Section I. **GENERAL PROCEDURAL STATEMENT**

It is the intent of Fuller Theological Seminary to protect the rights of human subjects involved with research projects affiliated with the seminary. Therefore, all projects involving human subjects, at any level, are subject to at least minimal review.

It is the responsibility of every investigator (student or faculty/advisor) to provide all pertinent information necessary to facilitate a complete review process *prior to collecting data*. Fuller has adopted the Federal guidelines as outlined in 45 CFR 46 for all projects that involve research with human subjects. Fuller has a valid Federalwide Assurance (FWA) approved by the Office of Human Research Protection with the Department of Health and Human Services. The identification number is FWA00007283.
Section II. **DEFINITIONS**

The following are terms and their definitions that are used throughout this document:

- **45 CFR 46** – Code of Federal Regulations Title 45 (Public Welfare), Part 46 (Protection of Human Subjects) (see Appendix A). The federal regulations are also available on the OHRP website: [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm)
- **Human Subject (Participant)** – a living individual about whom an investigator (whether professional or student) conducting research obtains:
  a) data through intervention or interaction with the individual, or
  b) identifiable private information
- **Research** – systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of the policy whether or not they are conducted or supported under a program which is considered research for other purposes
- **Intervention** – includes both physical procedures by which data are gathered and manipulations of the subject or the subject’s environment that are performed for research purposes.
- **Interaction** – includes communication or interpersonal contact between investigator and subject.
- **Private Information** – includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. (For information to be deemed “private” the information must be individually identifiable.)
- **Minimal Risk** – the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine psychological examinations or tests
- **Informed consent** – legally effective document that is obtained before involving a human being as a subject in research. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. See details in Section VIII of this document.
- **Children** – persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted (normally under 18 years of age; under 21 years of age for grants funded by the NIH)
- **Assent** – a child’s affirmative agreement to participate in research. Mere failure to object does not constitute assent.
- **Permission** – the agreement of parent(s) or guardian to the participation of their child or ward in research
- **Parent** – a child’s biological or adoptive parent
- **Guardian** – an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.
- **Vulnerable subjects** - include children, pregnant women, prisoners, physically or cognitively challenged, economic or socially disadvantaged, subordinate individuals (e.g. students and employees), and fetuses. The degree to which these potential subjects are vulnerable is directly related to the degree to which these individuals are capable of volunteering or providing informed consent to research participation. There are specific federal regulations (45 CFR 46 Subparts A - D) that apply to conducting research with vulnerable populations which assures that the risks associated with participation are minimal or that the research is of direct benefit to...
the subjects. Special considerations will be made by the IRB in reviewing protocols that include vulnerable subjects.

- **IRB** – general term that is used for an entity that is established in accord with and for the purposes expressed in the federal regulations to conduct the review of research with human subjects (Institutional Review Board)
- **HSRC** – Human Subjects Review Committee (the IRB for the School of Psychology at Fuller Theological Seminary)
- **OHRP** – Office for Human Research Protection
- **IRB approval** – the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB (HSRC) and by other institutional and federal requirements.
- **Certification** – the official notification by the institution to the supporting government agency or department, in accordance with the requirements of 45 CFR 46, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance
- **FWA (Federalwide Assurance)** - OHRP-approved assurance of compliance with the HHS regulations (45 CFR 46.103) for the protection of human subjects. If an institution is engaged in human subjects research (not otherwise exempt) that is conducted or supported by any agency of the U.S. Department of Health and Human Services (HHS), then the institution must have a FWA.
- **MPA** – Multi-Project Assurance. This document is often filed by larger institutions who do large quantities of research with federal funds. It assures the government that all research done with federal funds will be reviewed by an IRB as outlined in the federal regulations.
Section III. COMMITTEE COMPOSITION

The HSRC at Fuller Theological Seminary is composed of eight (8) regular-member seats. An additional active member is the HSRC manager, which can review limited types of projects through expedited review (see details in Section VI). Each seat is filled according to the following criteria:

1. Race, gender and cultural backgrounds should be given due consideration as well as the professional competence, experience and expertise of the members. However, per Section 46.107 of the Code of Federal Regulations, no selection shall be made solely on the basis of gender. Also, the committee may not consist entirely of members of one profession.
2. At least one member shall have primary concerns in scientific areas and at least one in non-scientific areas.
3. At least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
4. The HSRC, at its discretion, may invite individuals with competence in special areas to assist in the review of issues, which require expertise beyond or in addition to that available on the IRB. These individuals have no voting privileges.

No member may participate in the HSRC’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the HSRC.

The HSRC at Fuller Theological Seminary is composed of two (2) alternate-member seats. Each seat is filled according to the criteria outlined for regular-member seats. Alternate members participate in regular meetings and project reviews when regular members cannot attend a specific meeting or specific meetings (e.g. a regular member on professional sabbatical will be temporarily replaced by an alternate member). Every attempt will be made by the committee to have seven (7) members present at any given meeting.
Section IV. HSRC RECORDS AND DOCUMENTATION

A. HSRC Records
In conformity with the HHS regulations at 45 CFR 46.115, HSRC at Fuller Theological Seminary maintains documentation of IRB activities including the following:

- Copies of all research proposals reviewed, evaluation forms, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
- Records of continuing review activities.
- Copies of all correspondence between the IRB and the investigators.
- Copies of Certificates of Completion (of the Human Participant Protection Education for Research Course) for all investigators that submitted protocols following November 1, 2004.

Also, a record of HSRC members in the same detail as described in §46.103(b)(3) is maintained. All written procedures in the same detail as described in §46.103(b)(4) and §46.103(b)(5) and forms are available.

B. HSRC Minutes
Minutes of HSRC meetings will be recorded in such a way to include sufficient detail to show attendance at the meetings; actions taken by the HSRC; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution. Also, if the case the minutes will record the announcements and the information/discussion items. The minutes will be available in the Office of the HSRC Administrator.

C. Retention OF HSRC Records
All records shall be retained for at least 3 years, and records relating to research, which is conducted under the HSRC approval, shall be retained at least 3 years after the completion of research.

D. Additional Considerations
Continuing training for the HSRC members and staff will be provided at the convened meetings whenever needed. When a new individual is invited to become HSRC member, intensive training on the regulations and procedure will be provided.

All investigators are required to complete an online course on Human Participants Protection. Also, they are constantly updated on new requirements (if any) and deadlines, etc.
Section V. **PROTOCOL SUBMISSION PROCESS and MANAGEMENT**

As of September 2007, HSRC accepts online submissions only. The protocols should be submitted thru the IRBNet system, which Fuller HSRC subscribed to in May 2007.

The HSRC approval should be secured prior to any research activity (including recruitment process) begins thus the submission should be planned accordingly. The HSRC calendar is available before the academic year starts and it includes submission deadlines and meeting dates. The meeting is preceded by a submission deadline (3 weeks prior) and the deadline marks the beginning of a review round.

If the protocol is complex and/or involves international research, a minimum of 4 months from the submission deadline (or 3 months post initial HSRC meeting) should be allowed for the review process. For student investigators, unless the study uses archival data only, the review will be done after the thesis/dissertation committee has approved the proposal.

ALL INVESTIGATORS engaging in research activities that involve human participants, should submit to the HSRC the following documents (attached in separate files):

1) The project cover sheet
2) A protocol abstract
3) A protocol description, section that organizes information into the seven categories listed in the “Protocol Description” paragraph in the Guidelines document (Appendix B).
4) Informed consent/assent and recruitment materials
5) A file containing any other documentation that is relevant for the protocol
7) If submitting a revision in response to the HSRC initial review, investigator should attach a letter addressing all the suggestions and concerns. The updated documents should also be attached after highlighting the changes (gray background highlight).
8) If submitting an addendum, investigator should attach a letter with detailed explanation regarding the proposed changes (reasons, implications, risk/benefit evaluation, etc) and any relevant documents that will be affected by.
9) If submitting a final or continuing review report please follow the specific instructions in the Guidelines document.
10) If your project is being done in conjunction with another institution AND is being reviewed by an IRB at that institution, you may be eligible for a project waiver from this committee. Please contact the HSRC office for further details.

Details on the protocol preparation, continuing review and final reports and online submission are provided in the guidelines in Appendix B and online.

Prior to submitting a protocol, the investigator is encouraged to share the study with the HSRC manager for feedback and recommendations. The HSRC manager will review the draft depending on the timeline.

