PREFACE

The Institutional Review Board for the Protection of Human Subjects (IRBPHS) was established in the early 1990s by Fr. John Clark, S.J., Vice President for Academic Affairs at the University of San Francisco, in response to the University's commitment to the highest standards of ethics in research. It has evolved over the years, and is now under the Office of Provost and Vice President for Academic Affairs, James Wiser. The mandate of the IRBPHS is to review all research activities conducted under the aegis of USF, in compliance with federal regulations pertaining to the protection of human subjects in research under the Department of Health and Human Services, Office of Human Research Protection (OHRP). The purpose of this Manual is to define the obligations and responsibilities of the investigator who conducts research with human subjects, and to provide the guidelines that the investigator must follow when submitting an application for approval by the IRBPHS. The regulations and forms stipulated here supersede all previous versions of the Manual.

This manual is distributed to all full-time USF faculty members and is available for review at Gleeson Library, at the Dean's office of each school and college, and at the following web address: https://www.axiommentor.com/pages/irb/info.cfm

Although manuals are not provided to students by the Office of the Vice President for Academic Affairs, each school or college is permitted to duplicate all or part of the manual and distribute such materials to its students. The following pages have been adapted in part, with permission, from the procedures manual of the Committee on Human Research at the University of California, San Francisco. Additionally, excerpts from the federal government's Office of Protection from Research Risks (OPRR) 1993 publication “Protecting Human Subjects: Institutional Review Board Guidebook” have been included. Many current and past IRBPHS committee members contributed to the revision of this including Terry Patterson (School of Education), Pam Miller (Office of Sponsored Programs), and Christine Yeh (School of Education).

TO CONTACT THE IRBPHS OFFICE:

email: IRBPHS@usfca.edu website: https://www.axiommentor.com/pages/irb/info.cfm
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The mandate of the Institutional Review Board for the Protection of Human Subjects (IRBPHS) is to safeguard the rights and welfare of human subjects participating in research activities under the authority of the University of San Francisco.

The Risk-Benefit Ratio
For any proposed activity which falls under its jurisdiction (pp. 11-13), the IRBPHS is charged with deciding whether or not the potential risks to the subjects outweigh both the potential benefit to the subject and the potential knowledge gained as a result of the proposed activity. A decision to allow human subjects to participate in the proposed activity (and thereby accept the potential risks described) is allowed if it is determined that the potential benefits outweigh the potential risks. The assessment of the risk/benefit ratio is a complex task. There are risks of injury or discomfort to the individual that can be physical, psychological, and/or social. There can be potential benefits to the individual, to a group to which the individual belongs, and/or to society. In reviewing applications, the IRBPHS must carefully assess the types and degrees of both risks and benefits for a given subject population, as well as the investigator’s communication of these risks and benefits in the consent process and in the IRBPHS application itself.

While the IRBPHS is not charged with reviewing scientific design per se, there are occasions when it must do so in order to assess the risk/benefit ratio. If a study design does not seem adequate to attain the stated aim of the investigation, then no benefit can be anticipated from conducting the study, and there is no justification for placing any subject at risk, however minimal. Thus, the design of the study must be sound,
and the nature and likelihood of all risks and benefits must be clearly identified or specified in any application to the IRBPHS.

**Questionable Conduct in Research**

The IRBPHS reviews research protocols involving human subjects but does not monitor ongoing research activities. Therefore, the IRBPHS must rely on the integrity of the investigator during every phase of the research study. If the committee is informed of improper or questionable conduct in any research activity, however, it may conduct an appropriate inquiry. Reports of misconduct may come to the IRBPHS from subjects, personnel involved in the study, or from concerned members of the USF community who have become aware of questionable research methods, or significant deviations from approved procedures. The IRBPHS depends on investigators and others knowledgeable about research activities to assume the important responsibility of alerting the Board of any possible misconduct or concerns with research protocols conducted at USF. Results of inquiries into reports of improper or questionable conduct in research activities will be provided to the Academic Vice President and to the Dean of the researcher’s School or College.

**HISTORY AND COMPOSITION**

Since 1966, the United States Department of Health and Human Services (DHHS), formerly called the Department of Health, Education, and Welfare (DHEW), has required prior review and approval of all federally funded research using human subjects. In 1971, DHEW issued its Institutional Guide to DHEW Policy on Protection of Human Subjects. DHEW guidelines were revised and made regulation in 1974. Between 1974 and 1978, the National Commission on Protection of Human Subjects of Biomedical and Behavioral Research met and issued a series of reports and recommendations resulting in a revised set of regulations issued by DHHS in January of 1981. The United States Food and Drug Administration (FDA) was simultaneously developing its own regulations, which also were issued in January, 1981 and have since been revised, most recently in October, 1996. DHHS issued revised regulations in March of 1983 and again in June of 1991. Federal policies and regulations regarding protection of human subjects may be found on the web at the Office of Human Research Protection at [http://www.hhs.gov/ohrp/](http://www.hhs.gov/ohrp/). In 1991, USF adopted these regulations, which provide standards for review of human research activities by institutional review boards. The committee operates according to the policy and regulations under officially accepted assurances from the Department of Health and Human Services (DHHS). *These regulations apply to all research activities involving human subjects which are being conducted by a person affiliated with the University of San Francisco regardless of funding source or research site location.*

The Institutional Review Board for the Protection of Human Subjects (IRBPHS), which is University of San Francisco’s Institutional Review Board (IRB), was created in 1991. IRBPHS members are appointed by the Academic Vice President for staggered three year terms. The IRBPHS consists of two Co-Chairs, at least one full-time faculty member from each School or College, one member from the Office of Sponsored Programs, and one member not otherwise affiliated with USF. No member of the IRBPHS will participate in an initial or continuing review of any project in which the member has a potential conflict of interest, except to provide information to the IRBPHS. If the IRBPHS reviews research that involves a vulnerable category of subjects (e.g., children, prisoners, pregnant women, impoverished individuals, or persons with a handicap or disability), the IRBPHS may consult with one or more individuals with specific knowledge and experience in working with these subjects. Such individuals may not vote with the IRBPBHS in these instances.

**CHARGE**
It is the duty of the Institutional Review Board for the Protection of Human Subjects (IRBPHS) to review and make decisions on all protocols for research involving human subjects. Its primary responsibility is the protection of subjects from undue risk and from deprivation of personal rights and dignity. This protection is best assured by consideration of three principles that are the touchstones of ethical research: (a) that voluntary participation by the subjects, indicated by free and informed consent, is assured, (b) that an appropriate balance exists between potential benefits of the research to the subject or to society and the risks assumed by the subject, and (c) that there be fair procedures and outcomes in the selection of research subjects. These principles are summarized as respect for persons, beneficence, and justice in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April, 1979).

**Respect for Persons: The Voluntary Participation of Experimental Subjects**
Respect for persons means that researchers should obtain the informed consent of all human subjects invited to participate in research. In order to respect subject autonomy, the consent process should include giving subjects full and comprehensible information about the research and provide clear assurances of the subject’s voluntary participation. An exception to this policy is the use of deception in research studies. Deception involves withholding information about the purpose of the study to prevent potential bias or influence in the results. Deception may be used if the benefits of the research outweigh the potential risks. Moreover, investigators using deception must debrief subjects of the full intention of the study at the conclusion of their participation.

**Beneficence: The Risk-Benefit Ratio**
Beneficence, or concern for the well-being of subjects, means that the risk of harm to subjects should be the least possible and that the sum of benefits to the subjects and the importance of the knowledge to be gained should so outweigh the remaining risk or harm to the subject as to warrant a decision to allow this risk.

**Justice: The Fair Selection of Research Subjects**
Justice means that the selection of human subjects should be fair and equitable and that the risks and benefits of research should be distributed among subjects in a fair and equitable manner, with particular concern for subjects whose personal status or condition (e.g., children, prisoners, patients, impoverished persons, persons with a disability) places them in a vulnerable or dependent status.

Hence, the IRBPHS is responsible for determining and assuring under the auspices of USF faculty, staff, and students that:

- the welfare and rights of human subjects are protected adequately and, if necessary, informed consent is given;
- human subjects are not placed at unreasonable physical, mental, or emotional risk as a result of research;
- the necessity and importance of the research outweighs the risks to the subjects; and
- the researcher(s) is(are) qualified to conduct research involving human subjects.

At times these issues are quite clear, and at times they are extremely difficult to evaluate. Researchers themselves should begin the process of examining their own projects in light of the three principles described above as they prepare to seek IRBPHS approval. The IRBPHS, in turn, brings to bear its collective experience in reviewing each proposal, always conscious of its primary responsibility to protect the rights of human subjects against exploitation, but within the context of the need for continued scientific and human
progress.

**JURISDICTION**

Refer to Figure A for assistance with questions regarding jurisdiction.

**Whose Research Must Be Reviewed**
The current campus policy (established January 1993) regarding requirements and eligibility for submitting applications to the Institutional Review Board for the Protection of Human Subjects (IRBPHS) is as follows: Review by the IRBPHS must be obtained for all research involving human subjects conducted on or off campus by any individual who is affiliated with USF (including but not limited to students, faculty, administrators, and staff). These provisions cover all research projects independent of the type of relationship the researcher has with USF (part- or full-time study or employment) or the type of funding received (internal, personal, extramural, or unfunded). Research involving human subjects which is conducted at USF by an investigator *not* affiliated with USF does *not* undergo review by USF’s IRBPHS; however, the researcher must demonstrate IRB approval from the investigator’s institution prior to recruitment or contact with potential subjects on USF’s campus. The researcher must also obtain a permission letter from the Senior Associate Provost Dr. Shirley McGuire <mcguire@usfca.edu>.

**Definition of Human Subjects**
A human subject is a living person about whom a researcher obtains: (a) data through intervention (e.g., venipuncture, cognitive tests) or interaction (e.g., interviews, surveys) with the person or (b) identifiable private information (e.g., observations or private records). A person may be a human subject when a researcher obtains data about the person from a third party (when the data are identifiable) as well as from the person directly. The researcher is expected to insure that women and members of minority groups are given the same opportunity as all other persons to be included in the research.

**USF Affiliation**
Research which must be reviewed by the IRBPHS includes research which is paid for by USF or with funds administered by the university, is conducted as part of an individual’s progress toward a degree to be awarded by the university, and research which is conducted by a USF faculty member or employee in the course of their employment by USF.

