

**DOMINICAN  
UNIVERSITY**  
*of* CALIFORNIA

**INSTITUTIONAL REVIEW BOARD FOR  
PROTECTION OF HUMAN PARTICIPANTS  
(IRBPHP)  
HANDBOOK**

## TABLE OF CONTENTS

1. INTRODUCTION .....	4
2. DEFINITION OF RESEARCH AND HUMAN PARTICIPANTS.....	4
<u>2.1. Research</u> .....	4
2.1.1 Student Projects .....	5
2.1.1.1 Research Practica.....	5
2.1.1.2 Research Projects.....	5
2.1.1.3 Research Involving Sensitive or Vulnerable Populations .....	5
2.1.2 Oral History .....	5
2.1.3 Other Types of Projects May or May not Require Review .....	5
<u>2.2 Human Participant</u> .....	6
3. REQUIRED REVIEW OF RESEARCH INVOLVING HUMAN PARTICIPANTS.....	6
<u>3.1. Course Instructors</u> .....	6
<u>3.2. Faculty Advisors</u> .....	7
<u>3.3. Researchers</u> .....	7
4. ETHICAL PRINCIPLES UNDERLYING PROTECTION OF HUMAN PARTICIPANTS.....	7
<u>4.1 Objectivity and Competence</u> .....	8
<u>4.2. Sensitivity and Responsibility</u> .....	8
<u>4.3. Precautions to Safeguard Participants</u> .....	9
<u>4.4. Informed Consent</u> .....	9
4.4.1 Waiver of Signed Consent.....	9
4.4.2 Proxy Consent for Participants Unable to Give Consent for Themselves.....	10
4.4.3 Consent Document Standard Format.....	10
<u>4.5. The Less Powerful</u> .....	10
4.5.1 Children in Research.....	10
4.5.2 Children’s Assent.....	11
4.5.3 Waiver of Children’s Assent .....	11
<u>4.6. Privacy</u> .....	12
<u>4.7. Deception</u> .....	12
<u>4.8 Review By Others</u> .....	12
<u>4.9 Experiments In Change</u> .....	12
<u>4.10 Uses of Research Knowledge</u> .....	12
5. INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN PARTICIPANTS .....	12
<u>5.1 IRBPHP Meetings</u> .....	13
<u>5.2 IRBPHP Functions and Operations</u> .....	13
<u>5.3 Categories of Review</u> .....	13
5.3.1 Exempt and Nonexempt Research.....	13
5.3.2 Expedited Review Procedures .....	15
5.3.3 Full Board Review Criteria.....	15
6. RESEARCH IN FOREIGN COUNTRIES .....	16
7. APPLICATION SUBMISSION PROCESS .....	16
<u>7.1 Initial Proposal Submission Process</u> .....	16
<u>7.2 Renewal Application Submission Process</u> .....	16
<u>7.3 Modification Application Submission Process</u> .....	17
8. INITIAL APPLICATION .....	17
<u>8.1 Application Information</u> .....	17

This section identifies who you are, your school and department, your local and home address, your email and phone number, and names of co-investigators if applicable.....	17
<u>8.2 Faculty Advisor Information</u> .....	17
<u>8.3 Project Information</u> .....	17
<u>8.4 Background and Rationale</u> .....	17
<u>8.5 Description of Sample</u> .....	17
<u>8.6 Recruitment Procedure</u> .....	18
<u>8.7 Participant Consent Process</u> .....	18
8.7.1 Human Participants’ Rights.....	18
8.7.2 Informed Consent Forms Needed.....	18
<a href="http://www.hhs.gov/ohrp/policy/consentckls.html">http://www.hhs.gov/ohrp/policy/consentckls.html</a> .....	19
8.7.3 Informed Consent Forms Not Needed.....	19
<u>8.8 Procedures</u> .....	19
<u>8.9 Potential Risks to Participants</u> .....	20
<u>8.10 Minimization of Potential Risk</u> .....	20
<u>8.11 Potential Benefits to Participants</u> .....	20
<u>8.12 Costs to the Participants</u> .....	20
<u>8.13 Reimbursement or Compensation to Participants</u> .....	20
<u>8.14 Confidentiality of Records</u> .....	20
<u>8.15 Signature Page</u> .....	20
9. THE PROPOSAL CHECKLIST.....	21
10. RENEWAL APPLICATION.....	21
11. MODIFICATION APPLICATION.....	21
12. HUMAN PARTICIPANT INCIDENTS.....	22
13. IRBPHP APPROVAL PROCESS FLOWCHART.....	23

**APPENDICES**

**APPENDIX A IRBPHP INITIAL APPLICATION..... 24**

**APPENDIX B IRBPHP SIGNATURE PAGE..... 27**

**APPENDIX C IRBPHP INITIAL PROPOSAL CHECKLIST ..... 28**

**APPENDIX D IRBPHP RENEWAL APPLICATION ..... 29**

**APPENDIX E IRBPHP MODIFICATION APPLICATION ..... 33**

**APPENDIX F RESEARCH PARTICIPANT’S BILL OF RIGHTS ..... 37**

**APPENDIX G CONSENT FORM TO BE A RESEARCH PARTICIPANT..... 38**

**APPENDIX H PROXY CONSENT FOR RESEARCH PARTICIPATION ..... 39**

**APPENDIX I CHILD ASSENT TO PARTICIPATE IN RESEARCH TEMPLATE (AGES 7-12 YEARS) ..... 41**

**APPENDIX J ADOLESCENT (AGES 13-17) ASSENT TO PARTICIPATE IN RESEARCH ..... 42**

**APPENDIX K CHILDREN’S VERBAL ASSENT TO PARTICIPATE IN RESEARCH TEMPLATE 44**

**APPENDIX L LETTER OF INTRODUCTION TO PARTICIPANTS IN ANONYMOUS SURVEY  
RESEARCH ..... 45**

**APPENDIX M LETTER OF PERMISSION TO DOMINICAN FACULTY..... 46**

**APPENDIX N LETTER OF PERMISSION TO AGENCY DIRECTORS ..... 47**

**APPENDIX O LETTER REQUESTING PERMISSION TO USE A PSYCHOLOGICAL TEST ..... 48**

**APPENDIX P IRBPHP HUMAN PARTICIPANT INCIDENT REPORT ..... 49**

# **DOMINICAN UNIVERSITY of CALIFORNIA**

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

### **1. Introduction**

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

As an institution using human beings as research participants, Dominican is required to provide an assurance to the Federal government that includes a statement of principles governing the institution in the discharge of its responsibility for protecting the rights and welfare of human participants or research conducted at, or sponsored by the institution, whether the research is participant 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 participants. The Institutional Review Board for the Protection of Human Participants of Dominican University of California complies with the Common Rule.

The IRBPHP was developed in accordance with the federal policy, Title 34, Code of Federal Regulations, Part 97, Protection of Human Participants <http://www2.ed.gov/policy/fund/reg/humansub/part97.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 Participants (Revised 1/15/2009) <http://www.hhs.gov/ohrp/humansubjects/guidance/> . Additionally material from the federal government's Office of Protection from Research Risks (OPRR) 1993 publication, "Protecting Human Participants: Institutional Review Board Guidebook," [http://www.hhs.gov/ohrp/archive/irb/irb\\_guidebook.htm](http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.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.ccdc.vt.edu/aoir/ethics/public/IRBSS.pdf>

California's legislature enacted several laws that set legal requirements requiring the addition of an Experimental Participants Bill of Rights when students or faculty are conducting medical research (California Health and Safety Code Section 24173(a) [http://oag.ca.gov/sites/all/files/agweb/pdfs/research/safety\\_24173.pdf](http://oag.ca.gov/sites/all/files/agweb/pdfs/research/safety_24173.pdf)

These documents are to be cited when appropriate in the text below. Some of the material in Dominican's original IRBPHP Handbook was modeled with permission after the University of San Francisco Institutional Review Board for the Protection of Human Participants Manual.

