

STANDARDS AND PROCEDURES FOR REVIEW OF PROPOSALS FOR RESEARCH WITH HUMAN PARTICIPANTS

All Programs, Claremont School of Theology

Introduction

All students whose research involves gathering information from human participants must follow these standards and procedures. The purpose is to ensure an adequate review of the research design regarding two central ethical concerns:

- That human subjects are treated in a manner consistent with their dignity and autonomy – specifically that they consent freely and in an informed manner to participation in the research.
- That they are protected from risks or harms that could be posed by the research. This includes assurance that their privacy is protected.

The Institutional Review Board at CST sets standards and oversees the procedures in order to protect the wellbeing of human research participants. A research plan must be submitted for IRB review and approval *prior to recruiting participants and beginning the actual research*. Course-related assignments that (1) are likely to seek eventual publication or (2) carry more than minimal risk to human participants must also be reviewed by the IRB. Any project involving protected classes or vulnerable populations (e.g., persons who are mentally impaired, victims of crime or abuse, or under legal age of consent) always require IRB approval.

No research participants may be approached, for pilot work or for the main study, until the researcher is formally notified that the proposed research plan has either been exempted by the IRB chair or has been approved by the IRB. Significant changes to the research plan after initial approval must also be approved by the IRB.

Students should gain the endorsement of their supervising faculty members and submit the endorsement along with the research plan for their proposed project. The advisor or mentor will assist the student with the IRB process, but obtaining IRB approval is the responsibility of the student. No project can receive final approval from the faculty mentor until IRB approval has been granted, but IRB approval does not guarantee final approval by the student's academic mentor/advisor. The IRB is charged only with ethical oversight regarding the well-being of human participants and not with academic oversight of any project.

Process for IRB submission

The IRB normally conducts its business via email. All correspondence to the IRB must be directed to the chair of the IRB and will be distributed by the chair as needed. The chair will convey IRB Decisions promptly. The chair may call for special, in-person, meetings of the IRB as needed.

- Proposals may be submitted at any time **during spring and fall semesters, but will be reviewed only after the first Monday of each month between September and December, and February and May.**
- The IRB does not conduct business during the summer term, winter break or other school holidays.

- The chair of the IRB will respond to the proposal within 14 days (with the exceptions noted immediately above).
 - The IRB chair may return the proposal to the researcher for revisions and resubmission. Projects that are under revision may not go forward until approval is granted from the IRB chair.
 - The IRB chair may declare the project as exempt from review by the full IRB. Exempt research may commence as soon as notice is received from the IRB chair. Exemptions may be granted to projects which meet three criteria:
 - (1) the project carries no more than minimal risk to the human participants;
 - (2) the project does not collect any personal identifiable information; and
 - (3) the project falls within the normal activities of educational enterprises.
 - The IRB chair may submit the proposal to the full IRB for full review and may appoint a member of IRB to make suggestions to the full committee. Full IRB review will be completed within 14 days from the date of the chair's distribution of the proposals to the committee (with the ~~two~~ exceptions noted above).
 - The IRB can approve, conditionally approve or disapprove the research plan. Only after IRB approval may the project go forward.

Many D.Min. or other qualitative or quantitative research projects carry no more than minimal risk to participants. *Minimal risk* means that the probability and magnitude of physical or psychological harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life.

If the IRB chair determines that the project poses more than minimal risk, a full IRB review will be required. Possible risks include:

- participants include protected classes or vulnerable populations (e.g., persons who are mentally impaired, victims of crime or abuse, or under legal age of consent); or
- responses or observations of the subject being recorded in such a way that direct identification of the subject may be possible; or
- the responses or observations of the subject, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability; or reputation, or
- the research deals with sensitive aspects of the subject's own personhood or behavior, such as exposing sensitive personal information or secrets, illegal conduct, drug use, sexual behavior, or use of alcohol; or
- participation in the investigative process may produce negative emotional, psychological, behavioral, or relational responses in some research subjects.

IRB approval demonstrates only that the human research participants have been adequately protected and does not imply anything about the academic merit of the project.

Annual Renewal by IRB

Projects for which the data collection is not completed within one year of initial IRB approval must seek renewed approval from the IRB. The process for renewal is submission of the original proposal with an addendum which explains any changes to the original research protocols and the new projected dates for completion of data collection. Projects which have not completed their data analysis, but which have completed their data collection do not require renewal.