**Research Conducted At or in Cooperation with Other Institutions**
Research conducted by persons affiliated with USF (as described above) that takes place at other institutions (including but not limited to other universities, hospitals, agencies, schools, or corporations) must be reviewed by the USF IRBPBS. Approval from another institution’s Human Subjects Review Board does *not* exempt the USF researcher from obtaining approval from the USF IRBPHS. The only exception to this policy is if the USF researcher is involved solely in data analysis/interpretation and publication of the research and is not in any way involved in the data collection phases of the research program. In such instances, it is the responsibility of the USF researcher to obtain approval from the host institution’s Human Subjects Review Board. Research by those not affiliated with USF is *not* reviewed by the USF IRB, but permission to access subjects must be obtained by a Dean Provost, or other responsible USF official.

**Definition of Research**
The 1991 Code of Federal Regulations (45 CFR 46.102) defines research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable...
knowledge. Pilot studies and screening tests as well as reliability and validity studies are considered part of the research.

**Student Research**

Research does not include (a) classroom or instructional demonstration, (b) surveys for evaluating the performance of faculty, staff, and students or other studies intended solely for institutional use, (c) student course work or undergraduate honors theses, unless they are potentially to be made available to the public or used by other researchers. Even when student work involving human subjects does not constitute research, faculty members who assign or supervise the work are responsible for educating their students to safeguard the well-being of the subjects. Sensitive data obtained from individuals regarding health matters, substance abuse, sexuality, or illegal behavior are reviewable, even though the results may not be presented publicly. Faculty who assign classroom research of a specific type on a regular basis are urged to consult with the IRB and may be granted blanket approval so long as the research content or process does not change. Students (undergraduate or graduate) who must apply for approval by the IRBPHS are required to do so before any data are collected but after the supervising faculty (e.g., advisor, directed research professor, thesis or dissertation advisor) has approved the research plan. Students must secure approval of the application from the advising faculty member by obtaining the faculty member’s signature on the application. Certain departments, colleges, or schools may have additional requirements that need to be met before approval by the IRBPHS is sought; therefore, students are required to check with their respective department, school, or college well ahead of time. In all instances, consultation with the IRB office is invited regarding any human subjects protection issue. Please note that student applications will not be reviewed until their advisor has indicated acceptance at the IRB online portal.

**Program Evaluations**

Research that involves program evaluations or quality assurance may or may not need to be reviewed by the IRB. If the purpose of the project is to develop or contribute to general knowledge, it should be reviewed by the IRB. If the project is for internal purposes only, to improve or understand a program, it does not have to be reviewed by the IRB. For clarification, contact the IRB office.

**Standard Diagnostic or Therapeutic Procedures and Innovative Procedures or Treatments**

Nursing, Education, and Psychology students and faculty should note that an established and accepted diagnostic or therapeutic procedure done for the benefit of the patient is not research and is not to be reviewed by the IRBPHS, unless it is done as part of a comparison of standard practices. Questions often arise about the necessity of submitting various innovations in diagnosis and therapy for IRBPHS review. Previous DHEW guidelines stated that this policy is not concerned with the risks inherent in professional practice, as long as these do not exceed the bounds of established and accepted procedures, including innovative practices applied in the interests of individual patient, student, or client. When innovative diagnostic or therapeutic procedures are considered part of a study, they must be reviewed by the IRBPHS in accordance with DHHS regulations. For example, a research study is by definition undertaken if, in addition to patient care, information is gathered for scientific purposes, that is, with the intent of obtaining generalizable knowledge, or if it is contemplated that innovative treatment on one patient will be repeated in the same or other patients in order to compare it with a standard treatment.

**Failure to Obtain IRBPHS Approval**

When it is determined by the prospective researcher that the proposed research will involve human subjects, the researcher must submit an application, as described in this Manual. The application must be reviewed and approved by the IRBPHS, as described in the Manual, before any subject recruitment, contact with subjects, or data collection begins.
Please note that the IRBPHS does not issue retroactive approval of research protocols under any circumstances. If research is begun without IRBPHS approval, upon discovery of the error, the researcher must stop the research and notify the IRBPHS immediately. The researcher must then submit an application to the IRBPHS along with a detailed explanation as to why the application was not submitted at the appropriate time. If the researcher is a student, a detailed letter from his or her faculty advisor must accompany the materials submitted to the IRBPHS. If this situation occurs, conducting further research, spending research funds, using data already collected, or filing a thesis may be disallowed by the Office of the Vice President for Academic Affairs.

RESPONSIBILITIES

Researchers

Although the Institutional Review Board for the Protection of Human Subjects (IRBPHS) acts as an independent review committee to insure that the rights of human subjects in research are protected, it is the responsibility of the individual research investigator to conduct scientific investigation in an ethical manner which respects the rights of individual subjects and minimizes potential harm. Thus, at all times, the researcher is expected to monitor any contact with human subjects, whether it be by the researcher himself/herself or by a colleague, student, or other supervisee. Ultimately, any harm experienced by a human subject is the responsibility of the principal investigator (except where the principal investigator is a student; in such instances, the faculty advisor is ultimately responsible). The IRBPHS is available for consultation and advice regarding individual research studies and human subject issues which may arise during the course of a scientific study.

Faculty Advisors

The faculty member charged with supervision of a graduate or undergraduate student who is conducting research is expected to insure that the research is conducted in an ethical manner and that human subjects are respected and protected from unnecessary harm. It is the responsibility of the faculty advisor to educate the student about human subjects issues and to teach them proper respect for the subjects in their research. By his or her signature on the student’s IRBPHS application, the faculty advisor indicates that he/she has carefully reviewed the application and is well aware of all procedures and protocols to be conducted with human subjects as part of the research study. Ultimately, any harm experienced by a human subject as a result of their participation in a research study conducted by a USF student is the responsibility of the student’s faculty advisor. The IRBPHS is available for consultation and advice regarding individual

IRBPHS REVIEW PROCEDURES

The general procedure for review of Institutional Review Board for the Protection of Human Subjects (IRBPHS) applications is depicted in Figure B (an IRBPHS Applicant Map is depicted in Figure A). If questions regarding procedure remain after reviewing this section, please contact the IRBPHS office by electronic mail at IRBPHS@usfca.edu for further information.

INITIAL APPLICATION

An application for IRBPHS approval is to be submitted at the online portal at <https://www.axiommentor.com/pages/irb/info.cfm> Applications from student researchers must include the approval of their faculty advisor. The IRBPHS office does not make copies of applications for applicants under any circumstances. It is strongly advised that applicants keep a copy of their application, as well as any revised materials that they are asked to submit for their own records before sending it to the IRBPHS office.
Paper applications will not be accepted. Review of applications which are sent to the incorrect address or to the incorrect department, school, or college, may be substantially delayed. Upon receipt, the application is given an IRBPHS number. Applications which are complete (e.g., faculty advisor approval when the researcher is a student, all relevant attachments and instruments) are reviewed within two (2) working weeks. Applicants who have submitted incomplete applications will be contacted and asked to submit the missing information and/or materials. Once the application is complete, all applicants will be sent an e-mail notice (Confirmation of Receipt of Complete Application; Appendix B) indicating that their completed application has been received and sent out to an IRBPHS committee member(s) for review. Applicants should expect to receive an e-mail a telephone call from the primary reviewer (requesting further information, clarification, or materials) within one week of receipt of the application (except during high volume periods of the academic year or during the summer or other holidays, as noted below). If no contact is made by the IRB office or primary reviewer within one week after submission, applicants should contact the IRB office in case of miscommunication or errors in addresses or telephone numbers. See Figure B for a graphic depiction of this process. Completed applications are assigned to a primary reviewer (once the application packet is complete) and, when necessary (e.g., where the nature of the research involves more than minimal risk to human subjects), to secondary reviewers and/or to USF’s FERPA Compliance Officer (for applications in which research with USF students as human subjects is proposed; see Appendix C).

The primary reviewer is assigned on a rotating basis; each of the IRBPHS committee members serve as primary reviewer for approximately 1 out of 6 applications received. Committee members do not review IRBPHS applications with which they are directly or indirectly involved. The primary reviewer (in cooperation with secondary reviewers and/or the FERPA Compliance Officer, where relevant) reads the completed application packet and decides if further information is needed from the applicant in order to determine whether potential risks to human subjects have been adequately addressed and minimized. Once the primary reviewer (and secondary reviewers and/or the FERPA Compliance Officer, where relevant) is satisfied that potential risks to human subjects have been addressed and minimized and that all relevant requirements have been met, he/she returns the application packet to the IRBPHS Chair. After approval by the primary reviewer, the IRBPHS Chair reviews the application and addresses any remaining concerns with the primary reviewer and/or the applicant. When all concerns have been adequately addressed, the Chair sends an electronic approval letter directly to the applicant (at the address provided on the application) and the advisor if the applicant.

If the initial IRBPHS application is complete and all potential risks to human subjects have been adequately identified and addressed, the review process typically lasts 2 - 3 weeks from date of receipt of the application. However, incomplete applications (e.g., missing measurement instruments, unclear or inadequate descriptions of subjects or of research protocol, missing signature of faculty advisor) or applications which do not adequately identify and address potential risks to human subjects may take substantially longer. It is therefore recommended that applicants submit applications for IRBPHS approval 6 - 8 weeks prior to the anticipated start of subject recruitment or data collection. Applications are reviewed in the order in which they are received; requests for a “quick review” cannot be honored. Be aware that review of applications may be slightly slower during high volume times of the year (e.g., beginning and end of semesters). Also, be aware that IRBPHS committee members do not review applications during the two weeks surrounding the Christmas and New Year’s holidays; thus, review of applications submitted between December 1st and January 1st may be slightly delayed.
The IRBPHS Initial Application can be found in Appendix A and is also available through the Dean’s office of each School or College, directly from the IRBPHS office, or from USF’s website (https://www.axiommentor.com/pages/irb/info.cfm). A detailed description of how to complete the IRBPHS Initial Application can be found in this manual.

