other vulnerable or sensitive populations (gifted children, alcoholics, homosexuals, etc.) Please identify \_\_\_\_\_
- Subjects studied at non-Dominican locations
- Filming, video-, or voice-recording of subjects
- Data banks, data archives and/or registration records
- There is a dual relationship between researcher and subject (explain)

**Recruitment Procedure.** Indicate how applicant will solicit participation (face-to-face, phone contact, mail, email, etc) along with copies of materials used to recruit subjects and permission letters if applicable

**Subject Consent Process.** Attach Informed Consent Forms to be used. If consent forms are not used explain why and provide copy of the Consent Cover Letter.

**Procedures:** Describe in detail what your subjects will experience and include copies of all written materials subjects will see including surveys, questionnaires, interview questions, etc.).

**Signatures:**

I acknowledge that all procedures will meet relevant local, state, and federal regulations regarding use of human subjects in research. I am familiar with and agree to adhere to the ethical principles in the conduct of research with human subjects as set forth by the Dominican University of California IRBPHS Handbook.

\_\_\_\_\_  
Signature of Applicant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Faculty Advisor\*

\_\_\_\_\_  
Date

\*Your signature indicates that you accept responsibility for the research described, including work by students under your supervision. It further attests that you are fully aware of all procedures to be followed, will monitor the research, and will notify the IRBPHS of any significant problems or changes.

Submit **2** copies of proposal for expedited or exempt review and **5** copies for full review.

**APPENDIX F**  
**RESEARCH PARTICIPANT'S BILL OF RIGHTS**

**DOMINICAN UNIVERSITY of CALIFORNIA**

Every person who is asked to be in a research study has the following rights:

1. To be told what the study is trying to find out;
2. To be told what will happen in the study and whether any of the procedures, drugs or devices are different from what would be used in standard practice;
3. To be told about important risks, side effects or discomforts of the things that will happen to her/him;
4. To be told if s/he can expect any benefit from participating and, if so, what the benefits might be;
5. To be told what other choices s/he has and how they may be better or worse than being in the study;
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study;
7. To be told what sort of medical treatment is available if any complications arise;
8. To refuse to participate at all before or after the study is stated without any adverse effects. If such a decision is made, it will not affect h/her rights to receive the care or privileges expected if s/he were not in the study.
9. To receive a copy of the signed and dated consent form;
10. To be free of pressure when considering whether s/he wishes to be in the study.

If you have questions about the research you may contact me at (insert student's Dominican e-mail address here). If you have further questions you may contact my research supervisor, (insert Faculty research supervisor's name and phone # here) or the Dominican University of California Institutional Review Board for the Protection of Human Subjects (IRBPHS), which is concerned with protection of volunteers in research projects. You may reach the IRBPHS Office by calling (415) 257-1389 and leaving a voicemail message, or FAX at (415) 257-0165, or by writing to IRBPHS, Office of Associate Vice President for Academic Affairs, Dominican University of California, 50 Acacia Avenue, San Rafael, CA 94901

**APPENDIX G**

**CONSENT FORM TO BE A RESEARCH SUBJECT**

**DOMINICAN UNIVERSITY OF CALIFORNIA**  
**SAMPLE**

1. I understand that I am being asked to participate as a subject in a research study designed to assess certain personal attitudes related to death and dying. This research is part of Sarah Student's Senior Thesis research project at Dominican University of California, California. This research project is being supervised by Afshin Gharib, Ph.D., Associate Professor of Psychology, Dominican University of California.
2. I understand that participation in this research will involve taking part in a one-hour phone interview, which will include a personal life history, as well as thoughts and feelings on the topic of death and dying.
3. I understand that my participation in this study is completely voluntary and I am free to withdraw my participation at any time.
4. I have been made aware that the interviews will be recorded. All personal references and identifying information will be eliminated when these recordings are transcribed, and all subjects will be identified by numerical code only; the master list for these codes will be kept by Sarah Student in a locked file, separate from the transcripts. Coded transcripts will be seen only by the researcher and her faculty advisors. One year after the completion of the research, all written and recorded materials will be destroyed.
5. I am aware that all study participants will be furnished with a written summary of the relevant findings and conclusions of this project. Such results will not be available until May 1, 2010.
6. I understand that I will be discussing topics of a personal nature and that I may refuse to answer any question that causes me distress or seems an invasion of my privacy. I may elect to stop the interview at any time.
7. I understand that my participation involves no physical risk, but may involve some psychological discomfort, given the nature of the topic being addressed in the interview. If I experience any problems or serious distress due to my participation, Sarah Student will provide, at no cost to me, a one-time consultation with a licensed therapist. Ms. Student may be contacted at (insert student's Dominican e-mail address here).
8. I understand that if I have any further questions about the study, I may contact Ms. Student at (insert student's Dominican e-mail address here) or her research supervisor, Afshin Gharib, Ph.D., Associate Professor of Psychology, Dominican University of California at 415-xxx-xxx. If I have further questions or comments about participation in this study, I may contact the Dominican University of California Institutional Review Board for the Protection of Human Subjects (IRBPHS), which is concerned with the protection of volunteers in research projects. I may reach the IRBPHS Office by calling (415) 482-3547 and leaving a voicemail message, by FAX at (415) 257-0165 or by writing to the IRBPHS, Office of the Associate Vice President for Academic Affairs, Dominican University of California, 50 Acacia Avenue, San Rafael, CA 94901.
9. All procedures related to this research project have been satisfactorily explained to me prior to my voluntary election to participate.