When a protocol is submitted an email is automatically sent to the HSRC Manager and the HSRC Submission Coordinator. The submission coordinator is responsible for checking if the submission is complete and the uploaded documents are formatted as required in the guidelines. The submission coordinator will contact the investigator(s) if any of the following occur:

- the project cover sheet is either missing or incomplete, OR
- the IRB certificate is not filled with HSRC nor attached in the system, OR

*Last edited September 11, 2009*
• the documents formatting, file distribution or file definition is not as required in the guidelines, OR
• any documents that investigator refers to are missing

The HSRC manager will review the protocol for content and if needed require further clarifications or make recommendations for protocol changes. The protocol would be unlocked at that time to allow the investigator to upload updated or new documents. If the protocol is incomplete or not ready for review because significant changes are required, the HSRC manager can change the submission status to “withdrawn” or “modifications required” and ask the investigator to resubmit. Again, all investigators are encouraged to share the study with the HSRC manager prior to submission.

When study is ready, the HSRC manager will proceed in assigning it to one or two reviewers (primary and secondary) in the IRBNet system. The designated reviewers will automatically receive an email notifying that a study has been shared and awaiting their review.

After evaluating the protocol, reviewers would need to fill out a form, which goes thru a set of questions available in a wizard format. At the end of the form after saving and exiting the wizard, a PDF online document is generated and attached along with the reviewers’ comments. Based on the reviewers’ feedback and the committee’s recommendations, a response letter is issued, posted online and mailed to the principal investigator and the status of the protocol will be updated in IRBNet.

While the review process is continuous for expedited, exempted and waived projects, the full protocols are assessed only during the review rounds and discussed at the meetings. Full protocols are initially reviewed by two (2) HSRC members but the rest of the committee would be involved in the conversation and have an important role in the decision making process. The final decision or recommendations are communicated to the principal investigators within 3 days after the HSRC meeting and that completes the review round.
Section VI. **REVIEW PROCESS**

The review process consists of three (3) review categories. Projects are assigned to categories based on their perceived level of risk to human subjects and their interaction with federal regulations (e.g.: 45 CFR 46). The categories are:

- Exempt from HSRC Review (HSRC Administrator review only)
- Expedited HSRC Review (One HSRC member review)
- Full HSRC Review (Convened HSRC meeting)

**A. Exemption from HSRC Review**

Faculty investigators, co-investigators, advisor, or a student doctoral committee may request an exemption from HSRC review by checking the Review Exemption box in the Project Cover Sheet (the Research Project Information section). A project is exempt from committee review if it meets the conditions set forth in 45 CFR 46.101(b). Each Fuller SOP faculty member has been provided with a copy of the requirements of 45 CFR 46.101(b), which are also attached as Appendix A to this document.

The HSRC Manager will review the exemption through the regular exemption procedure, which involves filling out an online exemption wizard form (Appendix C). In accordance with the Guidance on Written IRB Procedures, this process helps determine whether proposed research is exempt from the human subject regulations but also to identify the specific category justifying the exemption. If the HSRC office finds that the proposal meets the requirements, the investigator will be notified in writing that exemption has been granted. The proposal will then be filed, and the research can proceed. The HSRC reserves the right to require Full HSRC Review of any project, at any time. The HSRC will be notified at convened meetings of all projects approved through the Exempt from HSRC Review process.

**A.1 Qualifications for exemption:**

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies.

B. Expedited Review

Note: Students should allow a minimum of two (2) weeks for this process to be completed. Projects can take up to two (3) months for the review process to be completed if revisions are required or if the project is recommended for full review.

The Expedited Review process is designed to approve projects that do not involve more than minimal risk to human subjects, and to approve minor changes (addenda) in research previously approved during the research period (one year or less) [cf. 45 CFR 46.110].

1. If the Fuller faculty investigator, co-investigator, advisor, or the HSRC Manager finds that a project is not exempt from review, then the project shall be subject to either Expedited or Full Review. The HSRC manager shall determine whether the project qualifies for Expedited Review. The Expedited Review process involves review by one (1) committee member who has the authority to perform any of the following three actions:

   (a) Approve the project under 45 CFR 46.110 (see Qualifications for Expedited Review, below)
   (b) Recommend the project for Full Committee Review (project does not meet the requirements for Expedited Review under section 45 CFR 46.110)
   (c) Recommend detailed changes to the project, whereby the project will then be re-submitted to the reviewer after changes have been made.

2. If the study looks at de-identified archival data and would otherwise qualify for exemption except that it involves a vulnerable population (children, pregnant women, prisoners, etc), the protocol will be reviewed by the HSRC manager.

3. If the reviewing committee member finds that the proposal meets the qualifications set forth below for Expedited Review, and the reviewing member approves the research as presented, the reviewing member shall indicate such using the Initial Review Form and Informed Consent Checklist wizards (Appendices D and H)The HSRC Manager shall inform the investigator(s) of such approval in writing as soon as possible after receiving notice from the HSRC reviewer. The proposal will be filed, and the research can then proceed.

4. If the reviewing committee member finds that the proposal requires minor revision prior to being approved through Expedited Review, the following actions shall be taken:
(a) The member shall indicate the need for, and provide a detailed list of, changes in the Initial Review Form wizard. The Informed Consent Checklist should also be used to indicate any issues that would need to be addressed regarding the consent/assent.

(b) As soon as the HSRC office receives feedback from the reviewer, the manager shall inform the investigator(s) of the decision of the committee member in writing. (For projects recommended for Full Review by the Expedited Reviewer, please see section entitled Full Review, below).

(c) If changes were deemed necessary by the expedited reviewer, the project can be revised by the investigator and resubmitted, and the review process can continue. The burden to resubmit the proposal rests with the investigator(s).

The HSRC will be notified at convened meetings of all projects approved under the Expedited Review process. The HSRC reserves the right to require full review of any project, at any time.

5. If a project requires full HSRC review (see Full Review below), and after review the HSRC requires minor changes, the HSRC may elect to allow the project to be resubmitted and reviewed through the Expedited Review process. The review details of the resubmission shall be recorded thru the Comment Sheet (Appendix E) and the Informed Consent Checklist (Appendix H) online wizards. Such elections are normally made for projects requiring only minimal changes.

6. If an addendum (minor changes) to a previously approved project is submitted and is eligible for expedited review, the reviewing committee member will use the online Comment Sheet wizard (see Appendix E). When approved, the addendum is filed attached to the initial proposal and investigator will be informed on the review findings.

7. The committee member may not disapprove a research proposal under section 45 CFR 46.110(b.2). If a committee member believes a research proposal should be disallowed, the member should recommend the proposal for Full Committee Review on the Expedited Review Comment Sheet, indicating the objections to the proposal.

B.1 Qualifications for Expedited Review
To qualify for Expedited Review the project must not involve more than minimal risk to the subjects and the only involvement of human subjects will be in one or more of the following categories: Recording of data from subjects 18 years of age (21 years of age if proposal involves grant money from the National Institute of Health) or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject’s privacy. It also includes such procedures as weighing, testing sensory acuity, electroencephalography, and thermography. It does not include exposure to electromagnetic radiation outside the visible range (i.e., x-rays, microwaves).

1. Voice recordings made for research purposes such as investigations of speech defects.
2. Moderate exercise by healthy volunteers.
3. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
4. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the research investigator does not manipulate subjects’ behavior and the research will not involve stress to subjects.

C. Full Review
The Full Review process is used when proposals involve more than minimal risk to subjects, or for projects involving children (defined as those under 18 years of age [under 21 years of age if proposal involves grant money from the National Institute of Health]).

1. For projects recommended for Full Review when the HSRC cannot approve the project using the Expedited Review process. The determination of whether a project requires Full Review or not will be made by the HSRC manager or by the Expedited Reviewer as outlined below:

   (a) The Expedited Reviewer shall fill out the Initial Review and Informed Consent Checklist online wizards and indicate the proposal is not eligible for Expedited Review thus should be reviewed at the convened committee. If that is the case, the “yes” option on wizard item # 8 (Other issues) should be marked and the details should be added in the “Comments” section. The reviewers have the responsibility to indicate if they want the investigator to be present at the meeting.

   (b) Detailed suggestions or recommendations to the committee should be indicated in the same “Comment” section of the wizard form.

   (c) The HSRC office will place the proposal on the agenda for the next meeting. The investigator(s) will also be notified of the necessity for a Full Review of the proposal, and the date of the scheduled HSRC meeting.

2. For projects recommended directly for Full Review (not undergoing the Expedited Review Process), the following actions will be taken:

   (a) The HSRC manager will select two committee members to complete an Initial Review of the project.

   (b) The reviewers will familiarize themselves with the project and complete the Initial Review online wizard (Appendix D) and the Informed Consent Checklist (Appendix H). As soon as the protocol review is completed, the HSRC should be notified so that additional actions be taken. The reviewers’ comments will be used by the committee to generate discussion at the convened meeting.