RENEWAL APPLICATION

The Department of Health and Human Services and USF require at least annual review of all research projects involving human subjects. Accordingly, IRBPHS approval of an Initial Application will be granted for no more than one year. Researchers who wish to have contact with human subjects past the expiration date of initial approval must submit a Renewal Application (Appendix E). As a courtesy, approximately 6 weeks before initial approval expires, the IRBPHS office will send a Renewal Reminder (Appendix D) and a Renewal Application to all faculty and staff applicants, as well as student applicants who have not yet matriculated from USF. However, it is ultimately the researcher’s responsibility to initiate the Renewal Application, allowing sufficient time for review (see below) and approval prior to the expiration of the initial approval. If research activity occurs or continues after the expiration date and without renewal approval, the researcher is out of compliance with federal regulations and university policy. If unanticipated, emergency circumstances arise which prevent the researcher from completing the renewal process before initial approval expires, an extension of that approval can be requested by writing through the IRBPHS office. The Chair of the IRBPHS may grant such an extension for up to one month, but only if there is a substantive reason for failure to complete a timely Renewal Application. Retroactive approval for research conducted after the expiration date of initial approval will not be granted. The procedures for review of Renewal Applications are the same as the procedures for review of Initial Applications (described above). Renewal Applications are given the same IRBPHS number that was assigned to the Initial Application. Renewal applicants will be sent a notice indicating receipt of their Renewal Application, once the application is complete. Renewal Applications are approved for a one-year period and must be re-renewed if contact with subjects is planned past the expiration date. The IRBPHS Renewal Application can be found in Appendix E and is also available through the Dean’s office of each School or College, directly from the IRBPHS office, or from USF’s website (https://www.axiommentor.com/pages/irb/info.cfm). A detailed description of how to complete the IRBPHS

MODIFICATION APPLICATION

IRBPHS approval is based on the research as described in the IRBPHS Initial Application and/or Renewal Application. Any changes to the research protocol (e.g., subjects, timelines, procedures, wording of consent documents, instruments, correspondence, instruments) must be summarized in an IRBPHS Modification Application (Appendix F), submitted and approved prior to implementation of changes. This includes changes made to research procedures as a result of a student researcher’s masters’ or dissertation proposal defense. The procedures for review of Modification Applications are the same as the procedures for review of Initial Applications (described above). Modification Applications are given the same IRBPHS number that was assigned to the Initial Application. Modification applicants will be sent a notice indicating receipt of their Modification Application, once the application is complete. Modification Applications will be sent
to the Primary Reviewer of the Initial Application, if he/she is still serving on the IRBPHS. If the Modification Application is complete and all potential risks to human subjects have been adequately identified and addressed, the review process typically lasts 2 - 3 weeks from date of receipt of the application. However, incomplete applications (e.g., missing measurement instruments, unclear or inadequate descriptions of subjects or of research protocol, missing approval of faculty advisor) or applications which do not adequately identify and address potential risks to human subjects may take substantially longer. Modification Applications are reviewed in the order in which they are received; requests for a “quick review” will not be honored. Once approved, Modification Applications are approved only until the expiration date of the Initial Application. Therefore, if the researcher wishes to continue contact with human subjects past the expiration date, he/she must submit a Renewal Application. The IRBPHS Modification Application can be found in Appendix F and is also available through the Dean’s office of each School or College, directly from the IRBPHS office, or from USF’s website (https://www.axiommentor.com/pages/irb/info.cfm). A detailed description of how to complete the IRBPHS Modification Application can be found in this manual.

IRBPHS COMMITTEE MEETINGS
In addition to ongoing review of applications, the IRBPHS meets periodically to discuss policies, human subjects complaints, and to review controversial or sensitive applications. Due to the confidential nature of many items discussed in these meetings, they are closed to non-IRBPHS members.

THE IRBPHS INITIAL APPLICATION
Refer to Figure A for a graphic depiction of the initial application process. To obtain initial Institutional Review Board for the Protection of Human Subjects (IRBPHS) approval for their research with human subjects, complete the IRBPHS Initial Application (Appendix A; also refer to pp. 16 - 18). Please feel free to photocopy the form depicted in Appendix A. Initial Application forms are also available from the Dean’s office of each School or College*, from the IRBPHS office, and from USF’s website (https://www.axiommentor.com/pages/irb/info.cfm). Type the requested personal and contact information directly onto the Initial Application form. Respond to items 1 - 11 by typing in black ink using standard 12-point font on one side of separate, white sheets of paper, which should be stapled to the application form. Following is a detailed description of requirements for accurately completing the initial application form: Applicant’s Identifying Information: provide full name, identification number (if applicant is a student), university title (e.g., undergraduate student, graduate student, Associate Professor, Administrative Assistant), school or college (e.g., School of Education, College of Professional Studies, College of Arts and Sciences, School of Nursing, School of Business), department or group (e.g., Curriculum Development, Organizational Behavior, Sociology), home or campus address (for receipt of approval letter), home and work phone numbers and electronic mail address(s) (for contact regarding revisions and supplemental information, where necessary). You may also indicate how you would prefer to be contacted. Name(s) and University Title(s) of Other Investigators: provide full name and university title for each additional person who is substantially involved in the development, implementation, or analysis of the research project (e.g., consultants, research assistants, and other faculty members but not faculty advisors). Faculty Advisor’s Identifying Information: for student applicants, provide full name, university title (e.g., Assistant Professor, Full Professor, Adjunct Professor, Lecturer), home or campus address (for receipt of copy of approval letter), home or campus phone and electronic mail address(s) (for contact if difficulties are encountered in contacting applicant) of the primary supervising faculty member. Project Title: provide brief (less than 10 words), informative title that accurately describes the nature of the research project.
research problem, recent related research, and purpose of current study. Do NOT attach sections or complete copies of masters theses or dissertation proposals.

2. Description of Sample

   a. Provide a detailed description of the subject sample, including, at a minimum, age, gender, and ethnicity.
   b. Describe any special characteristics of the subject population (e.g., prisoners, children, dependent adults).
   c. Describe the way in which the researcher has obtained or intends to obtain access to the subjects (e.g., co-workers, students in a colleague’s classroom, persons employed at a particular company, mailing lists).
   d. If subjects are employees of a corporation, students in a particular elementary or secondary school, or are some other type of captive audience (e.g., prisoners, preschool students), provide a letter from corporate management, appropriate school leader(s), or institutional management indicating their awareness and support of the research project (see Appendix G). In cases where the corporation, school, or other institution will not grant permission prior to IRBPHS approval, the initial application may be conditionally approved, pending a letter of permission, at which time full approval would be granted.
   e. If any of the subjects will be persons for whom English is not their primary language and/or who are not proficient in reading, speaking, and writing English at the 8th grade level, the applicant must provide documentation that all written correspondence, consent documents, and measurement instruments will be provided to the subject in his or her preferred language. As such, the applicant will provide the qualifications of the translator of the document.
   f. Describe any potential dual relationships the applicant might have with the subjects or the institution in which they work or attend school (e.g., is applicant an employee or manager? Is applicant a member of the same community?)

3. Recruitment Procedure

   a. Describe the way in which the applicant will solicit participation from potential subjects (e.g., face to face request, phone contact, inter-office mail memo, U.S. mail introductory letter).
   b. Indicate the number and nature of attempts at recruitment that are planned for each potential subject (e.g., two introductory letters and one phone contact); be aware that the IRBPHS committee typically limits total contacts with potential subjects to three contacts.
   c. Provide copies of any memos, electronic mail messages, cover letters, flyers, newspaper ads, etc. that will be used to recruit potential subjects.
   d. If subjects are part of an archival data set subjects at an earlier point in time and already exists in a database that is now accessible to the researcher), describe the way in which the researcher has permission to access this data base. Include a letter of permission from institutional management indicating their willingness to allow the researcher to use the human subjects data set.

4. Subject Consent Process (see pp. 31 - 43)

   a. If project involves subjects less than 18 years of age (or subjects otherwise unable to consent for
themselves) (refer to p. 34), describe the procedure for obtaining parental consent. Include a copy of the Parental Consent Form (see p. 41 and Appendix J). If applicant does not wish to obtain parental consent for subjects under 18 years of age, provide a rationale and justification for not obtaining consent; be aware that the IRBPHS waives the requirement for parental informed consent infrequently and only in circumstances involving minimal risk to human subjects. The applicant may wish to obtain passive parental consent (a procedure in which a letter detailing the research study is sent home to parents, who are asked to return the signed form only if they do NOT wish their child to participate in the research). Passive parental consent is considered equivalent to lack of parental consent and therefore is permitted infrequently and only in studies involving minimal risk to human subjects.

b. If project involves face-to-face meetings of any kind (e.g., directed conversations, interviews, subject tasks or trials, observation of subjects, testing) with adults (except paper-and-pencil surveys which are hand-delivered and hand-collected), describe the procedure for obtaining informed consent. Include a copy of the Informed Consent Form (Appendix I). If the applicant conducting research which involves face-to-face meetings wishes the IRBPHS to waive the requirement of signed informed consent (see pp. 33-34), provide a rationale for this request and describe the non-signed consent documentation that will be utilized (see pp. 41 and Appendices J through L).

c. If project involves a survey that will be distributed and collected through the mail or hand-delivered and hand-collected, provide a copy of the Consent Cover Letter that will accompany the survey or questionnaire (Appendix K).

d. If project involves telephone interviews, provide a copy of the introductory letter that will be sent in advance to subjects (Appendix K) and describe the verbal protocol to be used at the start of the telephone interview for purposes of establishing informed consent (Appendix M).

e. If project involves the simultaneous administration of a survey or questionnaire to a large group of subjects (e.g., in a university classroom), either provide a copy of the Consent Cover Letter that will accompany the survey or questionnaire (Appendix K) or describe the verbal script that will used when speaking to the group of potential subjects prior to distribution of the survey or questionnaire (Appendix M).

f. If it is not possible to obtain informed consent from subjects, provide a detailed rationale for lack of informed consent and describe alternative procedures for ensuring voluntary participation of subjects.

g. If the applicant wishes to use a consent form required by another institution’s Human Subjects Review Board, provide a rationale for this request and a description of the consent document proposed (see p. 34).

5. Procedures

a. Describe in detail everything that the subjects will experience as a result of their participation in the research, including experimental interventions or manipulations (e.g., treatments, exposure to film or music, completion of stress tests), completion of surveys or questionnaires, initial and follow-up interviews or telephone contacts, etc.

b. Include copies of all written forms, surveys, questionnaires, and/or interview questions/topics that the subjects will see, complete and/or respond to during the course of their participation.

c. Include complete descriptions and/or samples of any interventions or manipulations that the subjects will experience.

d. If the researcher plans to obtain test scores or other data about the human subjects which may already have been collected (e.g., employee feedback on a new corporate program, achievement test scores for students in elementary school), the way in which the researcher will access such information
must be described in detail. The researcher should be aware that use of standardized test scores or grades without a subject’s permission is prohibited by FERPA (Family Educational Rights and Privacy Act of 1974; see Appendix C); therefore, research studies which will use such data must include a signed consent document (Informed Consent Form or Parental Consent Form).

Potential Risks to Subjects
Describe in detail all potential risks to subjects. Include such risks as emotional discomfort, frustration, and loss of confidentiality, as well as any risk particular to the nature of the research project. Be aware that all research projects involve some potential risks to subjects; applicants who do not describe such risks will be contacted by the Primary Reviewer and asked to submit revised materials adequately describing potential risks. The OHRP defines “risk” as potential harm outside the realm of normal experience.