### **2. Definition of Research and Human Participants**

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

#### **2.1. 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)

<http://www.gpo.gov/fdsys/pkg/CFR-2009-title34-vol1/xml/CFR-2009-title34-vol1-sec97-102.xml> Most of the research conducted in the social sciences, clinical, and biomedical specialties would fall within the definition of “systematic investigation.”

### 2.1.1 Student Projects

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

#### **2.1.1.1 Research Practica**

Research practica are classroom research projects, which provide research training. This would include practical application of studied theories of research methods 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 participants are not identifiable by name or description and do not include vulnerable populations. Projects must not require participants to discuss personal issues or behaviors that might place them at risk by virtue of their participation.

#### **2.1.1.2 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 participants 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.)

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

These research projects identify the human participant. 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 participants 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 IRBPHP expedited or full board review.

### 2.1.2 Oral History

Scholarly and journalistic activities (e.g., oral history, biography, literary criticism, , and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected is not considered research per the 2017 Common Rule and is therefore not subject to IRB review.

### 2.1.3 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.

## **2.2 Human Participant**

Human participant 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.” <http://www2.ed.gov/about/offices/list/ocfo/humansub.html> Intervention includes both physical procedures by which data are gathered and manipulations of the participant or the participant’s environment performed for research purposes. Interaction includes communication or interpersonal contact between investigator and participant. 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.

## **3. Required Review of Research Involving Human Participants**

The Institutional Review Board must review ALL research involving human participants. This means all research involving human participants conducted by Dominican University of California undergraduate and graduate students under the supervision of Dominican faculty, by graduate students from other institutions using Dominican participants, 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 IRBPHP 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 are considered “exempt”, the IRB must make that “exempt” judgment after considering the parameters of the project under review.

### **3.1.Course Instructors**

Faculty members who teach courses that require students to conduct research with human participants as a part of the activities of the course must act as an extension of the IRBPHP 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 participants is minimized, participants are protected, and students act in an ethical manner at all times. Please see section 2.1.1 on types of classroom research for clarification of the need for IRB review of classroom projects using human participants.

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 IRBPHP.

### **3.2. Faculty Advisors**

It is expected that faculty advisors supervising undergraduate or graduate students conducting research involving human participants 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 participants and are legitimate and appropriate scientific methods of inquiry. The IRBPHP 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 participant 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 IRBPHP 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 participants.

### **3.3. Researchers**

It is expected that research scientists are familiar with the federal regulations that govern their particular area of research involving human participants. The principle investigator is responsible for any harm to human participants 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 participants are treated so as to minimize harm and safeguard their rights.

## **4. Ethical Principles Underlying Protection of Human Participants**

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

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 participants research clear and complete information regarding the research and clear indications that the participant 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 participants 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 participant 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 participants. 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 participants. Justice also demands that benefits arising from the research are distributed fairly and equitably among all participants.

The IRBPHP is responsible in providing assurance of compliance for human participant research that the above ethical principles are maintained. The IRBPHP must ensure risks to participants are minimized, risks to participants are reasonable in relation to anticipated benefits, and the selection of participants is equitable



<http://www2.ed.gov/policy/fund/reg/humansub/part97-2.html#97.119> (34 Part 97). Researcher should examine their projects in light of these principles prior to seeking IRBPHP approval.

Dominican University of California expects students and faculty conducting research using human participants to conform to basic ethical responsibilities as outlined by the Belmont Report. The task of the IRBPHP 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 participants 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 IRBPHP. (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.)

**4.1 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.

**4.2. 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 participants, be knowledgeable about issues of ethics and values, and consider these when making research decisions and actions.

### **4.3. Precautions to Safeguard Participants**

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

### **4.4. Informed Consent**

The informed consent process is at the heart of the ethical principal for the respect for human participants. Human participants 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://www.hhs.gov/ohrp/policy/consentckls.html>

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 participant, 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 participant'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 participant may address complaints about the experiment. Questions about the research are usually best answered by the researcher but questions concerning rights as a research participant should be referred to the research supervisor, if the researcher is a student. The IRBPHP may also be listed as a contact for questions posed by the participant and as the contact for reporting the event of a research-related injury to the participant. (See Appendices F and G for sample forms)

It is important that research participants 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://www.hhs.gov/ohrp/policy/consentckls.html>

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

#### **4.4.1 Waiver of Signed Consent**

The IRBPHP may waive the requirement for a signed consent form if the only record linking the participant 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 participant entailed in signing the consent form (e.g. for immigrants who might be identified as being undocumented), or in a retrospective records review or analysis of previously collected data where the participants 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 participants 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 participants and a returned questionnaire is considered as evidence of implied consent.

In cases where the signed consent is waived, the IRBPHP requires the researcher to provide participants with a written statement regarding the research. (Modeled after Appendix I)

#### 4.4.2 Proxy Consent for Participants Unable to Give Consent for Themselves

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

#### 4.4.3 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 participant 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 participants are themselves professionals.

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

**Grammatical Person:** Form should be written in the first person (e.g. “I have been asked to participate.”). If the participant 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.

### **4.5. 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.

#### 4.5.1 Children in Research

Special regulations outlined in [45 CFR 46, Subpart D](#) apply when research involves participants who are children. Children are described as inherently more vulnerable than adults and are covered by the additional

protections in the federal regulations. In California, individuals under the age of 18 years qualify as a “child” or “minor” and cannot consent to participation in research (except in cases of emancipated or self-sufficient minors).

When planning a study that will involve children, the IRB needs to consider four main issues (adapted from UCSF Office of Ethics and Compliance):

- Rationale for inclusion: What unique outcomes will come from studying children?
- Risks and benefits: What is the risk level of the study? What benefits and risks will come from studying children?
- Study procedure versus standard procedure: How are study procedures different from standard procedures for participants (such as an educational intervention in a classroom environment)?
- Consent and Assent: What are consent (permission) and assent requirements for the study?

#### 4.5.2 Children’s Assent

Federal regulations include requirements for both parental permission (consent) and **assent** from children.

**Assent** is a child's affirmative agreement to participate in research. Assent should be obtained from children capable of providing assent, "[taking] into account the ages, maturity, and psychological state of the children involved" [45 CFR 46.408]. Mere failure to object should not, absent affirmative agreement, be construed as assent. The IRB relies on the expertise of the primary investigators to aid in determining the capability of a particular child or groups of children to assent. In general, out of respect for children as developing persons, children should be asked whether or not they wish to participate in the research.

Assent Guidelines (adapted from UCSF Office of Ethics and Compliance):

<b>Age of Minor Participant</b>	<b>Assent Form Recommended</b>	<b>Separate Parental Permission Form</b>
Infant-6 years old	No*	Yes
7-12 years old	Yes	Yes
13-17 years old	Yes	Yes**

\* The investigator may deem a child in this age range (Infant-6 years old) capable of being involved in the assent process. If so, give the child a simple verbal explanation of what will happen to him/her, and then document on the parental permission form or in the study records that you obtained verbal assent (See Appendix K).

