Policy on Human Subjects Research & Review

Central Baptist Theological Seminary's Human Subjects Research Review Board (HSRRB) exists to promote and ensure ethical and responsible treatment of human subjects involved in research conducted at Central Baptist Theological Seminary (hereafter CBTS) by students, faculty, or other official entities of CBTS. Following the practice of many other theological institutions, CBTS accepts three historical documents–the Nuremburg Code (1949), the Helsinki Declaration (1964), and the Belmont Report (1979)–as expressing the general philosophical and ethical foundation of the HSRRB. The Belmont Report establishes three foundational requirements for the ethical conduct of human subject research: *Respect for persons* (involving a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy), *Beneficence* (entailing an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm), and *Justice* (requiring that the benefits and burdens of research be distributed fairly). The decisions of the HSRRB are informed by these three requirements and are governed by these HSRRB Policies and Procedures, and by federal policy (also sometimes called "The Common Rule") codified at Title 45 Part 46 of the Code of Federal Regulations. Where HSRRB Policies and Procedures and federal policy come into conflict, the federal policy will govern. This requires that all federally funded research must comply with the Common Rule. CBTS is committed to the standard that all research, not just federally funded research, involving human subjects will comply with federal policy as delineated in the Common Rule (45 CFR 46).

Policies

Definition of Terms

Research – Is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (45 CFR 46.102)

Human subject – Is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains data or private information (45 CFR 46.102)

Risk – Is defined as the extent to which a human, subject to research procedures, may be exposed to physical, psychological, or other types of harm.

Minimal risk – Refers to 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. (45 CFR 46.102)

Informed consent – Is defined as the subjects' willingness to participate after the researcher communicates to subjects, in language they can understand, information that the subjects may reasonably be expected to desire in considering whether or not to participate, and that minimizes the possibility of coercion or undue influence.

Assent – Is defined as a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Permission – Is defined the agreement of parent(s) or guardian to the participation of their child or ward in research.

Confidentiality – Refers to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

Privacy – Refers to the control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Protocol – Is defined as the formal design or plan of an experiment or research activity; specifically, the plan submitted to an HSRRB for review. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

Human Subject Review Board – Refers to the specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in behavioral research.

Full Review – Is defined as a review of proposals by the entire HSRRB. This will be conducted for research that involves greater than minimal risk, or if the research is of a psychologically sensitive nature.

Expedited Review – Is defined as a review by the chair of the HSRRB and/or one other member of the HSRRB for research that involves no more than minimal risk, or to review minor revisions in previously approved research, or review revisions for proposals that were approved with contingencies.

Exempt Status – Is defined as a research proposal where the subjects are at no more than minimal risk, the subjects' confidentiality is maintained, and the proposal meets one of the five criteria for exemption.

Jurisdiction of the CBTS HSRRB

When CBTS faculty, staff, or students, are involved in research conducted with human subjects at risk, the research activity must be reviewed by the HSRRB. The HSRRB has the authority to approve, require modification in, or disapprove of all such research activities. Further, the HSRRB has the authority to suspend or terminate approval of research that is not in compliance with the HSRRB's determinations and is, or has been, associated in the execution with unexpected risk to subjects. For HSRRB purposes these decisions are based on the criteria set forth in these HSRRB Policies and Procedures and the Federal Policy.

Human subjects are involved if: 1) there is an intervention or an interaction with a living person that would not be occurring or would be occurring in some other fashion, but for research, or 2) identifiable

private data/information will be obtained for this research in a form associable with an individual. For example, secondary analysis of aggregate data does not require HSRRB approval.

The HSRRB has the authority to suspend or terminate approval of a project that is determined not to be in compliance with CBTS's mission, practices, or policies, or one that has been approved but during its execution is determined to have incurred unexpected risks. For HSRRB purposes these decisions are based on the criteria set forth in these HSRRB Policies and Procedures and applicable local, state, federal, or international governmental regulations and/or policies.

Dissertation and Thesis Projects

All faculty review and approval processes applicable to Doctor of Ministry (DMin) or Master of Arts in Theological Studies (MATS) dissertation and thesis proposals must be completed before the proposal will be considered by the HSRRB. Not all projects and theses are subject to HSRRB review. Determination should be made by the DMin or MA(TS) Director and the student's project or thesis advisor.

HSRRB Membership

The HSRRB at CBTS shall consist of at least three members with varying backgrounds from the Faculty Senate in addition to the Provost, the Director of the DMin program and the Director of the MATS program. To the degree possible membership shall include both genders, representation from racial and cultural backgrounds, representation from practice of ministry and academic course areas, and at least one person who has had experience in the planning and conduct of research with human subjects. Appointments to the HSRRB are for three-year revolving terms. Temporary appointments will be made to complete a term in the instance of a vacancy. Members will be appointed by the Dean, who will designate one member to serve as Chair. The HSRRB may, at its discretion, invite persons with appropriate competencies to aid in its review of complex issues.