1. Minimization of Potential Risk Describe in detail the ways in which potential risks (described in #6) will be minimized by the researcher. Include a detailed description of the debriefing procedure in research in which the subjects experience more than minimal risk. The researcher should describe how the procedures have been carefully scrutinized and there are no anticipated risks.

Potential Benefits to Subjects Describe in detail all potential benefits to subjects. Although you may include potential benefits to society, be sure to focus on the potential benefits to the individual subjects. If there are no known potential benefits, acknowledge this fact.

9. Costs to Subjects Describe the costs to be experienced by subjects. Include any monetary fees for participation in research (e.g., cost of treatment, medications, psychological testing, cost of transportation to or parking at research site), as well as costs in terms of time and effort.

2. Reimbursements/Compensation to Subjects Describe any reimbursement or compensations to be made to subjects in response to their participation in the research. Provide a rationale and justification for the reimbursement and/or compensation. Be aware that compensation that is for more than reasonable costs of involvement is not appropriate, given that it can compete with the objective decision to participate and become a subtle inducement not to drop out of the study. Furthermore, compensation that is contingent on completion of study participation is not appropriate, given that this is coercive. Thus, if the study involves multiple data collection points, subjects should either be compensated in full regardless of whether they complete the entire study OR they should be partially compensated as they complete each stage of the data collection process. The method and timing of compensation must be clearly delineated in advance during the consent process.

3. Confidentiality of Records State whether the data will be anonymous (e.g., researcher does not have knowledge of subject name, address, phone number, and/or other identifying information) or not anonymous. If the data will not be anonymous, describe the ways in which the researcher will assure that all data are kept confidential. Include a description of the way in which raw data and computerized data will be stored (e.g., locked filing cabinets, computer files accessible only by password), as well as the method of keeping subject identity separate from subject data. Given that many scientific publishers require authors to have raw data available after publication of research, it is not recommended that applicants destroy data files or original data collection instruments. Signatures: Sign and date the application. When the applicant is a student, the faculty advisor must also sign and date the application. Each copy of the application must have both signatures; however, the second copy need not contain original signatures.

THE IRBPHS RENEWAL APPLICATION
All persons who wish to have contact with human subjects past the date of expiration of initial
approval from IRBPHS (one year from date of initial approval) shall complete the IRBPHS Renewal Application (Appendix E; also refer to pp. 18 - 19). Please feel free to photocopy the form depicted in Appendix E. Renewal Application forms are also available from the Dean’s office of each School or College*, from the IRBPHS office, and from USF’s website (https://www.axiommentor.com/pages/irb/info.cfm). Type the requested personal and contact information directly onto the Renewal Application form. Respond to items 1 - 6 by typing in black ink using standard 12-point font on one side of separate, white sheets of paper, which should be stapled to the application form. Following is a detailed description of requirements for accurately completing the renewal application form:

1. **Applicant’s Identifying Information:** provide full name, identification number (if applicant is a student), university title (e.g., undergraduate student, graduate student, Associate Professor, Administrative Assistant), school or college (e.g., School of Education, College of Professional Studies, College of Arts and Sciences, School of Nursing, School of Business), department or group (e.g., Curriculum Development, Organizational Behavior, Sociology), home or campus address (for receipt of approval letter), home and work phone numbers and electronic mail address(s) (for contact regarding revisions and supplemental information, where necessary).

2. **Name(s) and University Title(s) of Other Investigators:** provide full name and university title for each additional person who is substantially involved in the development, implementation, or analysis of the research project (e.g., consultants, research assistants, and other faculty members but not faculty advisors).

3. **Faculty Advisor’s Identifying Information:** for student applicants, provide full name, university title (e.g., Assistant Professor, Full Professor, Adjunct Professor, Lecturer), home or campus address (for receipt of copy of approval letter), home or campus phone and electronic mail address(s) (for contact if difficulties are encountered in contacting applicant).

4. **IRBPHS Number:** provide IRBPHS number assigned to the project at the time of the Initial Application.

5. **Project Title:** provide title used in IRBPHS Initial Application.

6. **Subjects** Provide the number of human subjects who agreed to participate in the research study during the last year, the number of subjects who completed all phases of the research study during the last year, the number of subjects who were recruited but who declined to participate during the last year, the number of subjects involved in the study to date (number who initially agreed to participate but may or may not have completed all phases of the research study), and the number of subjects needed to complete the research study.

7. **Brief summary of results to date** provide a concise (300 words or less) summary of the results obtained thus far.

8. **Changes in Anticipated Risks.** Describe any change in potential risks to human subjects including, but not limited to, the potential impact of any changes to research procedures, instruments, follow-up plans, etc. during the past year.*

9. **Changes in Anticipated Benefits.** Describe any change in potential benefits to human subjects including, but not limited to, the potential impact of any changes to research procedures, instruments, follow-up plans, etc. during the past year.* Although you may include anticipated change in potential benefits to society, be sure to focus on any anticipated change in potential benefits to the individual subjects.

10. **Discussion of any side effects or problems noticed during the past year** Summarize any adverse effects or problems experienced or encountered by human subjects during the past year.

11. **Explanation of any modifications in the protocol made during the past year** Summarize any modifications to the research protocol (e.g., consent forms, procedures, instruments, follow-up contacts, subject sample) which were made during the past year. Signatures: Provide signature and date of signature of
the applicant and, when the applicant is a student, the faculty advisor. Each copy of the application must have both signatures; however, the second copy need not contain original signatures.

Note: Any changes to the research study, as it was described in the Initial Application, must be submitted on a Modification Application, which must be approved prior to implementation of such changes. ** Any adverse effects experienced by a human subject must be reported to the Chair of the IRBPHS in writing within 10 working days of their occurrence (refer to pp. 43 - 45 and Appendix N); the Renewal Application should provide a summary of the event(s).

THE IRBPHS MODIFICATION APPLICATION

The IRBPHS approval is based on the research as described in the IRBPHS Initial Application and/or Renewal Application. All persons who wish to make changes to the research protocol (e.g., subjects, timelines, procedures, wording of consent documents, instruments, correspondence, instruments) shall complete the IRBPHS Modification Application (Appendix F; also refer to pp. 19 - 20), which must be submitted and approved prior to implementation of changes. Please feel free to photocopy the form depicted in Appendix F. Modification Application forms are also available from the Dean’s office of each School or College*, from the IRBPHS office, and from USF’s website (https://www.axiommentor.com/pages/irb/info.cfm).

Type the requested personal and contact information directly onto the Modification Application form. Respond to items 1 - 5 by typing in black ink using standard 12-point font on one side of separate, white sheets of paper, which should be stapled to the application form. Following is a detailed description of requirements for accurately completing the modification application form:

Applicant’s Identifying Information: provide full name, identification number (if applicant is a student), university title (e.g., undergraduate student, graduate student, Associate Professor, Administrative Assistant), school or college (e.g., School of Education, College of Professional Studies, College of Arts and Sciences), department or group (e.g., Curriculum Development, Organizational Behavior, Sociology), home or campus address (for receipt of approval letter), home and work phone numbers and electronic mail address(s) (for contact regarding revisions and supplemental information, where necessary). Name(s) and University Title(s) of Other Investigators: provide full name and university title for each additional person who is substantially involved in the development, implementation, or analysis of the research project (e.g., consultants, research assistants, and other faculty members but not faculty advisors) Faculty Advisor’s Identifying Information: for student applicants, provide full name, university title (e.g., Assistant Professor, Full Professor, Adjunct Professor, Lecturer), home or campus address (for receipt of copy of approval letter), home or campus phone and electronic mail address(s) (for contact if difficulties are encountered in contacting applicant). IRBPHS Number: provide IRBPHS number assigned to the project at the time of the Initial Application. Project Title: provide title used in IRBPHS Initial Application. Description of Proposed Change(s) to Research Protocol: Describe in detail all proposed changes to the original research study as it was described and approved in the IRBPHS Initial Application. Include a detailed summary of proposed changes to wording of instruments, correspondence, and/or consent forms, as well as proposed alterations in research procedures, experimental manipulations or interventions, costs, and/or compensation. Provide a description of any proposed additional instruments or procedures, as well as any additional populations from which the applicant would like to sample subjects. Be sure to attach copies of the revised correspondence, consent forms, instruments, or other research tools that are proposed.

Rationale for Proposed Changes: Provide a detailed justification and rationale for the changes proposed above. Include relevant recent research findings, opinions of consultants, or findings from data collected from subjects.
3 Impact on Potential Risks to Human Subjects Describe the anticipated impact (increase or decrease), if any, on the level of potential risk to human subjects as a result of the proposed changes. If no change in potential risk is anticipated, state this clearly.

4 Minimization of Increased Potential Risk
If increased potential risk to human subjects is anticipated, describe the methods by which the applicant intends to minimize those potential risks.

5 Impact on Potential Benefits to Human Subjects
Describe the anticipated impact (increase or decrease), if any, on the level of potential benefit to human subjects as a result of the proposed changes. Although you may include anticipated change in potential benefits to society, be sure to focus on any anticipated change in potential benefits to the individual subjects. If no change in potential benefit is anticipated, state this clearly. Signatures: Provide signature and date of signature of the applicant and, when the applicant is a student, the faculty advisor. Each copy of the application must have both signatures; however, the second copy need not contain original signatures.

HUMAN SUBJECTS’ RIGHTS
Every person who agrees to participate in a research study has certain rights. These rights are detailed in the Research Subjects’ Bill of Rights (Appendix H). It is the responsibility of the researcher to ensure that every subject who is contacted, recruited, or who participates in his or her research study is guaranteed these rights. For research studies which involve more than minimal risk to human subjects, the Institutional Review Board for the Protection of Human Subjects (IRBPHS) expects that the researcher will provide every potential research subject with a copy of the Research Subjects’ Bill of Rights at the time of recruitment into the study. For studies which involve no more than minimal risk to human subjects, it is up to the discretion of the researcher whether he or she chooses to provide a copy of this document to his or her research subjects.

CONSENT PROCEDURES
Refer to Figure A for a map of decisions regarding consent procedures.

Introduction
Informed consent is one of the primary ethical requirements of research with human subjects. It reflects the basic principle of respect for the person. It is too often forgotten that informed consent is an ongoing process, not a piece of paper or a discrete moment in time. Informed consent assures that prospective human subjects will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. This assurance protects all parties both the subject, whose autonomy is respected, and the research investigator, who otherwise faces legal hazards. The “proxy consent” of someone other than the subject is not the same as the subject’s own consent, although it may be an acceptable substitute when a subject is unable to give informed consent (see below).