   (c) The reviewers will make recommendations to invite the investigator to the convened meeting if further clarifications will simplify the review process.

The proposal will be automatically placed on the online agenda for the next scheduled meeting of the HSRC. At the convened meeting, HSRC will decide the course of actions and in case the project is incomplete and not eligible for an Expedited Review, the process will be repeated and reviewers will use the Comment Sheet and the IC checklist wizards at the time of the resubmission (see Appendix E).

All federally funded proposals by governing law must have the entire grant reviewed. All other requirements outlined for submission will still apply.

**D. Project waiver**

If a project by a Fuller student or faculty is done in conjunction with another institution whose IRB has already reviewed the proposal; the requirements for review by the HSRC at Fuller may be waived if:

1. The IRB of the other institution has a MPA on file with the corresponding federal agency. (The investigator should ask the IRB of the other institution for a copy of the MPA)
2. The IRB at the other institution has approved the proposal in the exact same form presented to this committee.

If both qualifications are met, the investigator can submit the project in its entirety as approved by the other institution’s IRB, along with: a) a copy of the MPA for that institution, and, b) a copy of the
approval letter. The study could also be shared thru IRBNet by the institution that originally approved (the HSRC office should be contacted for further details). The information should be submitted to the HSRC office. The HSRC office will inform the investigator in writing if the project has met the requirements for the waiver. The HSRC reserves the right to require a formal review of any project at any time.

**E. Continuing Review and Final Report**

Projects are granted approval for one year only. Investigators should apply for renewal at least 1 month before the approval expiration date marked on the HSRC approval letter. The IRBNet system automatically generates a reminder at 90 days and at 60 days to the principal investigator. Given that the protocols are usually valid for one year, the continuing review will not be less often than once a year. The investigator(s) is required to submit a proposal that helps assessing progress, significant new findings and additional risks if any. Specific guidelines for continuing review submission are included in the general Guidelines document attached in Appendix B.

The procedures for continuing review by HSRC include a primary reviewer system. Generally, if research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time of continuing review except in limited circumstances as follows:

- the research is permanently closed to the enrollment of new participants; all participants have completed all research-related interventions, and the research remains active only for long-term follow-up of participants OR
- no participants have been enrolled and no additional risks have been identified; OR
- the remaining research activities are limited to data analysis

The reviewer(s) will evaluate the report by using the Continuing Review Form (Appendix F) and the Informed Consent Checklist which are both available as online wizards and make recommendations to generate discussion at the convened meeting (if full review).

In the event that the project is completed (data analysis included), the investigator should submit a Final Report. The submission and review procedure is similar to the continuing review. The Final Report form is available online and attached in Appendix G.
SUMMARY OF HSRC ACTIONS IN THE REVIEW PROCESS

General
The convened committee will review the proposal and the reviews provided on the Initial Review Form or the Comment Sheet or the Continuing Review Form. The committee will then discuss the proposal, and the Chairperson will determine consensus or vote with action being taken as follows:

1. Approve the project in its current form.
2. Approve the project pending minor changes
3. Request changes or clarifications to the project, indicating any changes necessary and the basis for requiring any change. The committee may also indicate if the proposal would be eligible for expedited review upon resubmission.
4. Disapprove or defer the project, indicating the basis for the action. HSRC will clearly indicate if the concerns refer to the protocol or the idea in general.

The investigator(s) will be notified in writing of the decision of the HSRC. If the investigator is a student, the faculty advisor and the academic advisor will each receive a copy of the HSRC decision. A copy is kept in the HSRC records.

Other special duties of the HSRC in the review process

Proposals involving vulnerable subjects

Proposals involving fetuses, pregnant women, or human in vitro fertilization. 45 CFR 46.205 outlines additional duties of the HSRC for proposed research involving fetuses, pregnant women, or human in vitro fertilization. In addition to the requirements outlined above, the committee must:

1. Determine that adequate consideration has been given to the manner in which potential subjects will be selected and provision for adequate monitoring of the actual informed consent process is in place. Mechanisms for such monitoring may include, if appropriate:
   a. Overseeing the actual process by which individual consents are secured by either random sampling of consent forms to insure that approved procedures are followed, or by actually approving each consent form as it is gathered.
   b. Monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen.

Proposals involving prisoners. Please refer to 45 CFR 46.304-305 for guidelines for IRBs when research involves prisoners.

Reporting continuing non-compliance and suspension of HSRC approval.

Any serious or continuing non-compliance with 45 CFR 46, suspension or termination of HSRC approval, or with the determinations of the HSRC, should be reported by the committee to any governing federal agency or other funding sources who have desired HSRC approval prior to research funding. Student investigators who exhibit continuous failure to comply with the instructions of the HSRC will be subject to referral to the Student Development Committee. Faculty investigators who exhibit continuous failure to comply with the instructions of the HSRC will be subject to referral to the Dean of the School of Psychology.

Unanticipated problems and adverse events:
The committee will determine if the event qualifies as an unanticipated problem by assessing the risks.
Unanticipated problems (UP), in general, include any incident, experience, or outcome that is:

- unexpected (in terms of nature, severity, or frequency) given (a) the research procedures, and (b) the characteristics of the subject population being studied;
- related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by participation in the research); and
- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known and recognized

1. Definition: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

2. The federal regulations do not specify requirements for how an unanticipated problem is reviewed by the IRB. When reviewing a report of an UP, the IRB should consider whether the affected research satisfies the requirements for IRB approval under 45 CFR 46.111 (see attached).

3. In order to make the determination required for approval of research, the IRB needs to receive sufficient information regarding the risk profile, the type, probability, and the expected level of severity. The investigator also should describe how the risks of the research will be minimized.

Corrective actions:

1. An incident, experience, or outcome that meets the three criteria for an UP generally, will warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects or others.

2. In addition, the IRB must ensure, if appropriate that the research includes adequate provisions for monitoring the data collected to ensure the safety of subjects.

If the event is determined to be an UP, the timeframe for reporting is:

- Serious UPs: Investigator should report to the IRB within 1 week of the investigator becoming aware of the event
- Other UPs: Investigator should report to the IRB within 2 weeks
- All UPs should be reported to appropriate institutional officials, the supporting agency head, and OHRP (under the Fuller FWA) within 1 month of the IRB’s receipt of the report of the problem from the investigator.
Section VII.  CRITERIA FOR PROPOSAL REVIEW

A. General Criteria
For approval of research proposals to be granted, the HSRC shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized:
   (a) By using procedures which are consistent with sound research design and which to not unnecessarily expose subjects to risk, and
   (b) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
   (c) Due consideration should be given to the cumulative effects of testing when subjects are used repeatedly for research.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be reasonably be expected to result. In evaluating the risks and benefits, the HSRC should consider only those risks and benefits that may result from the research, (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The HSRC should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment the HSRC should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective subject or the subject’s legally authorized representative in accordance with the terms set forth in the section entitled INFORMED CONSENT below.

5. Informed consent will be appropriately documented, in accordance with, and to the extent required by the section entitled INFORMED CONSENT below.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

B. Criteria for Research with Children

1. In general, the HSRC may approve research involving children if the committee finds that no greater than minimal risk to the children is presented, and only if it finds that adequate provisions have been made for soliciting the assent of the children and the permission of their parents or guardians (see section entitled INFORMED CONSENT – Informed Consent and Children).

2. If the HSRC finds that a proposal involving children would involve greater than minimal risk, such research may still be approved if, in the opinion of the HSRC:


3. If the subjects (children) are not likely to directly benefit from the study, the HSRC may still approve the proposal if, in the opinion of the HSRC:

   a) The risk represents a minor increase over minimal risk;
   b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual psychological, social or educational situations;
   c) The intervention or procedure is likely to yield generalizable knowledge about the subjects’ disorder or condition which is of vital importance for the understanding or treatment of the subject’s disorder or condition; and
   d) The requirements for assent and permission have been met.

Any other research with children that does not meet the above requirements may be approved under special circumstances defined in 45 CFR 46.407.

**C. Additional Requirements for Investigators**

1. **Proposing changes to approved research**
   Prompt reporting should be made to the HSRC when changes are necessary to previously approved research. Such proposed changes should be made in writing, and will require approval at the same level at which the original approval was granted. Changes may only be initiated without HSRC review and approval when necessary to eliminate apparent immediate hazards to the subject.