HSRRB Meetings

To conduct the business of the HSRRB, at least four of its members must be present. The HSRRB shall approve or disapprove research only with the concurrence of a majority of those members in attendance. The HSRRB will convene at regularly scheduled meetings on dates published in advance. The HSRRB will hold extraordinary meetings at the call of the Chair.

Research proposals must be submitted to the HSRRB at least seven (7) days before its meeting. Any research proposals submitted to HSRRB for a full review will be distributed to the members at least five (5) days prior to a meeting. Notification of the action taken by the HSRRB will be sent to the investigator no later than five (5) days after the meeting. Notification will be made in a standard form. It will, if necessary, include a description of any contingencies and, in the case of disapproval, include a statement of the HSRRB's reasons.

HSRRB Records

The HSRRB shall maintain the following records:

1. Copies of all applications reviewed, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

2. Minutes of HSRRB meetings which shall be in sufficient detail to document: attendance at the meetings; actions taken by the HSRRB; 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.
3. Records of continuing review activities.
4. Copies of all correspondence between the HSRRB and the investigators.
5. A list of HSRRB members in the same detail as described in 45 CFR 46.103(b)(3).
6. Written procedures for the HSRRB in the same detail as described in 45 CFR 46.103(b)(4) and 46.103(b)(5).
7. Statements of significant new findings provided to subjects, as required by 45 CFR 46.116(b)(5).
8. The records required by this policy shall be retained for at least 3 years, and records relating to research that is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times in a reasonable manner.

Procedures for Research Review Projects

Summary of the Review Process

1. The investigator identifies a research project. If the investigator is a student he or she discusses the project with his or her faculty advisor.
2. The required forms are completed following the guidelines available on the HSRRB section of CBTS's Moodle website.
3. The completed application form is signed by the investigator(s), and, where appropriate, the faculty advisor, and submitted to the HSRRB Chair with any required supporting documentation, such as the 100-150 word abstract of the proposed study, copies of cover letters, informed consent forms, surveys or questionnaires, letters of agreement from cooperating institutions, etc. If the application is incomplete it may be returned to the applicant without being reviewed.
4. Applications claiming Exemption from HSRRB Review will be evaluated by the HSRRB Chair to determine whether the proposal qualifies for exemption as involving minimal risk, falling within one of the five criteria for exemption specified in these procedures and policies, and meeting appropriate consent and confidentiality requirements. Applications for Expedited Review will be routed to the HSRRB Chair and one HSRRB member for evaluation and determination. Applications for Full Review will be scheduled for the next meeting of the HSRRB for which submission deadlines have been met.
5. A formal letter of approval or disapproval is sent by the Chair of the HSRRB to the principal investigator. In the case of required or suggested modifications, the principal investigator may be asked to "Revise and resubmit" the application.
6. If the application is disapproved, the investigator may appeal the decision.
7. All investigators will complete and submit a Continuing Review Form at the end of each academic year and a Project Completion Form upon completion of the project.

Types of Reviews

There are three types of research proposals:

1. Those that require Full Review by the HSRRB.
2. Research that meets specific criteria for an Expedited Review.
3. Proposals that are Exempt from HSRRB review.

A description of each type of research proposal and instructions for completing the application process is presented below.

Full Review

A full review by the HSRRB will be conducted for research that involves greater than minimal risk. A full review must be conducted at a meeting of the HSRRB under the procedures established below. In order to approve research under a full review, the HSRRB will consider the following:

1. Risks are reasonable in relation to expected benefits and minimized by the use of the safest procedures consistent with standard research practices.
2. Selection of subjects is equitable, taking into account the purpose of the research.
3. Privacy of the subjects and confidentiality data are protected.
4. Informed consent is obtained and documented.

Proposals for full review must include an original and six copies of a fully completed Application together with associated descriptions, forms and materials called for by the Application.

Expedited Review

An expedited review by the HSRRB will be conducted for research that involves no more than minimal risk, or to review minor changes in previously approved research, or review revisions for proposals that were approved with contingencies. An expedited review may be conducted by the HSRRB chair and by one or more reviewers designated by the Chair from among HSRRB members. In order to ensure that all members have involvement in the expedited review process, the chair will designate reviewers on a rotating basis. Care will be taken in the selection of expedited reviewers to avoid a conflict of interest.

The chair of the HSRRB will make the final decision regarding approval of proposals that were revised and resubmitted for expedited review. When an expedited review procedure is used, all HSRRB members will be advised of research proposals that have been approved under the procedure. If issues of concern arise in the process of full or expedited review, the investigator will be provided the opportunity to respond to those concerns prior to any action on that review.