Purpose of Consent Documentation
Just as the informed consent process is a vital component of research on human subjects, so is the documentation of that informed consent through use of a signed consent form, consent cover letter (an
unsigned document), or information sheet (an unsigned document) a most important part of the consent process. The consent document is neither meant to be a legal record of the consent process nor is meant to be the only communication between research and prospective subject. Instead, the document should be one part of the total process. Usually, the prospective subject will first be contacted in writing, followed by personal, verbal communication between investigator and subject. The individual will be told about the purpose, procedures, risks and benefits of the study, the subject’s rights in participating in research, and the freedom to decline to participate without jeopardy. If applicable, the alternative treatments available will be explained. The individual will also be given the opportunity to obtain further information and answers to questions related to the study. The consent form, consent cover letter, or information sheet should serve as a written summary of the exact information that was presented to the prospective subjects before their agreement to participate in the study. As such, it will provide a useful reference for both the subject and the investigator.

Elements of Consent

Certain information must be provided to each subject. Accordingly, any consent document, whether it be an Informed Consent Form (pp. 36-40 and Appendix I), a Parental Consent Form (p. 41 and Appendix J), a Consent Cover Letter (p. 41 and Appendix K), an Information Sheet (p. 41 and Appendix L), or a Verbal Consent Script (pp. 41-42 and Appendix M) must include the following elements:

(1) A statement that the prospective subject is being asked to participate in a research study;
(2) An explanation of the purpose and background of the research;
(3) A description of the procedures to be followed, including the expected duration of the subject’s participation and identification of any procedures which are experimental;
(4) A description of any reasonably foreseeable risks or discomforts to the subject;
(5) A description of any benefits to the subject or to others which may reasonably be expected from the research;
(6) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject, including no treatment;
(7) A statement describing the extent, if any, to which confidentiality or records identifying the subject will be maintained;
(8) A description of the costs to be incurred by the subject (including, but not limited to, financial costs, time, and effort);
(9) An explanation of any compensation or reimbursement to be received by the subject;
(10) An explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject (including, at a minimum, the name and phone number of the research investigator and the USF Institutional Review Board for the Protection of Human Subjects (IRBPHS) phone number);
(11) A statement that participation in the research is voluntary;
(12) A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled; and
(13) A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Waiver of Signed Consent

IRBPHS may waive the requirement for the investigator to obtain a signed consent form (i.e., allow the investigator to use a consent cover letter or information sheet, as described below) if it finds either: (1) that the only record linking the subject and the research would be the consent document, and the principal risk
would be potential harm resulting from a breach of confidentiality, or (2) that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Thus, the IRBPHS may approve a request for waiver of signed consent in the following situations:

(1) When the identities of subjects would be completely anonymous if the consent form is not signed (e.g., the investigator does not have access to or knowledge of subject names, addresses, or phone numbers), and there is minimal risk involved in the study;

(2) When obtaining signed consent is not appropriate or feasible according the cultural standards of the population being studied, and there is minimal risk involved in the study;

(3) When there is a possible legal, social, or economic risk to the subject entailed in signing the consent form (e.g., for immigrants who might be identified as being illegal aliens, or for HIV antibody-positive individuals who might be identified as such by signing the consent form);

(4) Retrospective records review or analysis of previously collected data where the subjects need not be contacted as part of the study and appropriate precautions to protect the confidentiality of the data are described. If the applicant wishes to waive the requirement for signed informed consent, he/she must provide a written justification for doing so, according to one of the categories listed above. In cases where the requirement for a signed consent document is waived, the IRBPHS may require the investigator to provide subjects with a written statement regarding the research (i.e., Consent Cover Letter or Information Sheet), which includes all or most of the same elements as a consent form, but does not require the signature of the subject.

Subjects Unable to Give Consent for Themselves: Proxy Consent

For studies involving subjects who cannot give signed or even verbal consent for themselves (e.g., persons under the age of 18 years, mentally handicapped persons, unconscious patients), the IRBPHS may waive the consent requirement if sufficient justification for use of the particular subject group is provided and if appropriate measures for obtaining consent from a legally authorized representative or a relative and/or subject advocate are followed (e.g., Parental Consent Form, described below). If the investigator wishes to have the requirement for a signed Parental Consent Form waived (i.e., wishes to use a consent cover letter or information sheet, as described below), he or she must request such a waiver from the IRBPHS and provide a rationale for the waiver of signed Parental Informed Consent (see above section “Waiver of Signed Consent”). In cases where the requirement for a signed consent document is waived, the IRBPHS may require the investigator to provide subjects with a written statement regarding the research (i.e., Consent Cover Letter or Information Sheet), which includes all or most of the same elements as a consent form, but does not require the signature of the parent/guardian.

Consent Form Requirements of other Human Subjects Review Boards

In some cases, a USF investigator may be involved in research which will be carried out only at another study site (refer to p. 12) where that site’s Human Subjects Review Board has different standards for consent documentation. In such cases, the IRBPHS will consider a request to approve use of the other Human Subject Review Board’s approved consent document or procedure provided it satisfies the federal requirements of informed consent (described on pp. 32 - 33).

Use of the IRBPHS Consent Document Standard Format

Whenever a signed (Informed Consent Form or Parental Consent Form) or unsigned (Consent Cover Letter or Information Sheet) consent document is to be used, the IRBPHS standard format, described in the following pages and in Appendices H through L, should be followed, with adaptations as appropriate.
Though variations may be accepted, provided all the required elements of consent (pp. 32 - 33) are included, the format described in the following pages is recommended and preferred by the IRBPHS. This standard format was developed with two goals in mind: (1) to satisfy federal and institutional informed consent requirements, and (2) to encourage the construction of a consent document which presents all necessary information to the prospective human subject in as clear and easily readable manner as possible.

**General Information about the IRBPHS Consent Document Standard Format**

*Understandable Reading Level:*
The primary goal of a consent form is to provide all required information about a study in language and format that is easily comprehensible, presented at the most likely level of understanding of the subject population. For most studies, it is recommended that the consent form be written at an eighth-grade reading level. Everyday vocabulary and simple sentence structure should be used throughout the consent form. While investigators always have the option of describing the study in more detail and in more scientific language during the consent process itself, the initial written description of the study should be simple and straightforward so that subjects will have an easily understood consent form to take home with them and to refer to in the future.

*Lay Language:*
Unless the subjects are themselves professionals proficient in the content area of the research study, scientific or technical terms should either be replaced with or defined in lay language.

*Non-legalistic Language:*
Avoid legalistic sounding language such as “I hereby agree,” “I certify that,” “I, and/or the undersigned, do acknowledge that.” Also avoid phrases such as “I understand that,” “I realize that,” “I have been told that,” or “It has been explained to me that.” These phrases do not insure a subject’s comprehension, and they also lend the appearance of a legal document to the consent form; the consent form is not a legal document.

*Consistency in the Application:*
The grammatical person in which the consent form is written should be consistent throughout. The IRBPHS usually recommends that the form be written in the first person (e.g., “I have been asked to participate in a research study”). However, use of an alternate format (e.g., the second person: “You have been asked to participate in a research study”). is acceptable as long as it is done consistently. If the first person format is used, the investigators should not refer to themselves as “we” but rather as “the researchers.” If the subject is less than 18 years of age or is otherwise unable to give consent for themselves, the consent form should be written in the third person format (e.g., “My child has been asked to participate in a research study”).

*Section Headings:*
It is usually preferred that section headings for each of the elements numerically listed on pp. 32 - 33 be used. The information in the form is more clearly organized and more easily read if each section is identified appropriately (see Appendices H through K).

*Proofreading:*
The entire form should be carefully proofread for correct spelling and grammar before it is submitted for IRBPHS review.

**Informed Consent Form**
Listed below is a detailed description of the information which must be included in the Informed Consent Form. Although the format that follows is recommended, it is not required, provided that the consent document addresses each of the issues listed below. A sample Informed Consent Form can be found in Appendix I.
Reference to USF, and the information that a research project is being discussed, should be included in the Informed Consent Form heading. If the study will be conducted at another site, the names of these institutions may also be included in the heading. Though the title of the study itself is not required, it may be inserted after the heading.

Purpose and Background
This section should present the introduction to the study, indicating: (1) who is conducting the research, (2) the aim of the study, (3) a brief summary of the background or reason for the project; and, (4) why the individual has been asked to participate. The reason a person has been asked to participate should be simply but specifically stated (e.g., “because I have tried to quite smoking in the past but have not been successful,” “because I am an employee of a company that has recently undergone downsizing,” “because I am a recent immigrant to the United States”) and should not include a discussion of the inclusion/exclusion criteria. The investigator(s) should be identified with titles and departments at the beginning of the form, so that it is clear who is carrying out the study. This section should not begin with such phrases as “I agree to participate…,” since the prospective subject has not yet had a chance to read the form, and could not yet make an informed decision about whether or not to participate. The form should indicate that the individual is being “asked” rather than “chosen” or “invited” to participate, since words like “chosen” or “invited” have connotations that are not necessarily those associated with being a subject in a research study.

Procedures
To emphasize the voluntary nature of participation in research, this section should begin with the phrase: “If I agree to be in this study, the following will happen.” Each procedure should be numbered and discussed separately. If the study involves screening procedures, these should be mentioned first and identified as steps that will determine who will participate in the study. This section should clearly state what will happen to the individual as a result of participation in the study, and, where appropriate, how this differs from standard treatment or what would happen to the individual if he/she did not participate in the study. When a study involves randomization, this is considered a research maneuver; it should be described as a study procedure, and the term “randomization” explained in lay language. Information about the probability of assignment to each treatment or condition should be given. Other terms which might not be familiar to the average person (e.g., “placebo”) should be defined the first time they are mentioned in the form. If a standard medical procedure is being done as part of the study, it should not be referred to as “standard” or “routine” since this could easily imply that the procedure would be done anyway for clinical reasons. Rather, what should be conveyed is that this procedure is an extra laboratory test that is commonly done for clinical purposes, but is being done here for research purposes. Amounts of blood or tissue to be taken for study purposes should be specified, using easily understood equivalents (e.g., teaspoons, ounces) for metric terms. If subjects’ records (e.g., medical records, school records, employment records) will be reviewed for purposes of the study, this should be listed as a procedure. The number of times a procedure will be done (e.g., initial data collection, 1 year followup, 2 year follow-up), the time involved for each procedure, and the total amount of time for participation in the study should be specified. The location(s) where the procedures will take place should also be stated.