\*\*Adding a line to the adolescent assent form for parent(s) to sign is an acceptable option.

#### 4.5.3 Waiver of Children’s Assent

Assent may be unnecessary in certain circumstances. The IRB can consider waiving the requirement to obtain children’s assent, for example:

- “The capability of some or all of the children is so limited that they cannot reasonably be consulted;” or
- “The research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research” [45 CFR 46.408 21 CFR 50.55].
- The parents’ right to make decisions for their child may come into conflict with the child’s right to give or withhold assent. In this situation, assent may not be mandatory, though it always should be sought.

In such cases, the PI may propose a waiver of child’s assent in the IRB application. The IRB’s decision about waiver of assent will depend on the specifics of the study.

Additional Parental Consent and Child Assent Guidelines (according to UCSF Office of Ethics and Compliance):

- If the child is considered capable of providing assent, always provide a simple verbal explanation of what will happen to him/her and the opportunity for questions and discussion.
- Even if the requirement for assent is waived, it is always preferable to seek the child's assent, if possible.
- Document on the parental permission form or in the study records that the child was appropriately informed about the study.

#### **4.6. 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.

#### **4.7. 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.

#### **4.8 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 Participants. If participants 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.

#### **4.9 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 participants have accepted this possibility or resources are sufficient to offer the most desirable treatment to all persons.

#### **4.10 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.

### **5. Institutional Review Board for the Protection of Human Participants**

The Institutional Review Board for Protection of Human Participants reviews and approves all human participant 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 IRBPHP must have a minimum of five members with varying backgrounds and provide discipline expertise for proposals coming before the Board. The Associate Vice President for Academic Affairs appoints the members

for staggered three-year terms. If the IRBPHP 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 IRBPHP functions. IRB members are expected to complete NIH approved training every three years.

If the IRBPHP reviews research that involves a vulnerable category of participants, 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 participants.

An investigator may be a member of the IRBPHP 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 IRBPHP.

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

### **5.1 IRBPHP Meetings**

The IRBPHP meets as needed. Most applications are reviewed electronically. In addition to ongoing review the IRBPHP may meet several times each semester to discuss policies, human participant'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-IRBPHP members.

### **5.2 IRBPHP Functions and Operations**

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

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 IRBPHP 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.

### **5.3 Categories of Review**

The three categories of review are exempt, expedited and full board review.

#### **5.3.1 Exempt and Nonexempt Research**

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

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

The exemptions are found in the Code of Federal Regulation and for ease of access, excerpted below.

Research activities in which involvement of human participants 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 participants and disclosure could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation. Subpart D amends this exemption, in part: If the participants are children, research involving interview, survey procedures or 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 participants cannot be identified, directly or through identifiers linked to participants.
4. Research involving survey or interview procedures, except where responses are recorded in such a manner that the human participants can be identified, directly or through identifiers linked to the participants, and either:
  - a. The participant's responses, if they become known outside the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing or employability, or
  - b. The research deals with sensitive aspects of the participant'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 participants can be identified, directly or through identifiers linked to the participants, and either:
  - a. The participant's responses, if they become known outside the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing or employability, or
  - b. The research deals with sensitive aspects of the participant'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 the Code of Federal Regulation <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html> . 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 participants. Risk is for the IRBPHP 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.



### 5.3.2 Expedited Review Procedures

The IRBPHP 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 categories 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 or board member of the IRBPHP, carries out an expedited review. A single expedited reviewer may not disapprove of the research. A research activity can only be disapproved after review by the entire IRBPHP 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://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.110>

### 5.3.3 Full Board Review Criteria

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

- ❑ Minor participants (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 participants
- ❑ 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 participants to graphically violent or pornographic materials
- ❑ Inflicting physical pain upon, attaching electrodes to, or injecting any substance into participants
- ❑ Creating high levels of stress, fear, discomfort, or tension
- ❑ Threatening participants in any way
- ❑ Causing participants to violate laws or official university regulations
- ❑ Providing some participants 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 participants in intense exercise
- ❑ Placing individuals in confining physical settings or attaching other devices
- ❑ Exposing participants to extreme conditions (e.g., bright lights, loud noise, intense pressure, strong odors, complete darkness, extreme heat or cold, sudden movements, etc.)
- ❑ Leaving participants alone for periods of longer than 20 minutes
- ❑ Taking hair samples or nail clippings for participants
- ❑ Taking human tissue samples, drawing blood, or sampling any other bodily fluid



## **6. Research in Foreign Countries**

When research involving human participants takes place in foreign countries procedures normally followed in the foreign country to protect human participants 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) at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101> in developing their proposal.

## **7. Application submission Process**

There are three types of application submissions; initial, renewal and modification. All materials submitted in an application should be contained in a single file, either a pdf (preferred) or a Word document. IRB approval must be obtained before research is begun, no approval will be made after the fact.

### **7.1 Initial Proposal Submission Process**

It is the responsibility of the researcher to submit the required documents to the IRBPHP. All documents should be submitted electronically. The initial application is found in Appendix A and a separate link is provided <http://www.dominican.edu/academics/resources/irbforms>. Upon receipt the proposal will be given an IRBPHP review number. It is suggested that students keep copies of the materials submitted to the IRBPHP for their personal reference. Handwritten applications will not be accepted. Incomplete applications will be returned to the researcher. Applicants may expect notification from IRBPHP 3-4 weeks following date forwarded to IRBPHP members. If the application is incomplete in some way, missing measurement instruments, unclear or inadequate descriptions of participants or of research protocol, or missing signature of faculty advisor, the review may take longer. Student applications should be submitted in accordance with 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 participants to be recruited for the research.

The faculty advisor and departmental committee, if applicable, prior to submission to the IRBPHP, review each application. See the flowchart on in section 13 which diagrams the review procedure. When the advisor and committee are satisfied that potential risks to human participants have been addressed and minimized and that all relevant requirements have been met, s/he submits the application to the IRBPHP Office with a recommendation for an exempt, expedited or full review.

For both exempt and expedited reviews the Chair of the IRBPHP or a member of the Board reviews the application and addresses any concerns with the advisor and the applicant, seeking expert consultancy if necessary. In a full review the three members of the IRBPHP review the proposal and recommend approval/non-approval. For all reviews, the IRBPHP may identify issues or concerns with the application that require modifications to the application, in which case the applicant will make the requested changes and resubmit the application along with a cover letter indicating the changes that have been made. Requests for changes will be identified as either (a) changes that require re-review by an IRB member (such as providing a signed permission form) or (b) changes that do not require re-review by an IRB member (such as spelling errors). When all concerns have been addressed the Chair of the IRBPHP 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.

### **7.2 Renewal Application Submission Process**

Initial approval of research involving human participants is granted for a period of one year. Researchers must obtain IRBPHP 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 IRBPHP may grant an extension for up to one month. Request for extension must be made in writing to the IRBPHP Office and will be granted only for substantive reasons for failure to complete a timely Renewal Application.

### **7.3 Modification Application Submission Process**

The IRBPHP 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 participants, timelines, procedures, wording of documents, or instruments, it must be summarized in an IRBPHP 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.

## **8. Initial Application**

To obtain initial Institutional Review Board for Protection of Human Participants approval for research with human participants fill out the IRBPHP Initial Application.

