California Baptist University

Institutional Review Board (IRB)
Human Subjects Research

Faculty and Student

IRB HANDBOOK

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IRB HANDBOOK

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CBU Guidelines for Research with Human Subjects

I. INTRODUCTION

California Baptist University (CBU) encourages scholarly research in and among its colleges and schools, as well as collaboration with other education institutions, agencies, and organizations. The University, while respecting faculty and students' academic freedom, firmly adheres to the basic ethical principles underlying what is acceptable practice in conducting research involving human subjects/participants.

ADHERENCE TO THE COMMON RULE - In 1991, fifteen Federal Departments and Agencies adopted a common set of regulations known as the *Federal Policy for the Protection of Human Subjects* or "*Common Rule."* (See http://www.hhs.gov/ohrp/; 45 CFR 46). These federal regulations require all institutions requesting and receiving funds from a federal department or agency for research involving human subjects (optional for all other institutions, BUT most comply) to assure that research is reviewed and approved by the University's Institutional Review Board (IRB). The regulations are based on three internationally recognized ethical Principals discussed in the Belmont Report (1979), as follows:

> ***Respect for persons*** incorporates at least two ethical convictions: "first, individuals should be treated as autonomous agents; and second, that persons with diminished autonomy are entitled to protection" (thus, the need to obtain informed consent).
>
> ***Beneficence*** entails treating persons "in an ethical manner not only by respecting their decisions, but also by making efforts to secure their well-being. . . Two general rules: (1) do no harm; and (2) protect from harm by maximizing anticipated results and minimizing possible risks of harm."
>
> ***Justice*** requires that the "benefits and burdens of research be distributed fairly" (thus, the Principle of justice is applied in the selection of research subjects).
>
> Belmont Report: *Ethical Principles and Guidelines for the Protection of Human Subjects*: http://ohsr.od.nih.gov/mpa/belmont

RESEARCH DEFINED – *Research* is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46.102 [d]). A project or study is research if it is (A) conducted with the intention of drawing conclusions that have some general applicability, and (B) uses commonly accepted scientific methods.

HUMAN SUBJECTS DEFINED – *Human subjects* are "living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information" (§ 45 CFR 46.101[f]). If either condition applies and the project or study qualifies as research, then institutional IRB approval is needed, as stipulated by the *General Rule at CBU* stated below.

GENERAL RULE AT CBU – Any and *all* research involving human participants conducted by CBU faculty, staff, and/or students, inside or outside the classroom (excluding student research conducted to complete requirements in a specific course; see Page 7), and/or anyone conducting research identified in any way with or at the University, *must* seek appropriate approval from the CBU Institutional Review Board (IRB). The various conditions and processes defining "appropriate approval" are set forth in this handbook.

WHO MAY CONDUCT RESEARCH AT CBU? – Generally speaking, employees (faculty, adjunct faculty, and staff) and enrolled students may conduct research under CBU's identity, collect data on the CBU campus, and engage in research with other universities and organizations. However, ***ALL*** human-subjects research undertaken by CBU faculty, staff, or students and/or any such research conducted that includes or is identified with CBU must first secure approval from the CBU Institutional Review Board (IRB). The Principal Investigator (PI) is *required* to apply for and secure approval *before* engaging in the research; specifically, beginning to recruit participants and collect data.

NOTE: Research under CBU's purview and oversight that begins prior to securing appropriate IRB approval places the researcher(s) and CBU at potential moral and legal risk. In such cases the University reserves the right to order the researcher(s) to terminate the research. In all cases *post hoc* IRB approval is **not** an option and such requests are *never* considered by the IRB.

Faculty Liability - All CBU faculty engaged in professional activities directly related to their position (teaching, research, administration, student advising, etc.) are covered under CBU's liability insurance, as long as such activities are legal and comply with stated CBU policies. Generally speaking, faculty members are considered "agents" of the University and, therefore, may expect University support and assistance in the event they are sued for professional activities related to their employment.