2. **Reporting unanticipated problems**
   Any unanticipated problems involving harm or risks to subjects or others should be immediately reported to the Office of the HSRC Administrator.
Section VIII. **INFORMED CONSENT**

The purpose of this section is to assist the investigator(s) by providing guidance on how to obtain valid informed consent from potential research subjects. It has been designed to serve as much as an educational tool as a procedural guideline.

The informed consent process is fundamental to ensuring the continuous and adequate disclosure of research related risks and benefits. Written, informed consent is also required by federal regulations and state law.

**A. The Process of Informed Consent**

In the past, it was generally accepted that written, informed consent, obtained at a single contact between an investigator and a subject, was sufficient to meet legal and ethical obligations to patients and research subjects. Informed consent is now understood as an on-going process, which starts with the initial presentation of a research activity to a prospective subject by the investigator and continues through the research activity until the subject ends his/her participation or the study closes.

Research subjects are rarely aware of research activities prior to an initial presentation by the principal investigator or member of the principal investigator’s study team. The initial phase of consent requesting participation in a research activity commonly begins with the first contact between the subject and the investigator. Many subjects make their decision regarding whether to participate in research during the initial contact. As a result, the greatest potential for misunderstanding exists in the initial consent process. Researchers are encouraged to provide sufficient time for a potential subject to reflect on the nature of participation during the important initial presentation of a research activity. When subjects are presented with numerous research and clinical options, the consent process should include a clear description of the possible ramifications resulting from each option presented. The presentation should not include specific “leading” information about whether to participate in any particular project.

By providing a potential subject with understandable information in an initial session regarding complex research issues, potential subjects will have an improved comprehension of the elements within the consent form and provide a more informed consent for participation in the research.

The second step in the consent process is the presentation of the consent form to subjects. The investigator should separate the research consent form from other clinical information.

A member of the study team should ensure that the subject reads the consent form. After the subject reads the consent form, the member of the study team should ask the subject if he/she understands the information contained in the form. In situations where the ability of the subject to understand the form is in question, for example, the form includes complex scientific information (which should be avoided when possible) or the subject is possibly educationally or mentally challenged, the member of the study team may wish to ask questions of the subject to ensure an understanding of the basic elements of the consent form. In performing an assessment of the subject’s comprehension of the consent form, an investigator should request that the subject indicate the risks of participation, how the subject may withdraw, and what alternatives exist to participation in the research. The decision-making capacity of subjects with psychiatric disorders or cognitive deficits (such as dementia) should be evaluated by a practitioner not otherwise affiliated with the research.
All efforts should be made to offer potential subjects sufficient time to consider the information contained in the consent form. The subject should be given an opportunity to take the consent form home and sign the form on a return visit or the subject may be left alone to consult enrollment with family or friends. If the individual decides to participate, he/she would sign the consent form, the principal investigator would co-sign the form, and if the research involves more than minimal risk, the HSRC may require a witness to document the process by also signing the form.

Consent as a continuing process

Research is an ongoing process which involves the constant re-evaluation of current information procedures. Therefore, investigators are ethically obligated to keep subjects apprised of all issues related to their participation in the study. For example, adverse events may occur during a research activity that would directly affect whether prospective or enrolled subjects would wish to continue in a particular research activity. Subjects must also receive the new information as a part of the continuing consent process. Investigators should note that the HSRC requires committee review and approval prior to an investigator providing subjects with new research information.

Information may also arise regarding the study which should be shared with previously enrolled subjects after their completion of the study, or a specific treatment or procedure. For example, dysfunctional families may participate in qualitative research examining parenting techniques. Following data analysis, the investigator finds that a specific technique is superior to the other study arms of the project. As a health care and educational institution, Fuller Seminary investigators are morally obligated to provide this valuable new information to research participants.

In conclusion, it is difficult to be confident that volunteers truly understand the nature of their participation in research when they are confronted with volumes of complex scientific details in a brief and isolated consent session. By rejecting the outmoded belief that informed consent starts and ends with a consent document, investigators and subjects will work as partners in a healthy process of an equal exchange of information and scientific discovery. As a result, subjects will have an improved understanding of the risks and anticipated benefits (to themselves, others, and society) of participating in the research. Creating an ongoing consent process will facilitate an exchange of information between the subjects and investigators in a scientific environment of increasing complexity. In providing subjects with a continuing consent process we will ensure that subjects are completely informed about their participation in the research. By providing subjects with the opportunity to give effective and ongoing informed consent, in a process that incorporates the free exchange of information between both the researcher and the subject, investigators will continue to set the standards for the conduct of ethical research.

The consent form and the continuing review process

The informed consent and assent forms should be reviewed every year during the continuing review process. The renewal application has to be accompanied by the latest version of the approved consent. Unless the reviewer brings forth concerns, the consent (and assent if the case) is approved and will carry the new expiration date of the study.

Writing the consent form

Delays in HSRC approval may commonly result from the submission of an inadequate consent form. The design of the consent form should carefully reflect the process of informed consent, i.e.,
introduce the investigator to the subject; indicate why the subject is requested to participate in the study; articulate the purpose of the study; clearly separate the research procedures from any standard treatment; inform the subjects of the risks and benefits of participation; and ultimately document the subject’s willingness to participate in the project. Subjects should be told as much as can be told them without invalidating the research. Subjects need to know everything necessary for consent but not necessarily the intended outcome of the project. Also, oftentimes the consent form is too technical and includes scientific jargon which can prove incomprehensible and ultimately intimidating to the subject. Consent forms of this nature will likely be rejected by the HSRC.

No informed consent, whether oral or written, may include any exculpatory language through which the subject or the subject’s representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator(s) or Fuller Theological Seminary or its agents from liability or negligence.

For assistance when preparing a protocol submission specifically writing the informed consent, HSRC provides investigators with the following documents:

- Informed Consent Checklist (Appendix H)
- Informed Consent Template (Appendix I)
- Sample Informed Consent Document (Appendix J)

### Obtaining oral consent

There may be, on occasion, situations in which the requirements of consent need to be delivered orally, and not in the preferred, written method. If oral consent is used a short form written consent document stating that the elements of informed consent (as set forth in this section) have been presented orally to the subject or the subject’s legally authorized representative should be used. When this method is used, a witness to the consent should be present. The HSRC should approve a written summary of what is to be said to the subject or the representative. Only the summary form itself should be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary presented to the HSRC. The person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

### Basic elements of informed consent:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. 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; and

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

9. A signature line for the subject or guardian to sign. However, the signature line may be omitted if the ONLY identifying information linking the subject and the research would be such a signature and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject should be asked whether they want documentation linking them to the research and the wish of the subject should prevail.

**B. Informed Consent and Children**

When children are involved in research, the HSRC should seek to find that adequate provisions have been made for soliciting the assent of the children and the permission of their parents or guardians.

**Obtaining the assent of children**

The HSRC has the sole discretion in determining whether the children in question are capable of providing assent. In making such a determination, the HSRC will take into account the ages, maturity, and psychological state of the children involved. This judgement may be made for all children involved in the research, for each child, or for a group of children within the research, as the HSRC deems appropriate. If the HSRC determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the HSRC determines that the subjects are capable of assenting, the HSRC may still waive the assent requirement under other circumstances described in other sections of this procedure.

For assistance when preparing a protocol submission specifically writing the assent, HSRC provides investigators with the following documents:

- Assent Template (Appendix K)
- Sample Assent Document (Appendix L)

**Obtaining the permission of parents**

Where parental permission is to be obtained, the HSRC may find that the permission of one parent is sufficient for research to be conducted. However, when a proposal involves greater than minimal risk and does not provide direct benefit to the subjects (see **Criteria for Research with Children**, above), both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

If the HSRC finds that a research proposal is designed for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, abused or neglected children), it may waive the consent requirements provided an appropriate mechanism...
for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law. The choice of an appropriate mechanism would depend on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status and condition.

The HSRC will determine, if assent is required, whether and how assent should be documented.

**C. Additional Elements of Informed Consent**

When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject; and
6. The approximate number of subjects involved in the study.

**D. Additional Advice When Creating Consent Forms**

Studies have found that most subjects read at a sixth grade level or lower. Therefore, consent forms should avoid or define technical jargon or terminology, adjust for educational background and age, and provide translations for subjects who are not facile in English. The HSRC may require separate forms for different subject groups, such as parents, children, healthy control subjects, etc.

Consent forms that contain medical language, social science terminology, and metric equivalents for quantities are routinely returned to investigators for modifications. If the subject cannot understand the consent form they cannot give knowing consent for their participation in the research. It is suggested that investigators have a colleague or staff person, not familiar with the field of research, review the consent form for content and readability prior to submitting the form for HSRC review. This will save you a great deal of time that could be wasted if the committee had to recommend revisions and re-review the proposal at a later date.