**I HAVE READ AND UNDERSTAND ALL OF THE ABOVE EXPLANATION REGARDING THIS STUDY. I VOLUNTARILY GIVE MY CONSENT TO PARTICIPATE. A COPY OF THIS FORM HAS BEEN GIVEN TO ME FOR MY FUTURE REFERENCE.**

---

Signature

Date

**APPENDIX H**

**PROXY CONSENT FOR RESEARCH PARTICIPATION**

**SAMPLE**

**DOMINICAN UNIVERSITY of CALIFORNIA**

**PROXY CONSENT FOR RESEARCH PARTICIPATION**

Purpose and Background

Ms. Susan Fielding, an undergraduate student, and Dr. Samuel Togood, Professor, Department of Nursing at Dominican University of California, are doing a study on the social skills of children who have chronic ear infections. Because children with chronic ear infections miss many days of school and sometimes have difficulty hearing, the researchers are interested in learning whether these children are slower to develop social skills as compared with children who do not suffer from chronic ear infections.

My child is being asked to participate because s/he suffers from chronic ear infections.

Procedures

If I agree to allow my child to be in this study, the following will happen:

1. I will complete a questionnaire about my child's health, development, and friendship relationships.
2. My child will be observed through a one-way mirror while she plays with three other children she does not know but who are similar in age. The play period will be for 30 minutes.
3. The researchers will review my child's medical records to obtain information about the nature and extent of my child's ear infections.
4. I will complete the questionnaire and my child will participate in the 30-minute free play period at my pediatrician's office.

Risks and/or discomforts

1. My child may become uncomfortable or upset during the 30-minute free-play period. If this happens, the researchers will attempt to comfort my child. If my child continues to be upset, the researchers will return my child to me in the waiting room.
2. Study records will be kept as confidential as is possible. No individual identities will be used in any reports or publications resulting from the study. All personal references and identifying information will be eliminated when the data are transcribed, and all subjects will be identified by numerical code only, thereby assuring confidentiality regarding the subject's responses. The master list for these codes will be kept by Ms. Fielding in a locked file, separate from the transcripts. Only the researcher and her faculty advisors will see coded transcripts. One year after the completion of the research, all written and recorded materials will be destroyed.

Benefits

There will be no direct benefit to me or to my child from participating in this study. The anticipated benefit of this study is a better understanding of the effect of the chronic ear infections on the development of children's social skills.

Costs/Financial Considerations

There will be no costs to me or to my child as a result of taking part in this study.

Payment/Reimbursement

Neither my child nor I will be reimbursed for participation in this study.

Questions

I have talked to Ms. Fielding about this study and have had my questions answered. If I have further questions about the study, I may call her (510) 444-4444 or Dr. Togood (415) 778-9999. If I have any questions or comments about participation in this study, I should first talk with the researchers. If for some reason I do not wish to do this, I may contact the Dominican University of California Institutional Review Board for the Protection of Human Subjects (IRBPHS), which is concerned with protection of volunteers in research projects. I may reach the IRBPHS Office by calling (415) 257-0168 and leaving a voicemail message, or FAX at (415) 458-3755, or by writing to IRBPHS, Office of Associate Vice President for Academic Affairs, Dominican University of California, 50 Acacia Avenue, San Rafael, CA 95901.

Consent

I have been given a copy of this consent form, signed and dated, to keep.

**PARTICIPATION IN RESEARCH IS VOLUNTARY.** I am free to decline to have my child be in this study, or to withdraw my child from it at any point. My decision as to whether or not to have my child participate in this study will have no influence on my child's present or future status as a patient in my pediatrician's office.