The IRBPHP Initial Application is found in Appendix A, and in a separate link for interactive completion <http://www.dominican.edu/academics/resources/irbforms>. It can be completed online or printed and scanned for electronic submission.

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

### **8.1 Application Information**

This section identifies who you are, your school and department, your local and home address, your email and phone number, and names of co-investigators if applicable.

### **8.2 Faculty Advisor Information**

This section identifies your faculty advisor's name and contact information for your research project.

### **8.3 Project Information**

This section requests the title and duration of your research project.

### **8.4 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. All cited references should be included immediately following the summary.

### **8.5 Description of Sample**

The description of sample should include:

- detailed description of sample including age, gender, and ethnicity;
- special characteristics of participant population (e.g., prisoners, children, dependent adults);
- describe any dual relationships applicant has with the participants or the institution in which the participants 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)

## **8.6 Recruitment Procedure**

The recruitment procedure section should include how the researcher will solicit participation from participants (e.g., face-to-face, phone contact, mail) and provide copies of memos, email messages, facebook or other social media postings, cover letters, flyers, etc. that will be used to recruit potential participants. If recruiting through social media it should be stated clearly that participants must be 18 or older.

- method researcher is using to obtain access to participants (e.g., co-workers, students in classroom, mailing lists);
- if participants 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 participants 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 participant 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)

## **8.7 Participant Consent Process**

### **8.7.1 Human Participants' 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 participant 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 Participants 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.

### **8.7.2 Informed Consent Forms Needed**

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

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

If participants are 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).
- In addition to parental (guardian) consent, describe the procedure for obtaining child assent

- Include a copy of the Child Assent Form (see Appendices I and J ) or Script (see Appendix K).

Documentation of assent by children who are deemed capable can be documented via:

- Assent form signed by child (see Appendices I and J), retained with the study records.
- Assent form signed by person conducting the assent discussion (primary investigator or research assistant), retained with the study records.
- Verification of verbal assent can be asserted by the person conducting the assent discussion (primary investigator or research assistant) via signature added to parental permission/proxy consent form (Appendix H) or assent script (Appendix K) and retained with the study records.

Additional Guidelines:

- 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 participants 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 participants (e.g. implied consent when one completes a questionnaire).
- e. An informed consent checklist may be found at:  
<http://www.hhs.gov/ohrp/policy/consentckls.html>

### 8.7.3 Informed Consent Forms Not Needed

Informed consent forms are not needed for anonymous survey research with adults (18 or over). This research poses minimal risk to participants 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 “Participant 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 participants are identifiable and return is in a manner that will insure confidentiality.

## **8.8 Procedures**

Describe in detail what your participants 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 participants will see including surveys/tools, questionnaires/tests, interview questions, etc. If the researcher is using a previously developed test, permission to use test must be documented (appendix L) or a statement included that the tool is in public domain. If a researcher plans to use test scores or other data about human participants that has been previously collected, the researcher should be aware that use of that individual’s standardized test scores or grades without a participant’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 unless proxy consent will be obtained for the

inclusion of minors. All anonymous surveys should include a statement indicating that participants must be 18 or older.

### **8.9 Potential Risks to Participants**

All research projects involve some potential risks to participants. Describe in detail all potential risks to participants 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.**

### **8.10 Minimization of Potential Risk**

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

### **8.11 Potential Benefits to Participants**

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

### **8.12 Costs to the Participants**

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

### **8.13 Reimbursement or Compensation to Participants**

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

### **8.14 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 participant's identity separate from participant's data. Maintaining confidentiality of information collected from research participants means that only the investigator(s) or individuals of the research team can identify the responses of individual subjects; however, the researchers must make every effort to prevent anyone outside of the project from connecting individual subjects with their responses. (for example face to face experiments, interviews, oral histories). Providing anonymity of information collected from research participants means that either the project does not collect identifying information of individual subjects (e.g., name, address, Email address, etc), or the project cannot link individual responses with participants' identities. Collecting identifying information of research participants is most often unnecessary. (for example, survey research, online research using online survey platforms (e.g. survey monkey).

### **8.15 Signature Page**

All applications **must be** submitted with a scanned copy of the Signature Page, available at: <http://www.dominican.edu/academics/resources/irbforms>. Applications will not be reviewed without the completed signature page.

Applicant must sign and date the Signature Page. When the applicant is a student, the faculty advisor must also sign and date the Signature Page. The Category of Review (i.e. Exempt, Expedited or Full Board review) as explained in section 5.3 of this Handbook is determined by the faculty advisor or faculty researcher.

## **9. The Proposal Checklist**

There is a proposal checklist included in Appendix B researchers are expected 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.

## **10. Renewal Application**

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

IRBPHP Renewal Application is found in Appendix D and in a separate link:

<http://www.dominican.edu/academics/resources/irbforms>.

### **The Renewal Application must provide the following information:**

1. Participants. Number of participants used last year in project, number who completed the study and number of participants 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 participants due to changes in protocol.\*
4. Changes in Anticipated Benefits. Any change in potential benefits to human participants 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 participants 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, participant sample). \*\*

Signatures: Complete the Signature Page to 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 IRBPHP for approval on a Modification Application prior to implementation of the changes.

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

## **11. Modification Application**

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

The IRBPHP Modification Application is found in Appendix E and in a separate link,

<http://www.dominican.edu/academics/resources/irbforms>.

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 IRBPHP 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 Participants: Describe any impact on the level of potential risk to human participants 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 Participants: Describe anticipated benefit to human participants resulting from the proposed change. Focus should be on individual participants 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.

## **12. Human Participant Incidents**

If any human participant incurs injuries or experiences adverse events associated with study procedures, or any problems involving the conduct of the study arise the IRBPHP must be notified. In addition, if any individual of the Dominican community becomes aware of possible breach of human participant 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 Participants within ten working days. The Human Participant Incident Report Form is found in Appendix M.

The following problems having to do with human participant safety must be reported to the IRBPHP:

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

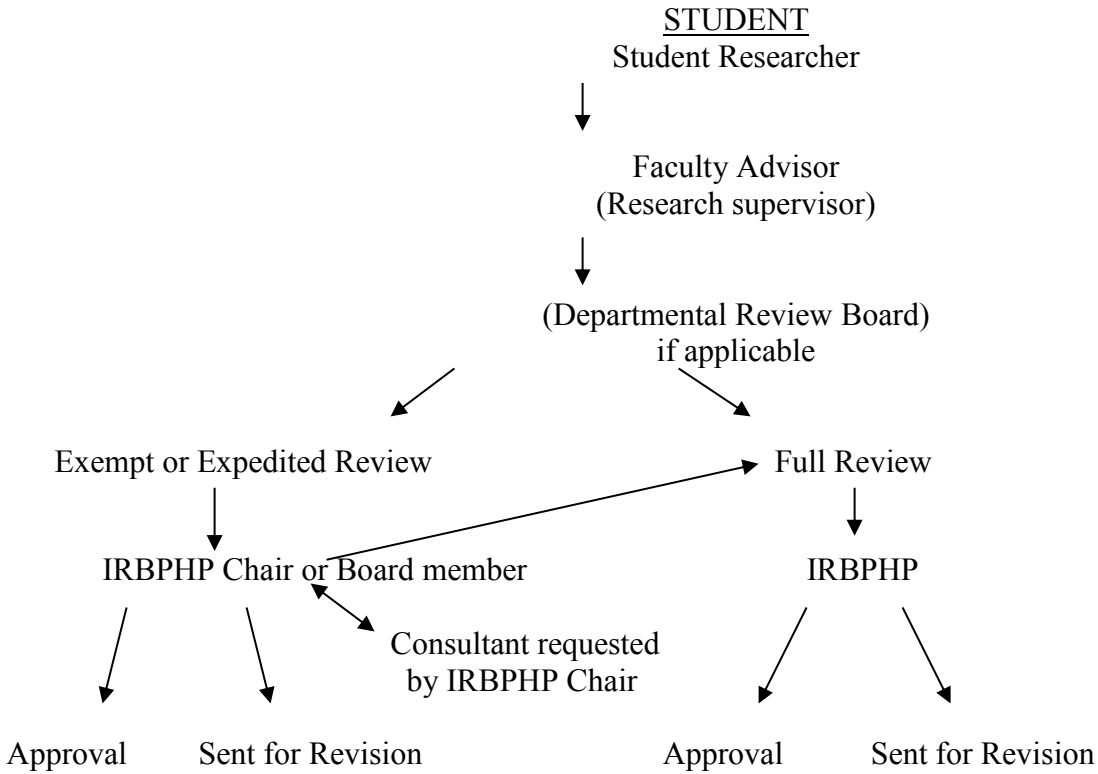
Any serious or recurring problem, any anticipated side effect, any adverse effect reported to a study sponsor, and adverse effect requiring treatment or any side effect about which the human participant is concerned should be reported to the IRBPHP.