**E. The Role of the HSRC and Informed Consent**

The HSRC may approve a consent procedure which does not include or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the HSRC finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not be practicably carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
Section IX. ADDITIONAL REQUIREMENTS FOR INVESTIGATORS

A. When Data are Obtained From a Clinical Source

When medical records are used (data originally gathered in a clinical, non-research, setting), the investigator is required to obtain permission from the institution that oversees the medical records. The permission should be in writing and should outline both the scope of the access and of the use of the records granted to the investigator. The written permission should be submitted with the proposal prior to beginning the review process.

B. When Data are Gathered in a Research Context from Another Institution

When data used originates from another institution, and when the data was gathered in a research context, the investigator is required to seek approval of the research in which the data was gathered from the Institutional Review Board overseeing such research. For instance, if the investigator is using data gathered from USC in a research context, the investigator shall request from the USC IRB a copy of the approval letter for the project in which the data were collected. The copy of the approval letter (or other evidence if necessary) should be submitted with the proposal prior to beginning the review process.

HSRC OFFICIAL: ______________________ APPROVAL DATE: ______________________

__________________________________________________________ Date
Dr. James Furrow, Chairman  
HSRC
List of Appendices

Appendix A – Federal Regulation (45 CFR 46)
Appendix B – Guidelines for Proposal Submission
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Appendix B
HSRC GUIDELINES FOR PROPOSAL SUBMISSION

New Study

GENERAL INSTRUCTIONS

Please note the following:

- These guidelines are designed for submission of a new study. If you are submitting a revision, addendum, continuing review or final report, please see the Portico Research Page for appropriate instructions.
- HSRC accepts online submissions only. Submissions are done through www.irbnet.org. Specific guidelines for the online process are found on the HSRC Portico webpage.
- For student researchers, the HSRC review will proceed only after the thesis or dissertation proposal has been approved by the faculty advisor or dissertation committee respectively.
- If the project is being done in conjunction with another institution AND is being reviewed by an Institutional Review Board at that institution, researcher may be eligible for a project waiver from this committee. Please contact the HSRC office for further details.
- If the protocol is complex and/or involves international research, researcher should allow extra time for the review process: minimum 4 months from the submission deadline or 3 months post initial HSRC meeting.

HSRC SUBMISSION PREPARATION DETAILS

All investigators engaging in research activities that involve human participants should submit to the HSRC the following documents (uploaded as separate files):

1. A project cover sheet (see details below)
2. A protocol summary (see details below)
3. A protocol description (this section organizes information into the eight categories listed in the “Protocol Description” paragraph below).
4. Informed consent and assent forms (see details below)
5. Recruitment materials
6. Copies of all instruments
7. Written permissions
8. A separate file containing any other documentation that is relevant for the protocol
9. Copy of Certificate for completion of “Human Participants Protection Education for Research” Course. Please see details in the “Certification” paragraph below.

PROJECT COVER SHEET

The Project Cover Sheet can be created online in the IRBNet system (see HSRC Online Submission [step 2]) OR on your own computer. If second option is preferred, the form can be found in Portico in the SOP Research / HSRC section.

PROTOCOL SUMMARY (max. 1 page, 1.5 Paragraph spacing, Arial 12 Font)

The summary should contain the following information: study title, investigator(s), brief description of hypothesis, recruitment procedure, informed consent/assent (please specify whether the informed consent/assent is attached or not, any particular aspects about the consent/assent procedure, are you requesting a signature waiver), participants’ characteristics, approximate number of participants expected to be recruited, types of questions you will be asking, risk level. Please provide information on all the items above. If some do not apply to your project, please indicate so.
PROTOCOL DESCRIPTION
Each area below should be clearly indicated in the protocol that you will submit to the HSRC, and, while each area should be addressed, not every item within each area will apply to each research project. If an area does not pertain to your study, briefly address the reasons why the area is not applicable. Do not submit more information for this section than is needed to explain your study, but be clear in your purposes and methodology, including all information that pertains to the treatment of human participants in your proposed research. Please use the active voice when appropriate, including the correct tense (i.e.: “I will be collecting data from…”, etc.).

1. Overview of the Research Study – (Limit this section only to 250-500 words)
This section should describe the research in clear language using lay terms. Included should be:
   a. a brief discussion of the prior research (literature) and/or a logical rationale forming a foundation for this study
   b. the research question(s) being asked.
Enumerate and state clearly each specific hypothesis. If the protocol involves a clinical intervention, this section should indicate such with a detailed explanation.

2. Characteristics of the Research Participants
This section should describe the participant pool (such as number, gender mix, ages, and ethnic background). If applicable, the protocol should address the rationale for using vulnerable populations (such as: pregnant women, children [anyone under the age of 18], mentally or emotionally disabled individuals, the physically challenged, prisoners, the elderly, or any other group likely to be vulnerable). If applicable, the protocol should provide rationale for specifically excluding particular groups.

3. Methodology & Procedures
Describe the detailed methods to be used (location of the study, proposed timeline, participants, instruments, and procedures – describe using detail similar to if you were submitting a journal article). Also include, in appendices, copies of instruments (such as questionnaires or tests) not frequently used in psychological research or practice - or a discussion of the instruments to be used if the actual instruments are not available or cannot be attached, and the protocol for administration.
Remember, the overall purpose of this section is to describe what the human participants will actually be doing.

4. Sources of the Research Material
This section should identify, in detail, the sources of research material obtained from individually identifiable living human participants in the form of records or other data. The protocol should indicate whether the material will be obtained specifically for this research or whether the study will make use of existing data previously collected. If data is to be obtained from other sources than the participants themselves the protocols should include the protocols for securing the consent of the participants for the use of their records (if the data contains identifiers) and the approval of the custodian of the records for the release of the data (if not publicly available). If access to a school, facility or institution/organization is required to conduct the research the protocol should describe: the school, facility, or institution/organization to be used; how the study has been presented to the authorized representative(s) of that school, facility, or institution/organization; and how permission for access has been obtained and documented. Also, please describe your involvement with this project, i.e., is the data to be obtained as part of a larger project?

Participant Recruitment and Informed Consent
This section should describe how participants would be recruited for the study (copies of advertisements, notices, and other materials should be included). The protocol should be explicit in its description of the informed consent process.
All forms, notices, scripts, and other materials relating to recruitment and informed consent should be included.
The protocol should describe:

- what will be communicated to, or read by, the participants to explain the research (using lay language)
- how potential risks of the research will be explained
- what questions will be asked to assess the understanding of the research and its risks
- when consent will be obtained
- who will obtain the consent of the participants
- how consent will be documented.

If applicable, the protocol will explain how fully informed consent would interfere with the objectives of the research and explain the process to be used for assuring participants that they will not be placed at risk without compromising the integrity of the study.

If applicable, the protocol will explain how consent will be obtained from participants belonging to a special class of participants and/or re-obtained over prolonged periods (and, if appropriate, how assent [assent is defined as: “a child’s affirmative agreement to participate in research”] will be obtained).

5. Potential Risks (including confidentiality)

This section should describe any potential risks -- physical, psychological, social, legal, or other -- and assess the likelihood and seriousness of each risk.

Special considerations should be given to:

- the use of private records
- a possible invasion of privacy
- the manipulations of psychological or social variables
- probing for sensitive or personal information
- the use of deception in an experimental protocol
- the presentation of materials which the participants might consider offensive, threatening or degrading
- any other possible physiological or psychological impact

When appropriate the protocol should describe alternative treatments and procedures that might be advantageous to participants particularly at risk for that particular study. The protocol should describe the precautions to be taken to minimize the risks to the participants, including risks to confidentiality. The protocol should assess the likely effectiveness of these precautions. When appropriate, the protocol should discuss provisions for insuring necessary medical or professional intervention in the event of adverse reactions or effects, short or long-term, to the participants. The protocols should discuss what provisions will be effected to maintain confidentiality, including: where participant data will be kept, how long it will maintained, how individual participants' data will be identified, and how access to the data will be controlled and protected. When appropriate, a process for debriefing the participants after their participation in the study should be included.

6. Anticipated Benefits of this Research

This section should discuss why the risks to the participants are reasonable in relation to the anticipated benefits to the participants and in relation to the importance of the knowledge that might result.

7. Compensation

Only when applicable, the protocol and the informed consent should describe any direct compensation to the participant, including any inducements before their participation or rewards after their participation. The circumstance of participant dropping out of the study should also be
considered and an explanation whether the participation would be pro-rated or not should be included. In the informed consent, language that would suggest any coercion should be avoided.