Proposals for expedited review must include an original and one copy of a fully completed application with all associated descriptions, forms and materials.

Exemptions from HSRRB Review

Exemptions from HSRRB Review pertain to research where the subjects are at no more than minimal risk, the subjects' confidentiality is maintained, and the research meets at least one of the five criteria for exemption in the federal policy and set forth below. Research proposals that meet the criteria for exempt status must still be processed through the HSRRB. The chair of the HSRRB will make the decision regarding exemption approval when an application contains a Request for Exempt Status. Although a research project may meet the criteria for exempt status, it does not mean the study is exempt from

meeting federal regulations regarding informed consent and storage of confidential materials. Proposals approved for exempt status are not required to submit a Continuing Review or Project Completion form.

In the case of minors, only research conducted in established or commonly accepted educational settings may be considered for exempt status, and then only under conditions and related to topics clearly defined by the HSRRB.

Proposals requesting exempt status must include one original copy of a fully completed application with all associated descriptions, forms, and materials.

The following types of research are exempt from the required review (45 CFR 46.101b):

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 if it is determined that there would be no adverse effect upon the learners or teacher. This is the only area of exception that may apply to minors, whereby the researcher is the minor's teacher, instructor, therapist, etc.
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; or (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal of civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving benign behavioral interventions where information is collected via verbal or written responses such as surveys or interviews, data entry, or observation of the subject(s), including audiovisual recording. This exemption does not permit data collection via physical procedures such as physical sensors (e.g. blood pressure monitors, EEG, FitBits) or minimally invasive procedures (e.g. blood draw or saliva collection).

The researcher must obtain "prospective agreement to the intervention and information collection" within the consent form, and there is to be no deception, except where the subject is told that they will be unaware or misled about the nature or purposes of the research and they agree to the process. Debriefing is still encouraged.

Self-exemption is permitted for projects that do not involve deception and where information collected is not identifiable or not sensitive. Limited Review is required for projects collecting sensitive and identifiable data.

1. Research involving the collection or study of existing data, documents, records or other artifacts, 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.
2. Research and demonstration projects which are conducted by or subject to the approval of deferral department or agency heads, and which are designed to study, evaluate, or

otherwise examine: (i) public benefits or services 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.

Possible Review Outcomes

Review of an Application may result in one or a combination of the following outcomes: (1) the proposal does not qualify for the level or review claimed as appropriate; (2) the proposal is approved as submitted; (3) the proposal is approved with specified required revisions; (4) the proposal must be revised and resubmitted; (5) the proposal is disapproved.

Informed Consent

In order to involve a human subject in research, a researcher must obtain the legally effective informed consent of the subject or the subject's legally authorized representative. Special care should be exercised when the subjects are legal minors or adults legally incapable of giving consent. Informed consent shall be documented by the use of a written consent form approved by the HSRRB (see HSRRB section of CBTS's Moodle website for a Sample Informed Consent Form and Sample Implied Consent Letter) and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form. By federal law, researchers are to keep signed informed consent forms for three years. (45 CFR 46.116)

In seeking informed consent, the following information should be provided to the subject:

1. A statement that the study involves research, an explanation of the purposes of the research and who will be conducting the research, expected duration of the subject's participation, a description of the procedure to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject (again, these may be emotional or psychological or social or financial in addition to physical risks);
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, if any, that might be advantageous to the subject;
5. A description of how the confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation is available, or whether any remediation is available if injury occurs and, if so, what it consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research (usually the investigators), of research subjects' rights (usually the HSRRB Chair), and whom to contact in the event of a research-related injury to the subject (usually the HSRRB Chair);
8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

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

1. A statement that a particular procedure may involve risks to the subject 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.

Copies of signed consent forms must be retained for three years after completion of the research and must be available for HSRRB review if necessary.

Appeals

In the instance of HSRRB disapproval of a project, or of a contingency approval, an investigator may request an appeal hearing before the HSRRB in full. Records and notice of action will be provided.

No other CBTS approval may be provided in opposition to HSRRB disapproval. However, HSRRB approved projects may be disapproved by other offices of the seminary.

Project Completion and Continuing Review

All investigators will complete a Continuing Review Form at the end of each academic year and a Project Completion Form upon the completion of the project. Forms will be sent by the HSRRB Administrator to the principal investigator. Once a research project is determined to be complete, all associated documents on file in the office of the HSRRB Chair will be retained for three years. It is the principal investigator's responsibility to provide secure storage of the Informed Consent forms and any audio/video tapes or photographs. These items must also be maintained for three years.