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 IRBPHP does not actively monitor compliance with the guidelines set forth for research with human participants, it is responsible for continuing review of research involving human participants 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 participants in research at Dominican is a breach of the conditions of approval and can result in suspension or revocation of IRBPHP approval.

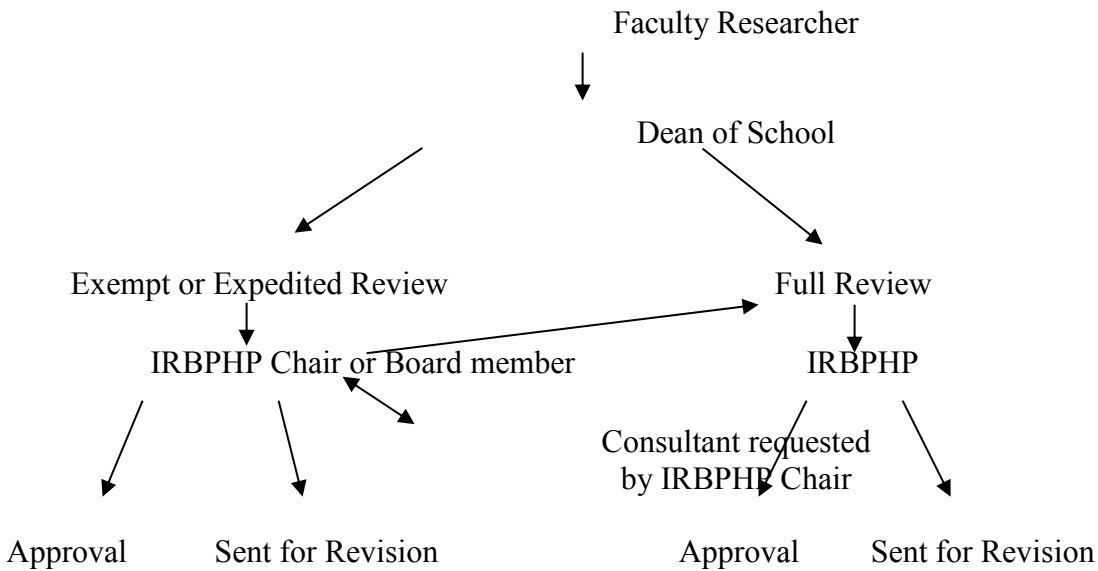
In addition, the IRBPHP, in cooperation with the Office of the Vice President for Academic Affairs, will conduct an inquiry following any report of possible misconduct that may be reported by members of the campus community relative to research involving human participants conducted at Dominican University 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 IRBPHP will forward information about the incident to the Dean of the researcher's school and to the VPAA for appropriate resolution.

**13. IRBPHP Approval Process Flowchart**



\*\*\*\*\*

**FACULTY MEMBER**





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

*All information must be typed and submitted electronically to Chilly Penguin (chilly.penguin@dominican.edu). Handwritten applications will be returned to researcher. A signature page must accompany all applications. Numbers in parentheses refer to explanatory sections in the IRBPHP Handbook. Please use these as a guide in providing the requested information.*

**APPLICANT INFORMATION (8.1)**

**Name:** Click here to enter text.

**School:** Click here to enter text.

**Department:** Click here to enter text.

**Campus or Local Address:** Click here to enter text.

**Home Address:** Click here to enter text.

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

Click here to enter text.

**Local Phone:** Click here to enter text.

**Work Phone:** Click here to enter text.

**E-mail Address:** Click here to enter text.

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): Click here to enter text.

**FACULTY ADVISOR INFORMATION: (8.2)**

**Name:** Click here to enter text.

**Campus Phone:** Click here to enter text.

**E-mail Address:** Click here to enter text.

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.

**RESEARCH PROJECT INFORMATION: (8.3)**

**Exact Title of Project:** [Click here to enter text.](#)

Duration of Project (cannot exceed 1 year): [Click here to enter text.](#)

**Background and Rationale** (no more than 300 words). Describe nature of research problem and purpose of current study. **(8.4)** Include references at end for any works cited.

[Click here to enter text.](#)

**Description of Sample:** (check the boxes that pertain to your sample) **(8.5)**

- Patients as participants
- Non-patient volunteers
- Students as participants
- Minor participants (less than 18 years)
- Participants whose major language is not English (Note: Include copies of translated documents)
- Mentally disabled participants
- Prisoners, parolees, or incarcerated participants
- Other vulnerable or sensitive populations (e.g. children, persons with alcoholism or drug addiction, LGBT individuals, etc.) Please identify:  
[Click here to enter text.](#)
- Participants studied at non-Dominican locations
- Filming, video, or voice-recording of participants
- Data banks, data archives and/or registration records
- There is a dual relationship between researcher and participant (explain):  
[Click here to enter text.](#)

**Recruitment Procedure:** Indicate anticipated sample size and how applicant will solicit participation (face-to-face, phone contact, mail, email, etc) along with copies of materials used to recruit participants and permission letters if applicable: **(8.6)**

[Click here to enter text.](#)

**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. **(8.7)**

[Click here to enter text.](#)

**Procedures:** Describe in detail what your participants will experience and include copies of all written materials participants will see including surveys, questionnaires, interview questions, etc. Permission to use any copyrighted materials should be included. **(8.8)**

[Click here to enter text.](#)

**Potential Risks to Participants:** Describe all potential risks.

*Note: All research projects involve some potential risks to participants. Applications that do not address risks will be returned. (8.9)*

[Click here to enter text.](#)

**Minimization of Potential Risk:** Describe ways the Potential Risks to Participants (detailed in section above) will be minimized by researcher. (8.10)

[Click here to enter text.](#)

**Potential Benefits to Participants:** Describe in detail all potential benefits to the individual (focus is individual not society). There is always some benefit – why else do the study. (8.11)

[Click here to enter text.](#)

**Costs to the Participants:** Describe any costs to participants (transportation, time, effort, etc.). (8.12)

[Click here to enter text.](#)

**Reimbursement or Compensation to Participants:** Describe and provide rationale for any reimbursement or compensation in response to participation in the research. (8.13)

[Click here to enter text.](#)

**Confidentiality of Records:** (8.14)

Data will be anonymous

How will anonymity be ensured?