**INFORMED CONSENT/ASSENT FORMS**
Templates and samples of both informed consent and assent are provided online in Portico or in the IRBNet Forms and Reference Library (under Library Manager). If you are requesting an informed consent waiver or signature waiver, please make sure you address the reasons for the request in the protocol description under section 5.

**OTHER ITEMS TO ATTACH (if applicable):**
- Recruitment materials: advertisement, letter of inquiry, notices, etc.
- Written permission to use archival data (if it is not publicly available)
- Written permission from an authorized representative to engage in research at another institution (schools, hospitals, etc.)
- Copies of all instruments (if available)
- If an outside entity is involved, a statement on company letterhead that the owner (entity) of the data in question is NOT a covered entity under HIPAA definitions; OR, the data being provided to you is "de-identified"; OR, provision of legal authorization demonstrating that the proposed use of the data for research has been adequately authorized by the participant.

Note: this authorization may be part of the consent document or may be a separate document.

**CERTIFICATION**
The course is provided online by NIH at the following link: [http://phrp.nihtraining.com/users/login.php](http://phrp.nihtraining.com/users/login.php). If you completed a similar course through a different provider you could check with the HSRC office for validity. *The certificate submission should be made along with your first project and will need to be renewed every two years (every four years for Fuller faculty).* The HSRC office reserves the right to reject your submission if a certification is not made available or is issued by an unrecognized provider.
Study Revisions

GENERAL INSTRUCTIONS

Study Revisions are submitted as a response to an HSRC initial review. If the initial review does not grant approval, but rather recommends modifications to the study, the investigator should submit a Study Revision highlighting the changes made in response to the HSRC letter. The Study Revision should not be confused with Study Modifications (Addendum), which applies only to already approved protocols.

HSRC SUBMISSION PREPARATION DETAILS

The following documents (attached in separate files) should be submitted to the HSRC for review:
11) The protocol summary (submit only if revisions affect the original protocol)
12) Letter of Response addressing all the suggestions and concerns.
13) The updated documents (protocol, informed consent/assent, etc) with highlighted changes (please use gray background highlight).

LETTER OF RESPONSE

The Letter of Response should address every area of concern or suggestion in the HSRC’s initial review. Researcher should list every point that was communicated in the HSRC decision letter and insert the response immediately following that. If the HSRC recommendation is not appropriate and would increase the risks, researcher should indicate so and provide an explanation.

UPDATED DOCUMENTS

Include a copy of each document that has been updated (documents that have not been affected but the revision should not be uploaded again). Within each document please highlight in gray background each change made. The more clearly the changes are communicated, the quicker the reviewers can complete the review process.
**Addendum**

**GENERAL INSTRUCTIONS**
Before making any changes to an approved study’s protocol, an addendum must be submitted and approved, highlighting the changes proposed. This includes, but is not limited to, changes in consent, assent, research instruments, addition of new instruments, changes or additions to advertising, and other changes in protocol.

**HSRC ADDENDUM SUBMISSION PREPARATION DETAILS**
The following documents (attached in separate files) should be submitted to the HSRC for review:

14) An Addendum Letter with detailed explanation regarding the changes you are proposing (reasons, implications, risk/benefit evaluation, etc).

15) If Applicable: Include documents being changed or added to the study.

**ADDENDUM LETTER**
The addendum letter should include give detailed explanation of the following:

1. What changes are being made or what documents are being added.
2. Why are said changes necessary for the study.
3. What are the implications? Give a risk/benefit evaluation if necessary.

**UPDATED DOCUMENTS**
Include a copy of each document that has been updated or added.
Continuing Review

HSRC CR SUBMISSION PREPARATION DETAILS
The following documents (attached in separate files) should be submitted to HSRC for continuing review.

1) A project cover sheet
2) A protocol summary
3) A status report on the progress of the research (see details below)
4) The current version of the informed consent and assent forms (see details below)
5) Copy of Certificate for completion of “Human Participants Protection Education for Research” Course (see details below)

PROJECT COVER SHEET
The Project Cover Sheet can be created online in the IRBNet system (see HSRC Online Submission directions) OR on your own computer. If second option is preferred, the form can be found in Portico in the SOP Research / HSRC section. Please create a new project cover sheet (do not submit original submission coversheet).

PROTOCOL SUMMARY (max. 1 page, 1.5 Paragraph spacing, Arial 12 Font)
This summary is usually the same as submitted for the original review and it is acceptable to upload the initial document. However, if the protocol undergoes any changes throughout the year, those should be reflected in a new protocol summary.

STATUS REPORT
The report on the progress of the research should include the following information:

- the number of participants accrued
- a summary of the amendments or modifications to the research since the last review (any addendum/a that have been submitted to HSRC) and the approval status and decision date
- a summary of adverse events and any unanticipated problems involving risks to participants or others and any withdrawal of participants from the research or complaints about the research since the last HSRC review
- a summary of any relevant recent literature, interim research findings since the last review
- an explanation regarding any newly proposed consent document, if applicable (the proposed document has to be attached too, as indicated below)
- any other relevant information, especially information about risks associated with the research

INFORMED CONSENT AND ASSENT FORMS
The current version of these documents should be submitted along, even if no adjustments were done. If a new consent document is proposed, that should be mentioned and explained in the Status report. If data collection is done then there is no need to include the consent and assent forms in the submission.

CERTIFICATION
The certificate submission is required only if the original certification was obtained more than two years before the continuing review submission date. The HSRC office reserves the right to reject your submission if a certification is not made available or is issued by an unrecognized provider.
Final Report

GENERAL INSTRUCTIONS

A final report form should be submitted when the research is completed and research activities come to an end. The Final report should be completed before the approval expiration date.

HSRC FINAL REPORT SUBMISSION PREPARATION DETAILS

The following documents (attached in separate files) should be submitted to HSRC for a final report.

1. A Final Report Form
2. Any report summaries as dictated by the Final Report Form.

FINAL REPORT Checklist

The Final Report form is available for download in Portico and through the Document Library in IRBnet.org.

According to the final report you might be required to give summary information in any of the following categories:

- Irregular termination of the study.
- Serious adverse events in the course of the study.
- Summary of significant new findings.
- Brief summary of research results.

Please include these summaries as separate documents accordingly.
## HSRC Protocol Online Submission Instructions

### REGISTERING AS A NEW USER

**New User Registration**
Go to the IRBnet Website at [www.irbnet.org](http://www.irbnet.org). Click on “New User Registration” under the Login section on the top right corner of the screen.

**New User Account Information**
Fill in the asked for information (Name, Username, Password and Password hint).

**Terms of Use**
Accept the Terms of Use posted.

**Choosing Institutional Affiliation**
Select “Fuller Graduate School of Psychology” as your institution affiliation. Please note that Fuller has two affiliation entries listed: one for investigators and one for the HSRC members. Unless you are a board member, you should be careful not to select the “Fuller Graduate School of Psychology HSRC”. If you do that by error, please go to User Profile (upper right corner) and change the affiliation when logged in.

**Confirmation**
IRBnet will give an e-mail confirmation of the registration, once you finish. Confirm the registration and you're done!

On the welcome page you will notice the “create a new project” button on the left panel. That would be the starting point for a protocol submission. Through the “study manager” button you will be able to access the studies you have created or that have been shared with you by other investigators. As the study progresses you will be able to see different types of status displayed: work in progress, submitted, review type (exempt, expedited, or full), final decision (approved, not approved, closed, deferred, withdrawn prior to review, etc).

### CREATING A NEW STUDY

#### STEP 1: Create a New Project
- **Research institution field** - should have Fuller Graduate School of Psychology, Pasadena.
- **Sponsor field** - insert information only if your study is sponsored by a federal agency. Students, DO NOT list your faculty advisor in this section.
- **Internal reference number field** - HSRC does not provide reference numbers so this field should remain blank

#### STEP 2: Study Designer
- Once you create a new project click on “Designer” on the left hand column to begin adding documents to your new package.
- When creating a new study, you will notice the option “Add New Document” in the Study Designer. You may attach documents by browsing in your computer or you may use the IRBNet document wizards, which are available in the system.
- The Project Cover Sheet is available as a wizard. Click on “Add New Document” then, simply select “Project Cover Sheet” in the Online Documents and click “Add”. That will take you thru a series of questions and it will generate your project cover page.
- In constructing your protocol, please follow the instructions provided in the Submission Guidelines [posted on Portico](http://portico.org).

Please note, a form library with templates and samples is
available to assist you in creating the study documents. The library is located in the Study Designer section.