Risks and/or Discomforts
The risks and/or possible discomforts of all study procedures should be listed and explained in this section. No study is free of risks or discomforts. It is usually best to describe the risks of each procedure in a separate
Risks should be arranged and described according to their severity and the likelihood of their occurrence. Since one of the risks of participating in research may be a loss of privacy, a discussion of confidentiality issues should be included in this section. The paragraph that discusses confidentiality should begin with the statement that “Participation in research may mean a loss of confidentiality (or privacy).” The consent form may then proceed to describe briefly how the confidentiality will be protected (i.e., coding of records, limiting access to the study records, not using any individual identities in publications or reports resulting from the study). For all statements regarding confidentiality of research records, it should be kept in mind that there is no legal privilege between investigator and subject as there is between physician and patient or between counselor and client. Thus, a guarantee of complete confidentiality, or “strictest confidentiality,” should not be given or implied. One should always state, instead, that confidentiality will be protected “as far as is possible” or “as far as is possible under the law.” Researchers should note that by law they are considered by law to be mandated reporters of child abuse and elder abuse, should reasonable suspicion of such behavior arise in the course of collecting data from human subjects. If researchers are collecting data from vulnerable populations (e.g., psychiatrically disturbed subjects), they should be aware that they may be required to assess for potential suicidality and/or homicidality and take appropriate action where necessary. Where appropriate, it should be indicated what precautions will be taken to avoid certain side effects or outcomes from occurring, and what will be done should they occur.

Benefits
Any potential direct benefits to the subject should be described first, followed by potential general benefits (e.g., to the group to which the subject belongs, to medical knowledge, to society, etc.). It is usually recommended that description of possible direct benefits be qualified with the phrase, “… but this cannot be guaranteed.” If there is no direct benefit to the subject anticipated from the study, this should be stated at the beginning of the section. Possible benefits such as medical or societal benefits resulting from a research study should be considered separately from payment/reimbursement for participation in the study. Thus, the discussion of payment/reimbursement should be separated from the benefits statement and placed in its own section (described below).

Alternatives
This section should discuss the various alternatives to participation in the study. This can be a short statement, but it should be made clear the possible choices (e.g., no treatment, standard therapy, other experimental treatments) that are available if the individual chooses not to participate in the study. If the study involves only normal, healthy volunteers, and thus the only alternative is to decline participation in the study, the ‘Alternatives’ section need not be included, since the individual’s right to choose not to participate will be made clear in the last section of the consent form (described below).

Costs/Financial Considerations
When there are no costs to be charged to the subject, this should be clearly stated in the consent form. However, a simple statement that there are no costs is often not sufficient and could be misleading. For example, a more accurate statement may be that the subject will have to pay for the usual costs of his or her medical care but will not be charged any extra for participating in the study. When participation in the study may result in any costs to subjects, clear information must be provided in the consent form regarding these costs. Special attention must be paid to this issue in studies where subjects are also patients. In such cases, where individuals may be undergoing various procedures, tests, or hospitalization that are part of their clinical diagnosis and treatment, and others that are part of the research study, the costs section of the consent form should clearly distinguish which costs will be charged to the patient or his third party carrier,
Payment/Reimbursement
In general, when referring to money which subjects will receive in return for participation in a study, the word “reimbursement” (for costs/effort incurred as a result of participating in the research project) is preferable to “payment,” though either may be used. The term “compensation” should not be used, since it is now used on consent forms to designate compensation for injury. Investigators should avoid connotations of undue influence to participate or that the subject is being employed by the investigator. Rather, the sense should be that subjects will be reimbursed for their time, travel expenses, and the inconvenience of being a research subject. This section should state the total dollar amount that the subject will be paid for participation in the study and should give any other relevant information such as prorating if a subject does not complete the study or bonus payment at the end of the study. If appropriate, a payment schedule should be included in this section. In addition, subjects should be informed how payment will be made (e.g., in cash, by check) and when they will be paid (e.g., immediately after the interview, approximately six weeks after they have completed participation in the study). If there will be no payment or reimbursement of subjects for study participation, this information should be clearly stated in this section.

Questions
This section should provide contact information in case the subject has questions about the study. At least one permanent name and telephone number of one investigator, usually the principal investigator, must be provided. If the person explaining the study and obtaining consent is not the principal investigator, the blank line in this section may be filled in with that person’s name and telephone number at the time the consent is obtained, in order to satisfy the IRBPHS’s requirement to include the name of the person obtaining consent on the form (see below). This section should also provide the IRBPHS office email at irbphs@usfca.edu and indicate to the subjects that any further questions or concerns about their participation as a research subject may be directed toward this office.

Consent
This section should state that the subject has been given (not just “offered”) a copy of the consent form. If the study is biomedical in nature, a copy of the Research Subject’s Bill of Rights (Appendix F) must be attached to the consent form. Non-biomedical research studies are not required to attach the Research Subject’s Bill of Rights, although this is permissible. This section should state the information that participation in research is voluntary and explain the individual’s right to decline to participate or to withdraw from participation in the study at any time. If the subjects are patients, students, or employees (or are in any other status/position which may render them vulnerable to the belief that they must participate in the research), a phrase must be added indicating that refusal to participate or withdrawal from participation will be without jeopardy to medical care, study status, or employment. Because communicating the voluntary nature of consent is so important, the IRBPHS recommends that the statement to that effect be in capital letters, and this section be placed at the very end of the form. In this section, the IRBPHS usually discourages such wording as “I have read this form and understand it; based on this understanding, I hereby agree to participate” since this does not guarantee an individual’s comprehension, legally or otherwise. Rather, it is recommended that investigators simply state that if the person wishes to participate in the study, he or she should sign the form; signature will then indicate agreement to participate.

Signature Section
The section should include lines for the subject’s signature and date of signature. Subjects should have a
record of who explained the study to them, so the consent form should include signature and date lines for the specific individual who explained and obtained consent.

**Parental Consent Form**
Several elements must be present in any consent document. The Parental Consent Form, which is to be used in studies in which some or all of the potential subjects are under the age of 18, must include each of these elements, as detailed above in the section “Informed Consent Form.” The Parental Consent Form is similar to the Informed Consent Form except that it refers to the potential subjects as “my child” or “your child” rather than “I/me” or “you.” The signature section of the Parental Consent form includes a line for the parent/guardian’s signature and date of signature rather than the subject’s signature and date of signature. Although it is not required, researchers may opt to solicit the assent of a subject who is less than 18 years of age. In such instances, the Assent Form should follow a format similar to the Parental Consent Form but should be written in language easily understood by the minor child. An Assent Form does not eliminate or change the requirement for a Parental Consent Form. A sample Parental Consent Form can be found in Appendix J.

**Consent Cover Letter/Information Sheet**
In cases where the requirement for a signed consent document is waived (see p. 33), the IRBPHS may require the investigator to provide subjects with a written statement regarding the research, which includes all or most of the same elements as a consent form, but does not require the signature of the subject. This Consent Cover Letter or an Information Sheet should include each of the elements detailed above in the section “Informed Consent Form” (purpose and background of study, study procedures, risks and discomforts, benefits, alternatives to participation in the research, costs/financial considerations, payment/reimbursement, questions, and consent). The signature section is not required. A sample Consent Cover Letter and Information Sheet can be found in Appendices J and K, respectively.

**Verbal Consent Script**
In cases where the requirement for a signed consent document is waived (see p. 33), the IRBPHS may require the investigator to provide a script of the verbal consent procedure that will be used with potential subjects. The Verbal Consent Script, used in telephone interview studies which involve minimal risk to subjects, must include all or most of the same elements as a consent form. The Verbal Consent Script should include each of the elements detailed above in the section “Informed Consent Form” (purpose and background of study, study procedures, risks and discomforts, benefits, alternatives to participation in the research, costs/financial considerations, payment/reimbursement, questions, and consent). The signature section is not required since the researcher will not be collecting any written consent document from subjects. A sample Verbal Consent Script can be found in Appendix M.

**HUMAN SUBJECT INCIDENTS**
The responsibilities of all USF investigators conducting research on human subjects include two types of incident reporting:

1. any subject injuries, adverse events associated with the study procedures, and/or problems involving the conduct of the study which may occur during the course of his or her own research projects and,
2. any possible breach of human subject protection in other research activities at USF of which the investigator may become aware.
Adverse Effects or Incidents in the Investigator’s Own Project

All problems having to do with human subject safety must be reported to the Institutional Review Board for the Protection of Human Subjects (IRBPHS) within ten (10) working days. Specifically, the following must be reported, in writing:

1. all adverse events associated with the study procedures; and
2. any incidents or problems involving the conduct of the study or human subject participation, including problems with the recruitment and/or consent processes. The “Human Subject Incident Report” (Appendix N) should be used in reporting any adverse effects to the IRBPHS office. As with all other IRBPHS forms, Human Subject Incident Report forms are available through the IRBPHS office, through the Dean’s offices of each School and College, and on the web at https://www.axiommentor.com/pages/irb/info.cfm

In general, any serious or recurring problem, any unanticipated side effect, any adverse effect reported to a study sponsor, and adverse effect requiring treatment or any side effect about which the human subject is concerned, should be reported to the IRBPHS. Any problems involving the conduct of the study or human subject participation, including problems with the recruitment and/or consent processes require reporting. For example, if a person who is contacted, either in writing or in person, about participating in a study becomes upset about the recruitment process, this should be reported.

Effect of Reporting

A report is not an admission of any liability. However, for adverse effects, the investigator should make an initial determination as to whether any changes are needed in the discussion of the risks and/or benefits in the consent procedures. In response to incidents, the investigator may need to reevaluate the recruitment and or consent process and modify existing procedures appropriately.

Review of Reports

The Chair of the IRBPHS and/or the committee members review all Human Subject Incident Reports in order to reevaluate the risks/benefits ratio of the study and/or the appropriateness of the recruitment/consent. If the investigator has already modified the protocol or consent procedure in response to these events, the appropriateness of these changes are also reviewed. While the IRBPHS does not actively monitor compliance with the guidelines set forth for research with human subjects, it is responsible for continuing review of research involving human subjects at USF through the annual review process required for any ongoing study (see pp. 26 - 27). Thus, all reported adverse effects should also be described in detail in the Renewal Application (Appendix E), so that the IRBPHS may consider renewal of the protocol in light of such information. Serious adverse effects or incidents are forwarded to the Dean of the investigator’s School or College and to the Academic Vice President, who must be informed in case of inquiries, institutional liability, publicity, or to apply to University compensation policies. If the research is supported by a public or private funding agency, and if the problem is of sufficient magnitude, the researcher is required to inform appropriate agency officials. A copy of this report to the funding agency should be sent to the IRBPHS.