My signature below indicates that I agree to allow my child to participate in this study.

|   |               |
|---|---------------|
| _____<br>Signature of Subject's Parent/Guardian | _____<br>Date |
| _____<br>Signature of Person Obtaining Consent  | _____<br>Date |

(Model letter adapted from USF IRPHS Handbook)

**APPENDIX I**

**SAMPLE LETTER OF INTRODUCTION TO PARTICIPANTS IN  
ANONYMOUS SURVEY RESEARCH**

Dear Study Participant,

My name is Steve Student and I am an undergraduate Psychology major at Dominican University of California. I am conducting a research project as part of my senior thesis requirements, and this work is being supervised by Matthew S. Davis, Ph.D., Professor of Psychology at Dominican University of California. I am requesting your voluntary participation in my study, which concerns people's television viewing habits and their attitudes regarding the content of popular TV programs.

Participation in this study involves keeping a record of the television shows you watch in the course of a one week period, and then filling out a five page questionnaire containing items on your opinions of television programming today, as well as some demographic questions to be used for statistical purposes. Please note that your participation is **completely voluntary and you are free to withdraw your participation at any time**. Likewise, your participation or non-participation **will not affect your class grade**. In addition your survey responses will be **completely anonymous**. Aside from keeping the television viewing record, filling out the survey is likely to take approximately 15 minutes of your time.

If you choose to participate in this study, please fill out the attached materials as honestly and completely as possible. You may then return them to me at your earliest convenience in the envelope provided via the Psychology Student research drop-box, located in the basement of Bertrand Hall. Remember, this survey is completely anonymous; do not put your name or any other identifying information on your survey form. If you choose not to participate, please return your unused survey materials to me in the envelope provided.

If you have questions about the research you may contact me at (student inserts Dominican e-mail address here). If you have further questions you may contact my research supervisor, (insert Faculty research supervisor's name and phone # here) or the Dominican University of California Institutional Review Board for the Protection of Human Subjects (IRBPHS), which is concerned with protection of volunteers in research projects. You may reach the IRBPHS Office by calling (415) 482-3547 and leaving a voicemail message, or FAX at (415) 257-0165, or by writing to IRBPHS, Office of Associate Vice President for Academic Affairs, Dominican University of California, 50 Acacia Avenue, San Rafael, CA 95901.

If you would like to know the results of this study once it has been completed, a summary of the results will be presented at Dominican University of California's Academic Showcase in April, 2010.

Thank you in advance for your participation.

Sincerely,

Steve S. Student  
Psychology Student Research Box  
Dominican University of California  
50 Acacia Avenue  
San Rafael, CA 94901

**APPENDIX J**

**LETTER OF PERMISSION TO DOMINICAN FACULTY**

**SAMPLE**

**DOMINICAN UNIVERSITY of CALIFORNIA**

**LETTER OF PERMISSION TO DOMINICAN FACULTY**

Joseph Professor, Ph.D.  
Psychology Department  
Dominican University of California

**RE: PRESENTATION OF RESEARCH PROJECT**

Dear Dr. Professor:

This letter confirms that you have read a brief description of my research project that examines student attitudes about the food served at the Student Cafeteria and that I have your permission to recruit participants for this project from your Research Methods class at a date and time convenient for you. I would only need 5-7 minutes of class time to summarize my project, ask for volunteers, and leave my materials.

This project is an important part of my undergraduate research requirements as a Biology major at Dominican. Dr. Richardson, Ph.D., Professor of Biology, is supervising my research. If you have questions about the project you may contact me at 555-5555. If you have further questions you may contact Dr. Richardson, at 666-6666, or the Institutional Review Board for the Protection of Human Subjects at (415) 257-0168.

Shortly after completion of my study, I will send you a brief summary of relevant findings and conclusions.

If my request to contact the students in your class meets with your approval, please sign this letter on the line provided below, date, and return this letter to me as soon as possible. I have enclosed a stamped self-addressed envelope for your convenience. I will then contact you to arrange a convenient time for visiting your class.

Thanks for your assistance.

Sincerely,

Sharon A. Senior  
50 Acacia Avenue  
Psychology Student Research Box  
Dominican University of California  
San Rafael, CA 94901

(415) 457-5533 x669

**I agree with the above request**

\_\_\_\_\_  
**Signature**

\_\_\_\_\_  
**Date**

**APPENDIX K**  
**LETTER OF PERMISSION TO AGENCY DIRECTORS**

**SAMPLE**

**DOMINICAN UNIVERSITY of CALIFORNIA**

**LETTER OF PERMISSION TO AGENCY DIRECTORS**

Mr. Stanhope  
Manager, Vanna White Health & Fitness Center  
123 Playa Del Sol, Suite C  
Marina Del Ray, CA 90111

Dear Mr. Stanhope:

This letter confirms that you have been provided with a brief description of my senior thesis research project, which concerns factors related to successful weight loss, and that you give your consent for me to visit your facility to interview a random sample of your clients. This project is an important part of my undergraduate requirements as a Nursing major, and is being supervised by Dr. Fred Montaque, Professor of Nursing at Dominican University of California.