[Click here to enter text.](#)

Data will not be anonymous

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

[Click here to enter text.](#)

How will raw data and computerized data be stored?

[Click here to enter text.](#)

How will participant identity be kept separate from participant data?

[Click here to enter text.](#)

*Note: all tapes and records should be destroyed after a period of one year following completion of the research project. Any recordings made using smart phones or other digital recording devices must be deleted entirely after transferring the recordings to a secure location, such as a passcode protected computer in a locked room. Care should be taken to delete not only the original recording on the recording device, but also any associated data backups of recordings to cloud-based services (iCloud, Google FileStream, Google Photos etc.) and/or backup server copies (Apple iTunes or Time Machine backups, automated backup utilities, etc.)*

**SIGNATURE PAGE (8.15)**

**Select Type of Application:** Choose an item.

**Applicant Name:** Click here to enter text.

**Project Title:** Click here to enter text.

**Signatures:**

I acknowledge that all procedures will meet relevant local, state, and federal regulations regarding use of human participants in research. I am familiar with and agree to adhere to the ethical principles in the conduct of research with human participants as set forth by the Dominican University of California IRBPHP 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 IRBPHP of any significant problems or changes.

\***Category of Review:** Determined by faculty advisor or researcher.

(*Note: See IRB Handbook pages 11-13 for category descriptions.*)

- Exempt *For Renewal and Modification Applications only.*  
 Expedited  Category of Review changed from Initial  
 Full Board Review

\_\_\_\_\_  
Signature of Department Chair

\_\_\_\_\_  
Date

\*\* Review by Dept Chair required for students in some disciplines.

\_\_\_\_\_  
Signature of Dean of School

\_\_\_\_\_  
Date

\*\*\*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.

Please print and scan this signature page for your file and return electronically to [chilly.penguin@dominican.edu](mailto:chilly.penguin@dominican.edu) or in person to Chilly Penguin in Guzman 210.

**APPENDIX C**  
**IRBPHP INITIAL PROPOSAL CHECKLIST**

Note: The numbers on this form correspond to the numbers in the IRBPHP Handbook and the numbers on the IRBPHP Initial Application. This Checklist is provided to aid researchers and their advisors in preparation of the IRBPHP Application and a timely response from the IRBPHP committee.

- 8.1 \_\_\_ Applicant accurately completed the section titled: Applicant Information
- 8.2 \_\_\_ Applicant, if a student, accurately completed the section titled “Faculty Advisor Information.”
- 8.3 \_\_\_ Applicant has titled and provided a duration date for their project.
- 8.4 \_\_\_ Applicant has provided a brief background of their research topic, a clear research question (or hypothesis) and has correctly cited all references used directly below this section.
- 8.5 \_\_\_ Applicant has thoroughly described their sample.
- 8.6 \_\_\_ Applicant has detailed how they will recruit their sample from start to finish and has placed all materials used to recruit in the Appendix section (alphabetized correctly for this specific project).
- 8.7 \_\_\_ Applicant has discussed the process of informed consent for participants. If consent forms are used copies are placed in the Appendix section (alphabetized correctly for this specific project).
- 8.8 \_\_\_ Applicant has described in detail what their procedures are with participant from start to finish. Applicant has placed copies of all materials used with participants in the Appendix section. When required by copyright or other restrictions, applicant has placed approvals to use materials in the Appendix section (alphabetized correctly for this specific project).
- 8.9 \_\_\_ Applicant has described any and all risks to participants.
- 8.10 \_\_\_ Applicant has described how they will minimize risks to participants.
- 8.11 \_\_\_ Applicant has described any and all benefits to participants.
- 8.12 \_\_\_ Applicant has addressed potential costs to the participants.
- 8.13 \_\_\_ Applicant has discussed any reimbursement or compensation provided to participants and the rationale for including such.
- 8.14 \_\_\_ Applicant has clearly indicated if participation or data from this study is anonymous or confidential and how they will handle and store data.
- 8.15 \_\_\_ Applicant has obtained all necessary signatures on the separate signature page and submitted a scanned copy along with the Initial Application Form.

**DOMINICAN UNIVERSITY OF CALIFORNIA**  
**INSTITUTIONAL REVIEW BOARD FOR  
THE PROTECTION OF HUMAN PARTICIPANTS**  
**RENEWAL APPLICATION**

*All information must be typed and submitted electronically to Chilly Penguin (chilly.penguin@dominican.edu).  
Handwritten applications will be returned to researcher.  
A signature page must accompany all applications.*

**IRBPHP Number on Initial Application:** Click here to enter text.

**APPLICANT INFORMATION:**

**Name:** Click here to enter text.

**School:** Click here to enter text.

**Department:** Click here to enter text.

**Campus or Local Address:** Click here to enter text.

**Home Address** (only if different from above): Click here to enter text.

*Note: This will be used for contact during periods when you may not be living on campus/locally.*

**Local Phone:** Click here to enter text.

**Work Phone:** Click here to enter text.

**E-mail Address:** Click here to enter text.

*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):** Click here to enter text.

**FACULTY ADVISOR INFORMATION:**

**Name:** Click here to enter text.

**Campus Phone:** Click here to enter text.

**E-mail Address:** Click here to enter text.

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

## **RESEARCH PROJECT INFORMATION** (from Initial Application)

**Exact Title of Project:** [Click here to enter text.](#)

Duration of Project (cannot exceed 1 year): [Click here to enter text.](#)

*Note: All requested information must be typed directly into the application form. Refer to page 18 in the IRBPHP 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. Include References at end for any works cited.

[Click here to enter text.](#)

**Description of Sample** (check all boxes that pertain to your sample.)

- Patients as participants
- Non-patient volunteers
- Students as participants
- Minor subjects (less than 18 years)
- Participants whose major language is not English (include copies of translated documents)
- Mentally disabled participants
- Prisoners, parolees, or incarcerated subjects
- Other vulnerable or sensitive populations (e.g., children, persons with alcoholism or drug addiction, LGBT individuals, etc.) Please identify:

[Click here to enter text.](#)

- Participants studied at non-Dominican locations
- Filming, video, or voice-recording of participants
- Data banks, data archives and/or registration records
- There is a dual relationship between researcher and participant (explain):

[Click here to enter text.](#)

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

[Click here to enter text.](#)

**Participant 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.

[Click here to enter text.](#)

**Procedures:** Describe in detail what your Participants will experience and include copies of all written materials Participants will see including surveys, questionnaires, interview questions, etc.). Permission to use any copyrighted materials should be included.

[Click here to enter text.](#)

**Potential Risks to Participants: Describe all potential risks.**

Note: All research projects involve some potential risks to Participants. Applications that do not address risks will be returned.

[Click here to enter text.](#)

**Minimization of Potential Risk:** Describe ways the Potential Risks to Participants (detailed in section above) will be minimized by researcher.

[Click here to enter text.](#)

**Potential Benefits to Participants:** Describe in detail all potential benefits to the individual (focus is individual not society). There is always some benefit – why else do the study. [Click here to enter text.](#)

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

[Click here to enter text.](#)

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

[Click here to enter text.](#)

**Confidentiality of Records:**

Data will be anonymous

How will anonymity be ensured?