IRB Proposal Format

See Appendix A for the format to follow. All the specified information must be included in your proposal.

Requirements for Informed Consent

Informed consent must be obtained in writing from all participants prior to the initiation of research. The informed consent document will assure confidentiality within the limits of the law. The information given to the participant should be in language understandable to the participant. Research involving participants who are not able to give legal consent (e.g., persons under 18 years of age or with cognitive impairments) requires the written consent of participants' parents or guardians and (when possible) written assent of the participants. The IRB is especially aware of the special considerations required for research involving vulnerable populations. Informed consent may not include any language through which the participant is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the researcher, the advisor, or the school from liability or negligence.

Submissions that lack clear evidence of the participant's informed consent will not be approved under any circumstances. The chair will always return such proposals to the researcher for revision.

Appendix B is a checklist of items that must be included in an informed consent document. Two sample documents are also provided (Appendices C and D).

Confidentiality/Anonymity

Researchers shall respect and attempt to protect the privacy of research subjects. Researchers shall protect confidential information given them, advising subjects in advance of any risks or limits upon their ability to insure that the information will remain confidential/ anonymous. Researchers shall document procedures for protecting confidentiality and shall document that these procedures were implemented and honored during the entire course of the study.

Permission to Obtain or Release Personal Information

CST does not allow any personally identifiable information regarding human research participants to be released in any school sponsored research or publication. This includes master's theses and doctoral dissertations. All personally identifiable information about human test participants must be fully anonymized before being included in any CST thesis, dissertation, public document or presentation.

However, study participants retain the right to release their personally identifiable information to third parties if the participants wish to release that information. Participants who wish to release their information to third parties (e.g., a therapist, counselor or pastor) should complete a Permission to Release or Obtain Personal Information form (a sample form can be in Appendix C of this document).

CST researchers who are seeking to obtain previously collected personally identifiable regarding their human research participants (e.g. records of prior therapy, counseling or interviews) may also do so by completing the same Permission to Release or Obtain Personal Information form (a sample form can be in Appendix C of this document) and securing the research participant's permission to examine this previously gathered information. Any information about a human research participant gathered through an authorized release of previously collected information is entitled to all the same protections and subject to all the same restrictions as information gathered directly from the test subject.

Non-English Program Guidelines: Programs that do not require facility in English for admission may develop alternative procedures to accomplish the goals of this policy in keeping with this policy's concern to maintain the highest ethical standards regarding the treatment of human participants involved in CST research.

Appendices

Appendix A: IRB proposal outline

Appendix B: Checklist for letters of consent

Appendices C & D: Sample letters of consent

Appendix E: Permission to release or obtain personal information

Appendix F: Sample faculty endorsement

The full IRB policy is available upon request from the IRB chairperson or the dean.

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Appendix A:
Claremont School of Theology
IRB Proposal Format

1. Date of submission
2. Project Title
3. Name(s) of Researchers
 - a. Principal Investigator
 - b. Department or Program
4. Project Period (beginning and ending)
5. Proposed funding sources, if applicable. Identify any potential conflicts of interest.
6. Summary of the research objective(s) (Explain what you hope to learn, demonstrate or achieve in 1 or 2 paragraphs)
7. Brief summary of the procedures to be utilized during the course of the research. Specifically identify those procedures, tests, or activities that will be used to collect data.
8. Describe the population(s) from which participants will be recruited, plans for the recruitment, and the consent procedures to be followed.
9. Summary of any risks of the topic, method, or to the population involved in the research plan.
10. Describe how participants' privacy and dignity will be protected.
 - a. Describe the procedures to assure confidentiality in the use, storage, and disposal of primary data
 - b. Indicate how long data will be maintained, where it will be kept, how it will be protected, and how it will be destroyed.
11. Describe how the outcomes of this project will contribute to a professional body of knowledge and/or benefit human welfare.
12. Include a copy of Informed Consent Form to be used.
13. Include the faculty advisor's endorsement of the research design.

Appendix B:
Claremont School of Theology
Checklist for Letters of Consent

Informed consent forms vary widely. We have provided two sample forms (Appendices C & D) in this document. You may adapt one of those forms for your purposes or create a form of your own. However, if you create your own form, it should contain the following elements.