Course-Based Student Research - A full-time or adjunct professor who requires students to complete course-based "exempt" research assignments (see Page 7) must fill out a short *Exempt Student Research Declaration* and file it with the Office of Institutional Research, Planning, and Assessment (OIRPA) ***before*** allowing their students to engage in the research. The declaration form is available on the OIRPA website.

Outside Researchers - In very limited cases an outside researcher (OR)—a person not employed by CBU or not an enrolled CBU student—is granted permission to conduct research on the CBU campus among CBU employees and/or students. Only outside research directly related to CBU's mission and Christian ethos is eligible for potential approval, a subjective decision made by the Office of Institutional Research, Planning, and Assessment (OIRPA), with the Provost's consent. If permission is granted, the OR does not become an agent of CBU and may not obligate CBU in any way or manner.

Without exception the OR must seek and secure CBU IRB approval before attempting to engage in research at CBU. As part of the application process, the OR must identify and secure approval from a qualified CBU employee—Faculty member, Academic or Student Services administrator at or above the director level—to serve as their Campus Liaison. The Liaison may or may not assist with the actual research, but she/he must agree to represent the OR and the OR's research at CBU and assist the OR, as needed, to comply with all CBU policies and procedures. A specific IRB Review application form is required (Form C; Appendix F).

Faculty Research to Complete a Graduate Degree – Full-time or adjunct CBU faculty members and staff may seek IRB approval to conduct research among CBU students and/or personnel in order to complete a doctoral degree at another institution. Faculty members in this category must complete application Form A or Form B, as appropriate, and also provide the CBU IRB with a complete copy of the finalized IRB forms approved by the IRB at the institution where the degree is being completed, along with appropriate documentation stating the IRB application was approved. Upon review, the CBU IRB *may* accept (not guaranteed) the IRB determination from the institution where the degree is being pursued and, consequently, not require the researcher to provide all the materials mandatory when completing a full CBU IRB application. If the CBU IRB does not accept the sponsoring institution's approved IRB review, the CBU

faculty member is obligated to submit all the items listed on CBU IRB application and subsequently receive CBU's approval before beginning sample selection and data collection at CBU.

Research with other Universities or Non-Profit Organizations – CBU faculty, staff, and enrolled students are encouraged to engage in collaborative research with other universities and non-profit organizations. Before doing so, however, the CBU Principal Investigator (PI) is required to secure IRB approval prior to undertaking the joint research. The IRB approval process is the same as campus-based research, with additional information on the collaborating organization provided in the Research Description (See Appendix B). A written and signed research agreement is required and a copy is submitted with IRB application. Prior to implementation, all agreements are subject to review and alteration by CBU legal counsel.

Research with For-Profit Business/Commercial Organizations – CBU faculty, staff, and enrolled students are encouraged to engage in research for or with for-profit business and commercial organizations. The IRB approval process is the same as campus-based research, with additional information on the business or commercial organization provided in the Research Description (See Appendix B). In addition, before starting the research and as part of the documentation included with the IRB application, the PI must obtain a signed written agreement stipulating all aspects defining and governing the research project, including accountability, intellectual property, and liability issues defined for all participating parties. Prior to implementation, all agreements are subject to review and alteration by CBU legal counsel.

Preliminary Research or Pilot Studies - IRB approval is required *before* preliminary research or pilot studies are undertaken. Most often such activities are considered initial steps in larger research projects. If so, the preliminary research or pilot study must be included among the protocols explained in the Research Description (See Appendix B). In cases where preliminary research or a pilot study stands on its own, such research requires submitting an application to the IRB for review and potential approval.

Animal Research – At present a separate animal research IRB does not exist at CBU. If a proposed research study includes animal (non-human) subjects then the human-subjects IRB reviews the research, augmented by at least two guest members, selected by the IRB Chair, who are qualified in such matters.