[Click here to enter text.](#)

Data will not be anonymous

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

[Click here to enter text.](#)

How will raw data and computerized data be stored?

[Click here to enter text.](#)

How will participant identity be kept separate from participant data?

[Click here to enter text.](#)

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

**PROJECT RENEWAL INFORMATION:**

**Research Project Information:**

**Participants:**

Number of Participants used last year in project: [Click here to enter text.](#)

Number of Participants who completed the study: [Click here to enter text.](#)

Number of Participants needed to complete the research study: [Click here to enter text.](#)

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



[Click here to enter text.](#)

**Changes in Anticipated Risks.** List any changes in potential risk to human Participants due to changes in protocol.  
[Click here to enter text.](#)

**Changes in Anticipated Benefits.** List any change due to impact of changes in research protocol.  
[Click here to enter text.](#)

**Discussion of Problems:** Summarize any problems experienced or encountered by human Participants during past year.  
[Click here to enter text.](#)

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

**DOMINICAN UNIVERSITY OF CALIFORNIA**  
**INSTITUTIONAL REVIEW BOARD FOR  
THE PROTECTION OF HUMAN PARTICIPANTS**  
**MODIFICATION APPLICATION**

*All information must be typed and submitted electronically to Chilly Penguin (chilly.penguin@dominican.edu).  
Handwritten applications will be returned to researcher.  
A signature page must accompany all applications.*

IRBPHP Number on Initial Application: [Click here to enter text.](#)

**APPLICANT INFORMATION:**

**Name:** [Click here to enter text.](#)

**School:** [Click here to enter text.](#)

**Department:** [Click here to enter text.](#)

**Campus or Local Address:** [Click here to enter text.](#)

**Home Address** (only if different than above): [Click here to enter text.](#)

*Note: This will be used for contact during periods when you may not be living on campus/locally.*

**Local Phone:** [Click here to enter text.](#)

**Work Phone:** [Click here to enter text.](#)

**E-mail Address:** [Click here to enter text.](#)

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

**Name(s) of Co- Investigator(s):** [Click here to enter text.](#)

**FACULTY ADVISOR INFORMATION:**

**Name:** [Click here to enter text.](#)

**Campus Phone:** [Click here to enter text.](#)

**E-mail Address:** [Click here to enter text.](#)

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

**RESEARCH PROJECT INFORMATION** (from Initial Application):

**Exact Title of Project:** [Click here to enter text.](#)

**Duration of Project:** (cannot exceed 1 year) [Click here to enter text.](#)

*Note: All requested information must be typed directly into the application form. Refer to page 22 in the IRBPHP 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. Include References at end for any works cited. [Click here to enter text.](#)

**Description of Sample** (check all boxes that pertain to your sample.)

- Patients as participants
- Non-patient volunteers
- Students as participants
- Minor subjects (less than 18 years)
- Participants whose major language is not English (include copies of translated documents)
- Mentally disabled participants
- Prisoners, parolees, or incarcerated subjects
- Other vulnerable or sensitive populations (e.g., children, persons with alcoholism or drug addiction, LGBT individuals, etc.) Please identify:

[Click here to enter text.](#)

- Participants studied at non-Dominican locations
- Filming, video, or voice-recording of participants
- Data banks, data archives and/or registration records
- There is a dual relationship between researcher and participant (explain):

[Click here to enter text.](#)

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

[Click here to enter text.](#)

**Participant 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.

[Click here to enter text.](#)

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

[Click here to enter text.](#)

**Potential Risks to Participants:** Describe all potential risks.

*Note: All research projects involve some potential risks to participants. Applications that do not address risks will be returned.*

[Click here to enter text.](#)

**Minimization of Potential Risks:** Describe ways the Potential Risks to Participants (detailed in section above) will be minimized by researcher.

[Click here to enter text.](#)

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

[Click here to enter text.](#)

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

[Click here to enter text.](#)

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

[Click here to enter text.](#)

**Confidentiality of Records:**

Data will be anonymous

How will anonymity be ensured?

[Click here to enter text.](#)

Data will not be anonymous

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

[Click here to enter text.](#)

How will raw data and computerized data be stored?

[Click here to enter text.](#)

How will participant identity be kept separate from participant data?

[Click here to enter text.](#)

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

**MODIFICATION(S) REQUESTED**

**Briefly describe the modification(s) for which you are seeking approval:**

[Click here to enter text.](#)

**Research Project Information:**

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

**Participants:**

Number of participants used last year in project: [Click here to enter text.](#)

Number of participants who completed the study: [Click here to enter text.](#)

Number of participants needed to complete the research study: [Click here to enter text.](#)

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

[Click here to enter text.](#)

**Changes in Anticipated Risks.** List any changes in potential risk to human participants due to changes in protocol.

[Click here to enter text.](#)

**Changes in Anticipated Benefits.** List any changes due to impact of changes in research protocol.

[Click here to enter text.](#)

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

[Click here to enter text.](#)

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

[Click here to enter text.](#)

**Discussion of any changes in risks or benefits related to the modification and how risks will be managed.**

[Click here to enter text.](#)

**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 Participants (IRBPHP), which is concerned with protection of volunteers in research projects. You may reach the IRBPHP Office by calling (415) 482-3547 and leaving a voicemail message, or FAX at (415) 257-0165, or by writing to IRBPHP, 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 PARTICIPANT**

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

1. I understand that I am being asked to participate as a Participant 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 (Name of faculty research supervisor, title, department), 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 Participants 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] or her research supervisor, [INSERT Dominican faculty research supervisor's name, phone and/or e-mail address], 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 Participants (IRBPHP), which is concerned with the protection of volunteers in research projects. I may reach the IRBPHP Office by calling (415) 482-3547 and leaving a voicemail message, by FAX at (415) 257-0165 or by writing to the IRBPHP, 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

**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 Participants will be identified by numerical code only, thereby assuring confidentiality regarding the Participant'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 Participants (IRBPHP), which is concerned with protection of volunteers in research projects. I may reach the IRBPHP Office by calling (415) 482-3547 and leaving a voicemail message, or FAX at (415) 257-0165, or by writing to IRBPHP, Office of Associate Vice President for Academic Affairs, Dominican University of California, 50 Acacia Avenue, San Rafael, CA 94901.

## **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.

\_\_\_\_\_  
Signature of Participant's Parent/Guardian                      Date

\_\_\_\_\_  
Signature of Person Obtaining Consent                      Date

(Model letter adapted from USF IRBPHP Handbook)

APPENDIX I

CHILD ASSENT TO PARTICIPATE IN RESEARCH TEMPLATE (AGES 7-12 YEARS)  
DOMINICAN UNIVERSITY OF CALIFORNIA

**ASSENT TO PARTICIPATE IN RESEARCH**

*[Insert title of the study]*

1. My name is *[identify yourself to the child by name]*.
2. We are asking you to take part in a research study because we are trying to learn more about *[outline what the study is about in language that is both appropriate to the child’s maturity and age]*
3. If you agree to be in this study *[describe what will take place from the child’s point of view in language that is both appropriate to the child’s maturity and age]*
4. *[Describe any risks to the child that may result from participation in the research]*
5. *[Describe any benefits to the child from participation in the research]*
6. Please talk this over with your parents before you decide whether or not to participate. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say “yes” you can still decide not to do this.
7. If you don’t want to be in this study, you don’t have to participate. Remember, being in this study is up to you and no one will be upset if you don’t want to participate or even if you change your mind later and want to stop.
8. You can ask any questions that you have about the study. If you have a question later that you didn’t think of now, you can call me *[insert your telephone number]* or ask me next time. *[if applicable: You may call me at any time to ask questions about your disease or treatment.]*
9. Signing your name at the bottom means that you agree to be in this study. You and your parents will be given a copy of this form after you have signed it.