- Title of the study
- Your name, contact information, and CST program
- Name of your faculty supervisor and his or her contact information
- A clear explanation that the consent is for a research study
- The purpose of the proposed research
- An explanation of how long the research and each stage of the process will take
- A statement indicating that the participants may decline to answer any or all questions
- A statement that participation is voluntary
- A statement that participants may withdraw from the study without penalty
- A statement of what compensation, if any, is being offered
- Description of all foreseeable risks, discomforts and inconveniences including physical, psychological, emotional, and financial risks
- Assurance of the confidentiality of the participants' information during the investigation
- Assurance of the anonymity of the study's public results
- A statement indicating whether or not the research findings will be available to the participants, and if so, how the findings will be communicated to them
- Include a statement indicating that the project has been reviewed and received clearance from the CST's IRB
- A notice that participants can express concerns or questions regarding their involvement in the study to the IRB chair (with contact information)
- A statement informing participants that they will receive a signed copy of the informed consent form to retain for their records

Appendix C:
Claremont School of Theology
Sample Letter of Informed Consent
for Participants Able to Give Legal Consent

Consent to Participate in Research

Identification of Investigator and Purpose of Study

You are invited to participate in a research study, entitled “[YOUR STUDY TITLE HERE].” The study is being conducted by [INSERT STUDENT NAME] under the supervision of [INSERT SUPERVISOR NAME] of Claremont School of Theology, 1325 N. College Ave; Claremont, CA 91711, [provide faculty’s email and phone #].

The purpose of this research study is to examine [YOUR INFORMATION HERE]. Your participation in the study will contribute to a better understanding of [YOUR INFORMATION HERE]. You are free to contact the investigator using the information below to discuss the study.

[INSERT YOUR ADDRESS, PHONE NUMBER AND EMAIL].

You must be at least 18 years old to participate.

If you agree to participate:

- The [ACTIVITY—interviews, counseling, type of interaction] will consist of approximately [APPROXIMATE TIME LENGTH OF STUDY—number, frequency and duration of interactions].
- Your participation is intended [purpose of study].
- Your participation will consist in [list exactly what the participants will do in detail]
- You [will or will not] be compensated. [COMPENSATION INFORMATION, including method of payment and timeframes for payment]

The purpose of this study is to gain insight into practical theology, pastoral care and/or spiritual care. Participation in this study should not be regarded as—or substituted for—therapy by a licensed professional.

Risks and Confidentiality of Data

There are [no known risks] or [some possible risks or discomfort which could cause you to feel uncomfortable, embarrassed, sad, tired, etc]. There will be no costs for participating. Your name, email address and other personally identifiable information [will or will not] be kept during the data collection phase. No personally identifiable information will be publicly released. Your personal information, if collected, will be used solely for tracking purposes. A limited number of research team members will have access to the data during data collection. Those research team members are: [List research team who will have access to data.]

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs, videos, or audio-tape recordings of your participation are used for educational purposes, your identity will be protected or disguised. Your information will be stored [until ?] and then destroyed.

Participation or Withdrawal

Your participation in this study is voluntary. You may decline to answer any question and you have the right to withdraw from participation at any time. Withdrawal will not affect your relationship with Claremont School of Theology in any way. If you do not want to participate, you may simply stop participating.

Contacts

If you have any questions about the study or need to update your email address contact the primary investigator **[INSERT NAME HERE]** at **[PHONE NUMBER]** or send an email to **[EMAIL ADDRESS]**. This study has been reviewed by Claremont School of Theology Institutional Review Board and the study number is **[STUDY NUMBER, the chair of the IRB will supply this number to the researcher]**.

Questions about your rights as a research participant.

If you have questions about your rights or are dissatisfied at any time with any part of this study, you can contact, anonymously if you wish, the chair of the Institutional Review Board by phone at (909) 447-6344 or email at irb@cst.edu.

Thank you.

❖ SIGNATURE OF RESEARCH PARTICIPANT

I have read the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form.

Name of Participant

Signature of Participant

Date

Address

Phone

Email

SIGNATURE OF INVESTIGATOR

Signature of Investigator

Date (same as participant's)

A copy of this document will be supplied for your records.