CBU Research Restrictions – In an effort to protect the rights and welfare of CBU personnel and students, all CBU researchers are required to comply with the follow restrictions when conducting research at CBU:

1. CBU and outside researchers may NOT use the CBU e-mail system to recruit participants or collect data. Exceptions to this policy are rare and granted only by the Office of Institutional Research, Planning, and Assessment (OIRPA), with the Provost's approval. Only the CBU President or a vice president may suspend this policy and utilize the CBU e-mail system to collect data directly supporting administrative or academic purposes.
2. If extra credit is offered in a course for student participation in a research project, a suitable alternative to earn extra credit must be offered to those students declining to participate.
3. In order avoid any perceived coercion to participate, full-time and adjunct faculty members may *not* recruit students in their courses to participate in research in which they serve as PI or Co-PI.
4. CBU undergraduate students are ***not*** permitted to serve as the PI in research studies conducted among a protected class of subjects (see 45 CFR 46, Subpart B, C, and D). CBU master's level graduate students may serve as a Co-PI along with a CBU faculty member. Only faculty and CBU doctoral students may serve as a PI in research involving a protected class of subjects.

II. IRB REVIEW CATEGORIES FOR HUMAN SUBJECTS RESEARCH

IRB approval is applied for and potentially granted based on one of four (4) categories (plus a specific category, not listed here, for "outside" researchers; see Page 5):

1. Exempt Student Research (course-based, required research)
2. Exempt (qualifies under one or more federally-defined categories)
3. Expedited (does not mean "accelerated" or quick review; not exempt, but less than a full review)
4. Full Review (convened IRB)

EXEMPT STUDENT RESEARCH

Required form: *Exempt Student Research Declaration* (Appendix C)

Criteria for Exempt Student Research – At CBU ***course-based***, required student research projects are deemed "classroom instruction" and formal IRB review is not necessary ***if*** the student research meets ***all*** six of the following criteria:

1. Based on instruction, supervision, and assessment by the course instructor.
2. Occurs in a classroom, department, student housing, or other campus setting, or in a public setting with unlimited access, such as a shopping mall, park, etc.
3. Involves learning research methods and is *not* intended for generalization (e.g., publication or public dissemination).
4. Involves **no** more than minimal risk to the subjects/participants (see "Minimal Risk" in the *Glossary*).
5. Qualifies under at least one exempt category stipulated in federal regulations, DHHS 45 CFR 46.101 (see *Exempt Categories* in *the next section and/or* available in InsideCBU under the Inst Research tap, *IRB*, *Does my Research Need IRB Approval?*).
6. Data are recorded anonymously (i.e., no subject names or any other information or codes that can link subjects to a list of names and/or might identify subjects through their behavior).

Professors who require their students to engage human-subjects research are expected to know and practice the applicable federal and CBU policies and procedures for protecting the rights and welfare of human research participants. Assuming compliance, the conditions stated previously in the "Faculty Liability" section (Page 5) are in effect.

Faculty members who are not certain about any or all criteria listed above are invited to contact the CBU IRB Chair at IRB@calbaptist.edu or (951) 343-4925.

Exempt Student Research Declaration – A CBU Faculty Member, the Instructor of Record, who requires the students in her/his course to complete a research project in compliance with the criteria set forth above, must *first* complete and file an *Exempt Student Research Declaration* form with the IRB—Office of Institutional Research, Planning, and Assessment (OIRPA)—*before the students begin their data collection*. One (1) Declaration submission is required for *each project* (assuming all students are doing the same or similar research projects), *in each* course, and the *Declaration* must be renewed *each* semester or calendar year as appropriate. In the case where a course has multiple sections taught by different faculty and a research project is required in the various sections, each Instructor of Record is required to file a *Declaration.*

The declaration form (Appendix C) is available on the OIRPA/IRB website or in InsideCBU under the *Inst Research* tab, *IRB*, *forms*. After reviewing the *Declaration, **if*** the IRB Chair determines the project is not exempt the professor is notified and told what corrective action is necessary.