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

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Person Obtaining Assent

\_\_\_\_\_  
Date

Adapted from UCLA Children’s Assent Form

**ADOLESCENT (AGES 13-17) ASSENT TO PARTICIPATE IN RESEARCH  
DOMINICAN UNIVERSITY OF CALIFORNIA**

**ADOLESCENT (Ages 13-17) ASSENT TO PARTICIPATE IN RESEARCH**

*[Insert title of the study.]*

You are asked to participate in a research study conducted by *[insert names and degrees of Principal Investigator—Faculty Sponsor as appropriate]*, and associates from the *[insert department affiliation]*, at Dominican University of California. You were selected as a possible participant in this study because *[explain why the potential participant is eligible to participate]*. Your participation in this research study is voluntary.

**Why is this study being done?**

*[Using a language that is easily understandable by the participants in the study and avoiding jargon and technical terms state what the study is designed to assess or establish - in approximately 2 sentences]*

**What will happen if I take part in this research study?**

Please talk this over with your parents before you decide whether or not to participate. We will also ask your parents to give their permission for you to take part in this study. Even if your parents say “yes” you can still decide not to do this

If you volunteer to participate in this study, the researcher will ask you to do the following:

*[List and describe the procedures/tests/activities and their frequency chronologically using simple language, short sentences and short paragraphs. Use bullets or number the paragraphs as appropriate. If there are questionnaires or interviews, describe types of questions. Specify location of the study activities, if appropriate.]*

**How long will I be in the research study?**

*[Short-term/simple study:]* Participation in the study will take a total of about *XX* hours *[over a period of XX days/weeks]*.  
*[Long-term/complex study:]* You will be asked to *XX* every *XX* for *[months, weeks/until a certain event]*. *[When appropriate, state that the study will involve long-term follow-up and specify time frames and requirements of follow-up]*.

**Are there any potential risks or discomforts that I can expect from this study?**

*[List and describe any reasonable foreseeable risks, discomforts, inconveniences, and how these will be managed. If there are significant physical or psychological risks to participation that might cause the researcher to end the participant's participation in the study, please describe them. If there are no anticipated risks or discomforts, please state "There are no anticipated risks or discomforts."]*

**Are there any potential benefits if I participate?**

You may benefit from the study ... *[Describe benefits to participants expected from the research. If the participants will not directly benefit from participation, please state, "You will not directly benefit from your participation in the research."]*

The results of the research may ... *[Describe the potential benefits, if any, to science or society expected from the research.]*

**Will I receive any payment if I participate in this study?**

You will receive ... *[describe amount of payment and how and when payment will be received. If participant will not receive payment, say "You will receive no payment for your participation."]*

**Will information about me and my participation be kept confidential?**

Any information that is obtained in connection with this study and that identify you will remain confidential. It will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of ... *[describe coding procedures and plans to safeguard data, including where data will be kept, who will have access to it, etc.]*

- **Withdrawal of participation by the investigator**

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. If *(describe include examples of the circumstances in which you would withdraw subjects from participation in the research)*, you may have to drop out, even if you would like to continue. The investigator will make the decision.

**What are my rights if I take part in this study?**

You may withdraw your assent at any time and discontinue participation without any penalty, negative consequences, or loss of benefits to which you are ordinarily entitled.

You can choose whether or not you want to be in this study. If you volunteer to be in this study, you may leave the study at any time without consequences of any kind. You are not waiving any of your legal rights if you choose to be in this study. You may refuse to answer any questions that you do not want to answer and still remain in the study.

**Who can answer questions I might have about this study?**

If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. Please contact *[add the name of the PI and faculty sponsor as appropriate]* at *[phone number(s)]*—add postal and/or email address if appropriate].

If you have questions about your rights as a research participant, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact the Dominican University of California Institutional Review Board for the Protection of Human Participants (IRBPHP), which is concerned with protection of volunteers in research projects. I may reach the IRBPHP Office by calling (415) 482-3547 and leaving a voicemail message, or FAX at (415) 257-0165, or by writing to IRBPHP, Office of Associate Vice President for Academic Affairs, Dominican University of California, 50 Acacia Avenue, San Rafael, CA.

**SIGNATURE OF STUDY PARTICIPANT**

I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

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

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

**SIGNATURE OF PERSON OBTAINING ASSENT**

In my judgment the participant is voluntarily and knowingly agreeing to participate in this research study.

\_\_\_\_\_  
Name of Person Obtaining Assent

\_\_\_\_\_  
Contact Number

\_\_\_\_\_  
Signature of Person Obtaining Assent

\_\_\_\_\_  
Date

Adapted from UCLA Children's Assent Form

**CHILDREN'S VERBAL ASSENT TO PARTICIPATE IN RESEARCH TEMPLATE**  
*(for children age <6 years – or others - who are capable of understanding that they  
 are being asked to participate in research, but who are not able to sign)*

---

**DOMINICAN UNIVERSITY OF CALIFORNIA**

**ASSENT TO PARTICIPATE IN RESEARCH**

The process of asking a child to participate in research should be carefully planned and implemented, using age-appropriate language and methods for any child who is considered capable of understanding and providing assent. This process should include a clear verbal explanation that includes:

- An introduction to the investigator(s).
- What the study is about
- Why the child is eligible or being invited to participate in the study
- Procedures the child will be expected to take part in
- Potential risks and/or discomforts to the child
- Potential benefits to the child or society
- That the child is completely free to choose whether or not to participate and may withdraw at any time without negative consequences
- That the investigators will also ask the child's parents
- An invitation to ask questions at any time

Name of Child \_\_\_\_\_

In my judgment participation is voluntary:

Name of Person providing the explanation \_\_\_\_\_ . Date \_\_\_\_\_

Signature of Person providing the explanation \_\_\_\_\_

Adapted from UC Berkeley Research with Children Guidelines

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

## SAMPLE

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 are designed to be **completed anonymously**. Anonymity cannot be guaranteed, however, and in the unlikely event an identity becomes known, all information will be held as completely confidential. 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 the email address below. 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 Participants (IRBPHP), which is concerned with protection of volunteers in research projects. You may reach the IRBPHP Office by calling (415) 482-3547 and leaving a voicemail message, or FAX at (415) 257-0165, or by writing to IRBPHP, 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. Contact me at the email address below for further information.

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  
Email address: [INSERT: Student's Dominican email address]

**APPENDIX M**  
**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 phone number or email address below. If you have further questions you may contact Dr. Richardson, at 666-6666, or the Institutional Review Board for the Protection of Human Participants at (415) 482-3547.

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  
Email address: [INSERT: Student's Dominican email address]  
(415) 457-5533 x669

**I agree with the above request**

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

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

**APPENDIX N**  
**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 Montague, 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 phone number or email address below. 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 Participants at Dominican University of California by calling (415) 482-3547.

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  
Email address: [INSERT: Student's Dominican email address]  
(415) 457-5533 x669

**I agree with the above request**

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

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



**APPENDIX O**

**LETTER REQUESTING 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