Appendix D:
Claremont School of Theology
Sample Letter of Informed Consent
for Persons Not able to Give Legal Consent

CONSENT TO PARTICIPATE IN RESEARCH

[Title of Project]

Parent Consent Form

We invite **[your child]** to participate in a research study conducted at the Claremont School of Theology by **[Researcher's Name]**, a student in the **[name program, Ph.D., M.A., D.Min, etc.]** program at Claremont School of Theology. This researcher may be contacted at any time at **[Student address, phone number and email]**.

[Faculty Member] is the CST faculty advisor for this study. **[Your child's]** participation in this study is voluntary. You should read the information below, and ask questions about anything you do not understand before deciding whether or not **[your child]** may participate.

- **PURPOSE OF THE STUDY**

The purpose of this study is to **[supply purpose]**.

The purpose of this study is to gain insight into practical theology, pastoral care and/or spiritual care. Participation in this study should not be regarded as—or substituted for—therapy by a licensed professional.

- **DURATION AND LOCATION**

Participation in this study will consist of **[describe frequency and duration of participation involvement]**.

- **PROCEDURE**

If you allow **[your child]** to participate in this study, we would ask them to **[describe EVERY expectation in detail]**.

- **POTENTIAL RISKS AND DISCOMFORTS**

Risks involved in this study include **[describe risks]**.

If at any time they feel uncomfortable, they are free to rest or to stop participating in the study.

- **ALTERNATIVES TO PARTICIPATION**

You have the right to refuse permission for [your child] to participate in this study. You may also choose to withdraw [your child] at any time from the study.

- **CONFIDENTIALITY**

When the results of the research are published or discussed in conferences, no information will be included that would reveal [your child's] identity. If photographs, videos, or audio-tape recordings of [your child] will be used for educational purposes, their identity will be protected or disguised. [Your child's] information will be stored [until ?] and then destroyed.

- **PARTICIPATION AND WITHDRAWAL**

Participation in this research is voluntary. If you do not allow your child to participate, that will not affect your relationship with Claremont School of Theology. If you allow [your child] participate, you are free to withdraw your consent and discontinue their participation at any time without prejudice.

- **WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR**

The investigator may withdraw [your child] from participating in this research if investigator believes that withdrawal from the study is in [the child's] best interest.

- **QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH PARTICIPANT**

If you have any questions about the study or need to update your email address contact the primary investigator [INSERT NAME HERE] at [PHONE NUMBER] or send an email to [EMAIL ADDRESS]. This study has been reviewed by Claremont School of Theology Institutional Review Board and the study number is [STUDY NUMBER, the chair of the IRB will supply this number to the researcher].

If you have questions about your rights or are dissatisfied at any time with any part of this study, you can contact, anonymously if you wish, the chair of the Institutional Review Board by phone at (909) 447-6344 or email at irb@cst.edu.

❖ **SIGNATURE OF PARENT OF RESEARCH PARTICIPANT**

I have read the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form.

Name of Legal Guardian

Name of Participant

Signature of Legal Guardian

Date

Address

Phone

Email

SIGNATURE OF INVESTIGATOR

Signature of Investigator

Date (same as participant's)

A copy of this document will be supplied for your records.

Appendix E:
Claremont School of Theology
Permission to Release or Obtain Personal Information

Participant's Name:

Date of Birth:

I hereby authorize [Name of Researcher] to (check one):

_____ obtain from the following

_____ release to the following

Name:

Address:

the following documents/information/information from the records pertaining to services received

Date of Service:

The documents to be released are described or listed as:

The records are required for the specific purpose of:

I understand that my authorization will remain effective from the date of my signature until, and that the information will be handled confidentially in compliance with all applicable federal laws. I understand that I may see the information that is to be sent, and that I may revoke the authorization at any time by written, dated communication. I have read and understand the nature of this release.

Signature of Participant/Participant's Designated Representative Date

Witness Date

**Appendix F:
Claremont School of Theology
Faculty Endorsement for Student Research**

I, [faculty name], have reviewed the research proposal “[Title of student project]” of [student name] and I have agreed to supervise this student research as a part of his or her research toward the following degree.

- Ph.D.
- D.Min.
- M.Div.
- M.A.
- Other (please specify) _____

I believe that the proposed project is consistent with customary academic research and that the project provides adequate protections for the human research participants.

Faculty Member

Faculty Signature

Date