As we discussed in our phone conversation, I will make every effort to ensure that my data collection does not interfere with your regularly scheduled classes and workshops, and that your clients are treated with the utmost discretion and sensitivity. If you have questions about the research you may contact me at 555-5555. If you have further concerns you may contact my research supervisor, Dr. Montague, at 666-6666 or the Institutional Review Board for the Protection of Human Subjects at Dominican University of California by calling (415) 257-0168.

After my research project has been completed in May 2004, I will be glad to send you a summary of my research results.

If my request to visit your establishment and to interview your clients meets with your approval, please sign and date this letter below and return it to me in the enclosed self-addressed, stamped envelope as soon as possible. Please feel free to contact me if you have any questions about this project.

Thank you very much for your time and cooperation.

Sincerely,

Bruce T. Rockford  
43 Thesis Terrace  
San Rafael, CA 94903

**I agree with the above request**

\_\_\_\_\_  
**Signature**

\_\_\_\_\_  
**Date**

**APPENDIX L**  
**PERMISSION TO USE A PSYCHOLOGICAL TEST**

**SAMPLE**

**DOMINICAN UNIVERSITY of CALIFORNIA**

**LETTER REQUESTING PERMISSION TO USE A PSYCHOLOGICAL TEST**

September 1, 2003

Princeton University Press  
41 Williams Street  
Princeton, NJ 08540

**RE: Couch Potato Inventory**

Dear Madame or Sir:

I am writing to request written permission to use the Couch Potato Inventory (Remote, 1993) in my undergraduate research project relating stress levels to the amount of time adolescents spend watching television. This project is part of an undergraduate senior thesis research requirement in psychology at Dominican University of California.

I would also appreciate receiving copies of the test/questionnaire, the standard instructions for administering the test, and scoring procedures.

My research is being supervised by my advisor, Dr. Robert Knodoz, Psychology Department, Dominican University of California, San Rafael, CA, 94901, (415-889-9000).

If this request meets with your approval, please sign, date, and return this letter to me in the enclosed self-addressed, stamped envelope. I am also enclosing an additional copy of this letter for your records.

If you have any questions, please do not hesitate to contact me or, if you prefer, Dr. Knodoz.

Thank you for your help.

Sincerely,

Samantha J. Student  
2001 Graduation Gardens  
San Rafael, CA 94903  
510-667-8888

**I agree to the above request.**

\_\_\_\_\_  
(Addressee's name)

\_\_\_\_\_  
Date

**APPENDIX M**  
**HUMAN SUBJECT INCIDENT REPORT**

**DOMINICAN UNIVERSITY of CALIFORNIA**

**HUMAN SUBJECT INCIDENT REPORT**

All incidents of injury or other adverse effects experienced by human subjects must be reported to the IRBPHS, Office of Associate Vice President for Academic Affairs, Dominican University of California, 50 Acacia Avenue, San Rafael, CA. 94901 (415-257-0168).

A written report, along with a copy of the original signed consent form, should be submitted as soon as possible, but **NO LATER THAN 10 WORKING DAYS** after first awareness of the problem.

Name of Researcher: \_\_\_\_\_  
University Title: \_\_\_\_\_  
Department: \_\_\_\_\_  
Home and/or Campus Address (s): \_\_\_\_\_  
Home and/or Work Phone (s): \_\_\_\_\_  
E-mail address: \_\_\_\_\_

Name(s) and University Title(s) of Other Investigators: \_\_\_\_\_

Name of Faculty Advisor: \_\_\_\_\_  
University Title: \_\_\_\_\_  
Campus Address: \_\_\_\_\_  
Campus Phone: \_\_\_\_\_  
E-mail Address: \_\_\_\_\_

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

IRBPHS # \_\_\_\_\_

Name of Human Subjects(s) \_\_\_\_\_

Respond to the items 1-4 on separate sheets of white paper, single-sided, typed in black ink using standard 12-point font. Responses to #1-4 should be stapled to this Human Subject Incident Report form.

1. Nature of Injury/Adverse Effect
2. Treatment(s)/Response Provided to Human Subject
3. Reporting (to whom has this already been reported?)
4. Additional Comments

\_\_\_\_\_  
Signature of Person Reporting Incident  
Name of Person Reporting Incident: \_\_\_\_\_  
Home and/or Campus Address(s): \_\_\_\_\_  
Home and/or Work Phones(s): \_\_\_\_\_  
E-Mail Address(s): \_\_\_\_\_

\_\_\_\_\_  
Date