- Please help facilitate the review process by splitting your protocol into separate files, especially for the following documents: protocol, informed consent/assent.
- Please attach the IRB certification of completion (NIH online course). The final decision on your study will not be released until the certificate is accessible to the HSRC.

STEP 3: Share this Project
- “Share this Project” is the third option under Project Administration on the left hand menu.
- Clicking on that button will take you to a screen with three options for sharing as well as a review of who the study has been shared with so far. Click on Share.
- This will take you to an institution menu. If sharing with the Research Manager, please select “Fuller Graduate School of Psychology, HSRC”. If you are sharing it with a faculty advisor or other students, then select “Fuller Graduate School of Psychology.”
- Studies can be shared with the Research Manager for feedback (at least 10 days prior to submission would be advised).
- Student investigators must share the study with the faculty advisor. The faculty should be given sufficient time to review the study (at least 10 days) and their electronic signature is required prior to submission. A study will not be reviewed until electronically signed by the faculty advisor/investigator.
- If the study has multiple investigators, please share it with all and attach one single document containing all NIH certifications (for PI, Co-PIs)

STEP 4: Sign and Submit the study
- Study has to be signed electronically before submitting it. Select the proper board for review: “Fuller Graduate School of Psychology HSRC”
- Please remind your Faculty advisor to sign the study.

Miscellaneous
- If you decide to drop the study, please click on the “Delete this Study” button (left panel)
- Other options the system offers: access the study history, send emails to the entire team
Appendix C

EXEMPTION FORM

Project #..........................

Project name ........................................................................................................……………

PI’s name ..........................................................................................................…

This form is developed in accordance with the federal regulations [45 CFR 46.101(b)]

General issues

In order for a proposal to qualify for exemption, all that applies from the following must be true:

<table>
<thead>
<tr>
<th>Requirement</th>
<th>True</th>
<th>False</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research is no greater than minimal risk</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No medical treatments are involved</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Vulnerable subjects (minors, prisoners, pregnant women) are not target population</td>
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<td></td>
</tr>
<tr>
<td>Information gathered does not have identifiers (is not recorded in such a way that can be linked back to the subject either directly or through use of a code)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Research activities do not involve:

- Human in-vitro fertilization;
- Surveys or interviews given to minors;
- Deception;
- Observation of minors if the investigator participates in the activities being observed unless there is a federal statute covering the activity;

If the research is funded, the sponsoring agency did not require that the proposed research receive full or expedited review even when the activities would qualify for exemption.

There is no invasion of the privacy of the potential subjects during the recruitment process

Note: There is often confusion about whether or not a study can be exempt if the subjects are minors. As long as the minor is not engaged in the activities noted above with bullets, and the procedures meet all applicable exemption criteria, a study involving minors can be approved for exemption.                                                                                                   
### Issues to be addressed when determining exempt status

Mark the category that applies to the proposal. In the qualifying category all mandatory questions should be answered with “yes” to qualify the proposal as exempt.

1. **(Category 1) Research in Educational Settings**
   
   [45 CFR 46.101(b)(1)]. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular or special educational instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

   1. Is the research activity conducted in established or commonly accepted education the settings? [ ] Yes [ ] No
   2. Does the research target regular or special educational instructional strategies or
   3. Does the research target effectiveness/comparison among instructional techniques, curricula, or classroom management methods

   **Note:** "Commonly accepted settings" are not necessarily restricted to accepted educational settings. It may be a situation where the educational setting is a car, such as in driver’s education class, or a kitchen where mentally retarded minors or adults are learning to cook. The federal code is vague on the definition of “established or commonly accepted education settings, involving normal educational practices…” Thus, it is important for the IRB to be able to determine whether the research procedures are instructional in nature and whether the procedures are conducted in a manner and location typical to that situation. For example, a study that compares web-based learning versus traditional large group lectures to determine which method is more effective in teaching students physiology could qualify as exempt under this category.

2. **(Category 2) Research involving educational tests, survey/interview/observation procedures**

   [45 CFR 46.101(b)(2)]. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND (ii) any disclosure of the human subjects responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, or reputation.

   1. Is the research involving the use of educational tests, survey/interview procedures or observation of public behavior? [ ] Yes [ ] No
   2. Is information recorder in such a manner that the subjects cannot be identified (directly or through identifiers)? [ ] Yes [ ] No
   3. Is research conducted in such a manner that there is no disclosure of the responses outside the research? [ ] Yes [ ] No
   4. No disclosure: subjects are not placed at risk of criminal or civil liability.
   5. No disclosure: subjects are not going to suffer damaging to their financial standing, employability, or reputation.
   6. Even though the human subjects can be identified (directly or through identifiers), the research is no greater than minimal risk.

3. **(Category 3) Research involving Public Officials**

   [45 CFR 46.101(b)(3)]. Research involving the use of education tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category (b) of
this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

1. Is the research involving the use of educational tests, survey/interview procedures or observation of public behavior? 
   - Yes □  No □

2. Is the population targeted for the research activity elected or appointed officials or candidates running for public office? **or**
   - Yes □  No □

3. Does the research program have federal statute and/or involves collecting data for specific federal programs?
   - Yes □  No □

4. Would the confidentiality of the personally identifiable information be maintained throughout the research and thereafter?
   - Yes □  No □

**Note:** The only circumstance in which an exemption application would be submitted to an IRB for consideration utilizing part (ii) of the criterion would be if a PI was issued a grant to conduct research involving specific programs by the Department of Justice or the National Center for Education Statistics.

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<table>
<thead>
<tr>
<th>(Category 4) Existing data</th>
</tr>
</thead>
<tbody>
<tr>
<td>[45 CFR 46.101(b)(4)]. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.</td>
</tr>
</tbody>
</table>

1. Is the research involving the collection or study of existing data, documents, records, and pathological or diagnostic specimens?
   - Yes □  No □

2. Is the source publicly available? **or**
   - Yes □  No □

3. Is the information recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers?
   - Yes □  No □

**Note:** OHRP interprets the term “existing” to mean that all of the data, documents, records, or specimens to be used in the research are in existence prior to IRB review and were collected for purposes other than the proposed research.

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<table>
<thead>
<tr>
<th>(Category 5) Demonstration Projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>[45 CFR 46.101(b)(5)]. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payments for benefits or services under those programs.</td>
</tr>
</tbody>
</table>

**Note:** Only projects that are conducted under federal statutory authority or the Social Security Act fit under this exemption criterion.

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<table>
<thead>
<tr>
<th>(Category 6) Agricultural Research</th>
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</thead>
<tbody>
<tr>
<td>[45 CFR 46.101(b)(6)]. Tests and food quality evaluation and consumer studies, (i) if wholesome food without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.</td>
</tr>
</tbody>
</table>
**Informed Consent**

1. Does the proposal have an informed consent or a letter of explanation attached?  
   - Yes [ ]  
   - No [ ]

2. If yes on 1, is the informed consent designed in such a manner that subjects are not placed at risk?  
   - Yes [ ]  
   - No [ ]

*Note:* Exempt research is not subject to federal regulations contained in 45 CFR 46 which include requirements for informed consent. Therefore, if the research is eligible for exemption, then “technically” informed consent is not required. It is up to the investigator to decide whether or not consent should be obtained and documented. Often the investigator will provide a letter of explanation or even a consent form. Again, this is not required by the federal regulations but may be the ethical thing to do to ensure the rights and welfare of the subjects are protected. If the research meets exemption criteria, the IRB may make suggestions on how the letter or form can be improved, but should not withhold approval to require revisions unless the study would not be eligible to be exempted without the changes.

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**HSRC Manager**

[initials]

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**FULLER THEOLOGICAL SEMINARY**

**HUMAN SUBJECTS REVIEW COMMITTEE**

180 N. Oakland Ave.

Pasadena, CA 91101
## Appendix D
### INITIAL REVIEW FORM

**Directions:** Please check the column to the right of each item if the project meets the listed requirements. Be sure to initial and date the document, and check the boxes at the bottom of the page.