Failure to Report

Failure to report adverse effects or incidents involving human subjects in research at USF is a breach of the conditions under which IRBPHS approval is given and can result in suspension or revocation of approval. Studies for which IRBPHS approval has been suspended or revoked may not continue contact with potential or actual human subjects. Suspension or revocation of approval can also result in loss of support by funding agencies.
**Incident Reports Related to Other Research Activities**

The IRBPHS, in cooperation with the office of the Academic Vice President, however, will conduct an inquiry following any report of possible misconduct related to human research activities that may come from subjects, study personnel, staff, students, or faculty. If, for instance, a research project is being conducted without IRBPHS approval, an improper method of recruiting subjects is being used, or undue influence is being placed upon prospective human subjects to participate in a study, the IRBPHS has no means of learning about such situations and rectifying them unless it is informed that they are taking place. Thus, in order to fulfill its mandate to protect human subjects in research, the institution must depend upon concerned individuals, including investigators, to inform the IRBPHS of any possible misconduct related to research activities of which they become aware.

Such incidents are usually reported by telephone or in writing to the IRBPHS Chair. An inquiry is made to the investigator conducting the research activity and, if the investigator is a student, to the student’s faculty advisor, maintaining requested anonymity of the individual submitting the report whenever possible. The IRBPHS will forward information about the incident to the Dean of the investigator’s school or college and to the Academic Vice President for appropriate resolution.
Appendix A: IRBPHS INITIAL APPLICATION

Name of Applicant: Shohei Yamamoto
USF Identification Number: 20268504
University Title: Assistant Professor
School or College: College of Arts and Sciences
Department or Group: The Department of Economics
Home or Campus Address (please include full street or P.O. Box, City, and Zip): 601 Las Palmas Ave, Sacramento, 95815
Home Phone: (415) 623-9414
Work Phone: (415) 623-9414
Electronic Mail Address(s): syamamoto2@dons.usfca.edu
Name(s) and University Title(s) of Other Investigators: None
Name of Faculty Advisor: Michael Jonas
University Title: Assistant Professor
Home or Campus Address: 2130 Fulton Street, OFFICE: CO 425, San Francisco, CA 94117
Home or Campus Phone: (415) 422-6160
Electronic Mail Address(s): mrjonas@usfca.edu
Project Title: Optimal Tobacco Tax level in Japan

Respond to items 1 - 11 white paper, single-sided, typed in black ink and using standard 12 point font. Responses to items 1 -11 should be stapled to this Initial Application form.

1 Background and Rationale
2 Description of Sample
3 Recruitment Procedure
4 Subject Consent Process
5 Procedures
6 Potential Risks to Subjects
7 Minimization of Potential Risk
8 Potential Benefits to Subjects
9 Costs to Subjects
10 Reimbursements/Compensation to Subjects
11 Confidentiality of Records

Signature of Applicant Date 6/4/2013

Signature of Faculty Advisor* Date Michael Jonas 6/4/13

*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 IRPBHS of any significant problems or changes.
Appendix B: CONFIRMATION OF RECEIPT OF COMPLETE APPLICATION
UNIVERSITY OF SAN FRANCISCO INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS

Dear                      : Your application to the Institutional Review Board for the Protection of Human Subjects (IRBPHS) was received on                        and has been assigned the following file number: ___________________. ___ Your application was complete when it was received and has been sent out for review. Your application was incomplete when it was received; it is now complete and has been sent out for review. Please allow 2 - 3 weeks from the date of this notice for review. You will be contacted by the primary reviewer of your application if additional materials and/or clarification is needed. Questions should be directed to the IRBPHS office by electronic mail at IRBPHS@usfca.edu; the office is staffed on a part-time basis, so be sure to leave a number(s) and electronic mail address(s) where you can be reached or where a response message can be left.
Appendix C: USF FERPA STATEMENT Notification of Rights Under FERPA

The Family Education Rights and Privacy Act (FERPA) affords students certain rights with respect to their education records. These rights include:

1. If the records are not maintained by the University official to whom the request was submitted, that official shall advise the student of the correct official to whom the request should be addressed.

2. Additional information regarding the hearing procedures will be provided to the student when notified of the right to a hearing.

3. A school official has a legitimate educational interest if the official needs to review an educational record in order to fulfill his or her professional responsibility. Directory information at the University of San Francisco includes: Student’s name, school of enrollment, credit hour load (full-time, part-time), periods of enrollment, degree(s) awarded and date(s) of conferral, honors, participation in athletic activities, weight and height of athletic participants, major and minor fields, and dean’s list.

4. The name and address of the office that administers FERPA is: Family Policy Compliance Office, U.S. Department of Education, 400 Maryland Avenue SW, Washington, D.C. 20202-4605
Appendix D: RENEWAL REMINDER
UNIVERSITY OF SAN FRANCISCO INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION
OF HUMAN SUBJECTS

RENEWAL REMINDER

Dear _________________________, Your application to the Institutional Review Board for the Protection of Human Subjects (IRBPHS) for your study, _________________________________________________________, was approved on ______________ (IRBPHS #__________). USF requires annual review of all research projects involving human subjects. Because your approval is about to expire, we are sending you this reminder notice. If all contact with human subjects (e.g., recruitment, data collection, and follow-up) has been completed, you are not required to renew your IRBPHS approval. If you are still conducting recruitment, data collection, follow-up, or any other type of contact with potential or actual human subjects, you are required to submit the attached “IRBPHS Renewal Application” before ________________.
Submit your status report to: USF IRBPHS at the IRB web site https://www.axiommentor.com/pages/irb/info.cfm
Appendix E: IRBPHS RENEWAL APPLICATION

Name of Applicant: USF Identification Number: University Title: School or College: Department or Group: Home or Campus Address: Home Phone: Work Phone: Electronic Mail Address(s): Name(s) of Other Investigators: Name of Faculty Advisor: University Title: Campus Address: Campus Phone: Electronic Mail Address(s): IRBPHS Number: Project Title:

Respond to items 1 - 6 on separate sheets of white paper, single-sided, typed in black ink and using standard 12 point font. Responses to items 1 - 6 should be stapled to this Renewal Application form.

1. Subjects
3. Brief summary of results to date
5. Changes in Anticipated Risks
7. Changes in Anticipated Benefits
9. Discussion of any side effects or problems noticed during the past year*
6. Explanation of any modifications in the protocol made during the past year **

Signature of Applicant Date

Signature of Faculty*** Date

* Any adverse effects experienced by a human subject must be reported to the Chair of the IRBPHS in writing within 10 working days of their occurrence; this report should provide a summary of the event(s).
** Any proposed changes to protocol must be approved by the IRBPHS prior to their implementation; this report should provide a summary of the changes.
*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 IRPBHS of any significant problems or changes.
Appendix F: IRBPHS MODIFICATION APPLICATION

Name of Applicant: USF Identification Number: University Title: School or College: Department or Group: Home or Campus Address: Home Phone: Work Phone: Electronic Mail Address(s): Name(s) and University Title(s) of Other Investigators: Name of Faculty Advisor: University Title: Home or Campus Address: Home or Campus Phone: Electronic Mail Address(s): IRBPHS Number: Project Title:

Respond to items 1 - 5 on separate sheets of white paper, single-sided, typed in black ink and using standard 12 point font. Responses to items 1 - 5 should be stapled to this Modification Application form.

1. Description of Proposed Change(s) to Research Protocol
2. Rationale for Proposed Changes
3. Impact on Potential Risks to Human Subjects
4. Minimization of Increased Potential Risk
5. Impact on Potential Benefits to Human Subjects

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 IRPBHS of any significant problems or changes.
Appendix G: SAMPLE PERMISSION LETTER FROM INSTITUTIONAL MANAGEMENT

19 December 1999

Institutional Review Board for the Protection of Human Subjects

University of San Francisco
2130 Fulton Street
San Francisco, CA 94117

Dear Members of the Committee:

On behalf of the ABC Toy Company, I am writing to formally indicate our awareness of the research proposed by Ms. Jane Washington, a student at USF. We are aware that Ms. Washington intends to conduct her research by administering a written survey to our employees. I am responsible for employee relations and am an executive officer of the company. I give Ms. Washington permission to conduct her research in our company. If you have any questions or concerns, please feel free to contact my office at (415)1234567.

Sincerely,

Amanda Barley
Vice President of Human Resources,
ABC Toy Company

*letter should be printed on proper institutional letterhead*
Appendix H: RESEARCH SUBJECTS’ BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As a research subject, I have the following rights:

Research Subjects

Bill of Rights

Research subjects can expect:

◗ To be told the extent to which confidentiality of records identifying the subject will be maintained and of the possibility that specified individuals, internal and external regulatory agencies, or study sponsors may inspect information in the medical record specifically related to participation in the clinical trial.

◗ To be told of any benefits that may reasonably be expected from the research.

◗ To be told of any reasonably foreseeable discomforts or risks.

◗ To be told of appropriate alternative procedures or courses of treatment that might be of benefit to the subject.

◗ To be told of the procedures to be followed during the course of participation, especially those that are experimental in nature.

◗ To be told that they may refuse to participate (participation is voluntary), and that declining to participate will not compromise access to services and will not result in penalty or loss of benefits to which the subject is otherwise entitled.

◗ To be told about compensation and medical treatment if research related injury occurs and where further information may be obtained when participating in research involving more than minimal risk.

◗ To be told whom to contact for answers to pertinent questions about the research, about the research subjects’ rights and whom to contact in the event of a research-related injury to the subject.

◗ To be told of anticipated circumstances under which the investigator without regard to the subject's consent may terminate the subject's participation.

◗ To be told of any additional costs to the subject that may result from participation in the research.

◗ To be told of the consequences of a subjects' decision to withdraw from the research and procedures for orderly termination of participation by the subject.

◗ To be told that significant new findings developed during the course of the research that may
relate to the subject's willingness to continue participation will be provided to the subject.

❖ To be told the approximate number of subjects involved in the study.
❖ To be told what the study is trying to find out;
❖ To be told what will happen to me and whether any of the procedures, drugs, or devices are different from what would be used in standard practice;
❖ To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research purposes;
❖ To be told if I can expect any benefit from participating, and, if so, what the benefit might be;
❖ To be told of the other choices I have and how they may be better or worse than being in the study; To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study;
❖ To be told what sort of medical or psychological treatment is available if any complications arise;
❖ To refuse to participate at all or to change my mind about participation after the study is started; if I were to make such a decision, it will not affect my right to receive the care or privileges I would receive if I were not in the study;
❖ To receive a copy of the signed and dated consent form; and
❖ To be free of pressure when considering whether I wish to agree to be in the study. If I have other questions, I should ask the researcher or the research assistant. In addition, I may contact the Institutional Review Board for the Protection of Human Subjects (IRBPHS), which is concerned with protection of volunteers in research projects. I may reach the IRBPHS by electronic mail at IRBPHS@usfca.edu.