<table>
<thead>
<tr>
<th>Regulatory Review Requirement</th>
<th>Questions to Guide Review</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The proposed research design is scientifically sound &amp; will not unnecessarily expose subjects to risk.</td>
<td>(a) Is the hypothesis clear? Is it clearly stated?</td>
<td></td>
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<tr>
<td></td>
<td>(b) Is the study design appropriate to prove the hypothesis?</td>
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<tr>
<td></td>
<td>(c) Will the research contribute to generalizable knowledge and is it worth exposing subjects to risk?</td>
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<tr>
<td>2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result.</td>
<td>(a) What does the HSRC consider the level of risk to be?: Low □ Medium □ High □ Other □ N/A N/A</td>
<td></td>
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<tr>
<td></td>
<td>(b) What does the PI consider the level of risk/discomfort/inconvenience to be? Low □ Medium □ High □ Other □ N/A N/A</td>
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<tr>
<td></td>
<td>(c) Is there prospect of direct research benefit to the subjects? (excluding payments made for participation)</td>
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<tr>
<td>3. Subject selection is equitable.</td>
<td>(a) Is it clear who is to be enrolled been identified? Men? Women? Minorities? Children (rationale for inclusion/exclusion addressed)? Seriously-ill/healthy volunteers?</td>
<td></td>
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<tr>
<td></td>
<td>(b) Are these subjects appropriate for the protocol?</td>
<td></td>
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<tr>
<td>4. Additional safeguards required for subjects likely to be vulnerable to coercion or undue influence.</td>
<td>(a) Are appropriate protections in place for vulnerable subjects, e.g., pregnant women, fetuses, socially- or economically-disadvantaged, decisionally-impaired? N/A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Informed consent is obtained from research subjects or their legally authorized representative(s).</td>
<td>(a) Does the informed consent document include the nine required elements? (See reverse)</td>
<td></td>
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<tr>
<td></td>
<td>(b) Is the consent document understandable to subjects?</td>
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<td>(c) Is it clear who will obtain informed consent (PI, nurse, other), and in what setting?</td>
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<td>(d) If appropriate, is there procedure for assent of children?</td>
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<td></td>
<td>(e) Is the IRB requested to waive or alter any informed consent requirement?</td>
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<tr>
<td>6. Subject safety is maximized.</td>
<td>(a) Does the research design minimize risks to subjects?</td>
<td></td>
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<tr>
<td></td>
<td>(b) Do the circumstances of the project warrant an observation team to ensure participant safety?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Subject privacy &amp; confidentiality are maximized</td>
<td>(a) Will personally-identifiable research data be protected to the extent possible from inappropriate access or use? N/A</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>(b) Are all special privacy &amp; confidentiality issues properly addressed, e.g., use of medical records, etc.?</td>
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<tr>
<td>8. Other</td>
<td>(a) Are there other issues that need to be addressed? (Please discuss in comment area, below)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**NOTES** (comments on a “no” answer above or items from #8):

**RECOMMEND APPROVAL** □  **MAKE CHANGES AND RESUBMIT** □  **REJECT** □

**Should the investigator be invited to attend the meeting?**  YES □  NO □
Appendix E
COMMENT SHEET

PROJECT NAME
INVESTIGATOR
REVIEWER: …….
DATE: ……

To facilitate communication between the reviewers (you) and the HSRC, please use the following form. For a resubmission, please pay careful attention to the findings from the previous full-committee review. You are reviewing to ensure that the previous findings have been adequately addressed. Please be clear in your explanations below, if any.

PLEASE SELECT THE APPROPRIATE OPTION:

☐ The resubmitted proposal meets the requirements of the committee and should be approved.

☐ Resubmission not complete

(insert comments here)

Should the investigator be invited at the next HSRC meeting? Yes ☐ No ☐

Thank you for reviewing this resubmission/addendum. Please be reminded to complete the informed consent checklist.
# Appendix F
## CONTINUING REVIEW FORM

**Directions**: Please check the column to the right of each item if the project meets the listed requirements. Be sure to initial and date the document, and check the boxes at the bottom of the page.

**Comment**: Although research might qualify for an expedited review, this would not be appropriate if project was initially reviewed by a convened IRB (full review) unless no recruitment has been initiated yet or the data collection is completed.

<table>
<thead>
<tr>
<th>Regulatory Review Requirement</th>
<th>Questions/Statements to Guide Review</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Continuing review date</td>
<td>(a) Is the continuing occurring within 1 year of the date of final approval? (see letter of approval)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(b) Is there a lapse in continuing review? (more than 1 year from project approval date)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Interim findings, amendments and modifications</td>
<td>(a) Any relevant recent literature, interim findings?</td>
<td></td>
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<tr>
<td></td>
<td>(b) If yes, does that alter the subjects’ treatment?</td>
<td></td>
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<tr>
<td></td>
<td>(c) Are there any modifications/amendments?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(d) If yes, does that alter the subjects’ treatment?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Additional risks to the subjects</td>
<td>(d) Is there any relevant new information about risks associated with the research?</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>(e) Any adverse events, unanticipated problems, withdrawal of subjects or complaints since the last review?</td>
<td></td>
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<tr>
<td></td>
<td>(f) If any modifications/amendments, are there additional risks for the subjects?</td>
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<tr>
<td></td>
<td>(g) The risks are reasonable in relation to anticipated benefits.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Informed consent</td>
<td>(f) Currently approved consent document is still accurate and complete</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Other</td>
<td>(a) Are there other issues that need to be addressed?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NOTES** (comments on a “no” answer above or items from #8):

**RECOMMEND APPROVAL** [ ] **MAKE CHANGES AND RESUBMIT** [ ] **REJECT** [ ]

**Should the investigator be invited to attend the meeting?**  YES [ ] NO [ ]
Appendix G
FINAL REPORT FORM

Use this form for all completed studies. “Completed” means that all study procedures, follow-up, phone calls or surveys are done, no future contact with the subject will occur.
Note: If the study never started, check box below, answer B and C, sign and return to HSRC.

A. APPROVED PROTOCOL

Principal Investigator: ________________________________

Title of Project: ________________________________

HSRC Approval #: ________________________________

B. DATE OF TERMINATION: _____________________

☐ Check if the protocol was never initiated.

C. REASON FOR TERMINATION
☐ Study Completed
☐ Grant/Contract was never funded
☐ Other (please explain, attach additional sheet if needed)

D. SUBJECT RECRUITMENT [Answer A and/or B]

a) How many subjects signed a consent form? _________

Did any subjects refuse participation? ☐ Yes ☐ No
If YES, explain why:

How many patients who gave consent were not enrolled?
Explain: ________________________________

b) How many subjects completed the study? _________

c) How many subjects ended the study early, and why? _________

E. SERIOUS ADVERSE EVENTS
Have there been any serious adverse events or unexpected reactions/complications during the course of this study?
☐ Yes ☐ No
If yes, provide a summary on a separate sheet.
F. NEW FINDINGS
Have there been any significant new findings (good or bad) that should be disclosed to subjects who have participated in this study?
☐ Yes ☐ No  
If yes, provide a summary on a separate sheet.

G. PROGRESS REPORT
On a separate sheet, provide a brief summary of research results, if known.
*only if applicable*
(i) a summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
(ii) any relevant multi-center reports, if applies; and
(iii) any other relevant information, especially information about risks associated with the research.

*H. STORAGE OF INFORMED CONSENT FORMS
[must be retained for six (6) years.]
Check one:
☐ PI will retain the consent forms
☐ Other party will retain the consent forms
Please specify name, title and involvement in the study if any:

☐ Consent forms will be retained by the institution that facilitated the data collection.
Please specify, if applicable __________________________________________

__________________________________  ___________________
Principal Investigator     Date

__________________________________ ___________________
Faculty Advisor (if PI is a student)     Date
Appendix H
INFORMED CONSENT CHECKLIST

<table>
<thead>
<tr>
<th>Yes/No</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a list of the researchers (both students and supervisors), a description of the procedures to be followed, and identification of any therapeutic procedures which are experimental;</td>
</tr>
<tr>
<td></td>
<td>2. A description of any reasonably foreseeable risks or discomforts to the subject;</td>
</tr>
<tr>
<td></td>
<td>3. A description of any benefits to the subject or to others which may reasonably be expected from the research;</td>
</tr>
<tr>
<td></td>
<td>4. A disclosure of appropriate alternative therapeutic procedures or courses of treatment, if any, that might be advantageous to the subject;</td>
</tr>
<tr>
<td></td>
<td>5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;</td>
</tr>
<tr>
<td></td>
<td>6. For research involving more than minimal risk, an explanation as to whether any psychological or medical treatments are available if distress or injury occurs and, if so, what the treatment might consist of, or where further information may be obtained;</td>
</tr>
<tr>
<td></td>
<td>7. 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 distress or injury to the subject;</td>
</tr>
<tr>
<td></td>
<td>8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;</td>
</tr>
<tr>
<td></td>
<td>9. A signature line for the subject or guardian to sign. However, the signature line may be omitted if the ONLY identifying information linking the subject and the research would be such a signature and there is risk of significant potential harm resulting from a breach of confidentiality. Each subject should be asked whether they want documentation linking them to the research and the wish of the subject should prevail.</td>
</tr>
</tbody>
</table>