References: JCAHO and Research Regulatory Bodies

(1) To be told what the study is trying to find out;
(2) To be told what will happen to me and whether any of the procedures, drugs, or devices are different from what would be used in standard practice;
(3) To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research purposes;
(4) To be told if I can expect any benefit from participating, and, if so, what the benefit might be;
(5) To be told of the other choices I have 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 or psychological treatment is available if any complications arise;
(8) To refuse to participate at all or to change my mind about participation after the study is started; if I were to make such a decision, it will not affect my right to receive the care or privileges I would receive if I were not in the study;
(9) To receive a copy of the signed and dated consent form; and
(10) To be free of pressure when considering whether I wish to agree to be in the study. If I have other questions, I should ask the researcher or the research assistant. In addition, I may contact the Institutional Review Board for the Protection of Human Subjects (IRBPHS), which is concerned with protection of volunteers in research projects. I may reach the IRBPHS by electronic mail at IRBPHS@usfca.edu.
Appendix I: SAMPLE INFORMED CONSENT FORM
UNIVERSITY OF SAN FRANCISCO
CONSENT TO BE A RESEARCH SUBJECT

Purpose and Background Ms. Amanda Jacobs, a graduate student in the School of Education at the University of San Francisco is doing a study on self-esteem of adults who attend college after the age of 35. Over the past several years, more and more people are beginning college later in life. The researchers are interested in understanding the differences in self-esteem among these older-than-traditional-age students as compared to students who begin college immediately upon graduation from high school. I am being asked to participate because I am over 35 years of age and am attending college. Procedures If I agree to be a participant in this study, the following will happen:
1. I will complete a short questionnaire giving basic information about me, including age, gender, race, religion, and job history.
2. I will complete a survey about self-esteem.
3. I will participate in an interview with a research assistant, during which I will be asked about my educational history, my educational goals, and my career aspirations. I will complete the surveys and participate in the interview at the office of Dr. Susan Washington in the School of Education at the University of San Francisco.

Risks and/or Discomforts
1. It is possible that some of the questions on the self-esteem survey may make me feel uncomfortable, but I am free to decline to answer any questions I do not wish to answer or to stop participation at any time.
2. Participation in research may mean a loss of confidentiality. 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. Study information will be coded and kept in locked files at all times. Only study personnel will have access to the files.
3. Because the time required for my participation may be up to 2 hours, I may become tired or bored.

Benefits There will be no direct benefit to me from participating in this study. The anticipated benefit of this study is a better understanding of the effect of the college experience on students who are older than traditional age.

Costs/Financial Considerations There will be no financial costs to me as a result of taking part in this study. Payment/Reimbursement I will be reimbursed $5.00 for my participation in this study. I will be paid in cash immediately after I have completed the questionnaire, survey, and interview. If I decide to withdraw from the study before I have completed participating or the researchers decide to terminate my study participation, I will still receive full reimbursement. Questions I have talked to Ms. Jacobs or her research assistant about this study and have had my questions answered. If I have further questions about the study, I may call her at (415) 422-1234.

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 IRBPHS, which is concerned with protection of volunteers in research projects. I may reach the IRBPHS office by e-mailing IRBPHS@usfca.edu. Consent I have been given a copy of the “Research Subject’s Bill of Rights” and I have been given a copy of this consent form to keep. PARTICIPATION IN RESEARCH IS VOLUNTARY. I am free to decline to be in this study, or to withdraw from it at any point. My decision as
to whether or not to participate in this study will have no influence on my present or future status as a student or employee at USF. My signature below indicates that I agree to participate in this study.

Subject’s Signature Date of Signature

Signature of Person Obtaining Consent Date of Signature
Appendix J: SAMPLE PARENTAL CONSENT FORM
UNIVERSITY OF SAN FRANCISCO
PARENTAL CONSENT FOR RESEARCH PARTICIPATION

Purpose and Background Mr. Brian Richards, undergraduate student, and Dr. Pamela Miller, Professor, of the School of Nursing at the University of San Francisco 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 he/she 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 he/she plays with three other children he/she does not know but who are similar in age for a period of 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. 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. Participation in research may mean a loss of confidentiality. 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. Study information will be coded and kept in locked files at all times. Only study personnel will have access to the files.

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 Mr. Richards or his research assistant about this study and have had my questions answered. If I have further questions about the study, I may call him at (415) 422-1234 or Dr. Pamela Miller (415) 422-4321. 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 IRBPHS, which is concerned with protection of volunteers in research projects. I may reach the IRBPHS office by e-mailing IRBPHS@usfca.edu
Consent
I have been given a copy of the “Research Subject’s Bill of Rights,” and I have been given a copy of this consent form 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 Subject’s Parent/Guardian Date of Signature

Signature of Person Obtaining Consent Date of Signature
Mr. John Doe 123 Sunny Circle Anywhere, CA 90000

Dear Mr. Doe:

My name is Lorraine Garcia and I am a graduate student in the College of Professional Studies at the University of San Francisco. I am doing a study on management styles of people with and without advanced management training. I am interested in learning the impact of advanced courses, books, and seminars on the management style of mid-level managers in high-technology corporations. Your company management has given approval to me to conduct this research. You are being asked to participate in this research study because you are a mid-level manager in a high-technology corporation. I obtained your name from a mailing list of management personnel in high-technology companies. If you agree to be in this study, you will complete the attached survey that asks about your educational background, management training experiences, and management style. Return the survey in the enclosed pre-addressed, pre-stamped envelope to me.

It is possible that some of the questions on the survey may make you feel uncomfortable, but you are free to decline to answer any questions you do not wish to answer, or to stop participation at any time. Although you will not be asked to put your name on the survey, I will know that you were asked to participate in the research because I sent you this letter and survey. Participation in research may mean a loss of confidentiality. 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. Study information will be coded and kept in locked files at all times. Only study personnel will have access to the files. Individual results will not be shared with personnel of your company. While there will be no direct benefit to you from participating in this study, the anticipated benefit of this study is a better understanding of the effect of management training on management style in high-technology corporations. There will be no costs to you as a result of taking part in this study, nor will you be reimbursed for your participation in this study.

If you have questions about the research, you may contact me at 555-5555. If you have further questions about the study, you may contact the IRBPHS at the University of San Francisco, which is concerned with protection of volunteers in research projects. You may reach the IRBPHS office by e-mailing IRBPHS@usfca.edu

PARTICIPATION IN RESEARCH IS VOLUNTARY. You are free to decline to be in this study, or to withdraw from it at any point. The JMC corporation is aware of this study but does not require that you participate in this research and your decision as to whether or not to participate will have no influence on your present or future status as an employee at JMC Corporation. Thank you for your attention. If you agree to participate, please complete the attached survey and return it to me in the enclosed pre-addressed, pre-stamped envelope.

Sincerely,
Lorraine Garcia
Graduate Student University of San Francisco
Ms. Lorraine Garcia, a graduate student in the College of Professional Studies at the University of San Francisco is doing a study on management styles of people with and without advanced management training. She is interested in learning the impact of advanced courses, books, and seminars on the management style of mid-level managers in high-technology corporations. You are being asked to participate in this research study because you are a mid-level manager in a high-technology corporation.

If you agree to be in this study, you will complete a survey that asks about your educational background, management training experiences, and management style; you will return the survey in a pre-addressed, pre-stamped envelope to the researchers. Some of the questions on the survey may make you feel uncomfortable, but you are free to decline to answer any questions you do not wish to answer, or to stop participation at any time. Although you will not be asked to put your name on the survey, participation in research may mean a loss of confidentiality. 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. Study information will be coded and kept in locked files at all times. Only study personnel will have access to the files. Individual results will not be shared with personnel of your company. There will be no direct benefit to you from participating in this study. The anticipated benefit of this study is a better understanding of the effect of management training on management style in high-technology corporations. There will be no costs to you as a result of taking part in this study, nor will you be reimbursed for your participation in this study.

If you have questions about the research, you may contact the researchers at 555-5555. If you have further questions about the study, you may contact the IRBPHS at the University of San Francisco, which is concerned with protection of volunteers in research projects. You may reach the IRBPHS office by e-mailing IRBPHS@usfca.edu

PARTICIPATION IN RESEARCH IS VOLUNTARY. You are free to decline to be in this study, or to withdraw from it at any point. The JMC corporation is aware of this study but does not require that you participate in this research and your decision as to whether or not to participate will have no influence on your present or future status as an employee at JMC Corporation.
Hello; my name is Lorraine Garcia and I am a graduate student working with Dr. Michael Franz, Assistant Professor of the College of Professional Studies, at the University of San Francisco. We are doing a study on management styles of people with and without advanced management training. We are interested in learning the impact of advanced courses, books, and seminars on the management style of mid-level managers in high-technology corporations.

You are being asked to participate in this research study because you are a mid-level manager in a high-technology corporation. If you agree to be in this study, you will complete a survey that asks about your educational background, management training experiences, and management style. You will complete the survey now and return it to directly to me when you are finished.

Some of the questions on the survey may make you feel uncomfortable, but you are free to decline to answer any questions you do not wish to answer, or to stop participation at any time. Although you will not be asked to put your name on the survey, participation in research may mean a loss of confidentiality. 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. Study information will be coded and kept in locked files at all times. Only study personnel will have access to the files. Individual results will not be shared with personnel of your company.

While there will be no direct benefit to you from participating in this study, the anticipated benefit of this study is a better understanding of the effect of management training on management style in high-technology corporations.

There will be no costs to you as a result of taking part in this study, nor will you be reimbursed for your participation in this study.

If you have questions about the research, you may contact me at 555-5555. If you have further questions about the study, you may contact the IRBPHS at the University of San Francisco, which is concerned with protection of volunteers in research projects. You may reach the IRBPHS office at irbphs@usfca.edu

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Thank you for your attention. If you agree to participate, please complete the survey and return it directly to me.
Appendix N: HUMAN SUBJECT INCIDENT REPORT

All incidents of injury or other adverse effects experienced by human subjects must be reported to the IRBPHS at irbphs@usfca.edu

Name of Investigator: USF Identification Number: University Title: School or College: Department or Group: Home and/or Campus Address(s): Home and/or Work Phone(s): Electronic Mail Address(s): Name(s) and University Title(s) of Other Investigators:

Name of Faculty Advisor: University Title: Home and/or Campus Address(s): Home and/or Campus Phone(s): Electronic Mail Address(s): Project Title: IRBPHS #: Name of Human Subject(s):

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

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

7. Additional Comments

Signature of Person Reporting Incident Date Name of Person Reporting Incident: Home and/or Campus Address(s): Home and/or Work Phone(s): Electronic Mail Address(s):