Not Exempt Student Research – When a faculty member chooses to have students design and conduct individual research projects that *do not qualify as exempt research*, *each individual student project must be submitted to the IRB for review* and receive IRB approval *before* data collection may begin. In such cases, please note carefully the next paragraph.

Non-exempt student research projects intended for completion during the fall semester require submitting an IRB application no later than October 10; non-exempt projects completed during the spring semester require submitting an IRB application on or before February 10. It is the supervising faculty members' responsibility to familiarize themselves with CBU policies and procedures for approving research, to review and, if necessary, assist students in modifying each project *before* it is submitted to the IRB. If requests for IRB review are not submitted as stated above, securing IRB approval and completing the projects may not be accomplished in a timely manner.

Masters or Doctoral Research – All student research intended to satisfy requirements for completing a master's or doctoral degree *MUST* be submitted by the individual student to the IRB for formal review under one classification category: exempt, expedited, or full review (convened IRB). Data collection must ***not*** begin prior to securing IRB approval.

EXEMPT RESEARCH

Required form: *Form A – Exempt Research Project* (Appendix D)

Exempt Research – Some research involving human subjects may be **exempt** from federal regulations, but still needs IRB approval described in this section. Applications submitted to the IRB for exempt review that in fact do not meet the exempt criteria are usually delayed because the Principal Investigator (PI) is required to withdraw the application (Form A) and resubmit a revised application using the appropriate review category, either expedited or full IRB review (Form B). Please make review category selections carefully.

Exempt Categories – The federal regulations, 45 CFR 46, identifies six minimal-risk exempt research categories. CBU follows the federal guidelines and classifies research as exempt if it fits into one or more of the following categories:

(1) **Research conducted in established or commonly accepted CBU educational settings**, involving normal educational practices, such as. . .

   A. Research on regular and special-education instructional strategies, or
   B. Research on the effectiveness of or comparison among instructional techniques, curricula, classroom management methods, or student learning outcomes (assessment, program review).

(2) **Research using survey questionnaires, interview procedures, educational tests,** (cognitive, diagnostic, aptitude, and achievement), **or observing public behaviors** are exempt**, *unless*** one or more of the following potentially negative consequences are **true:**

A. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects.

B. Any disclosure of the human subjects' responses outside the search could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

C. The human subjects are elected or appointed public officials or candidates for public office.

D. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

E. Research subjects are minors (under 18 years old in California); research involving survey or interview procedures or research involving observing public behavior in which the researcher participates in the activities being observed is ***not*** **exempt**. However, research involving the use of educational tests and research involving observing public behavior in which the researcher(s) do not participate in the activities being observed ***are*** exempt.

(3) **Research involving the collection or study of existing data (archival), 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.

(4) **Research and demonstration projects which are conducted by or subject to approval by department or agency heads are exempt –** The proposed research is designed to study, evaluate, or otherwise examine any of the following:

A. Public benefit or service programs.

B. Procedures for obtaining benefits or services under those programs.

C. Possible changes in or alternatives to those programs or procedures.

D. Possible changes in methods or levels of payment for benefits or services under those programs.

(5) **Taste and food quality evaluation and consumer acceptance studies** – Research that involves (A) wholesome foods without additives are consumed or (B) 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.

(6) **Oral History Research –** The Office for Human Research Protection in the U.S. Department of Health and Human Services has determined that oral history interviewing projects are exempt from board review. This does not mean interviewing projects in general, but only those that fit within the definition of oral history. For further information, see the posting by the Oral History Association at http://omega.dickinson.edu/organizations/oha/org_irbquestion.html.

The IRB makes the final determination on whether or not the research project does in fact meet the criteria for at least one exempt category. If an exempt status is appropriate and confirmed, **no expiration date** is listed in the approval notice (e-mail) and exempt studies **do not require an annual review**.

The Principal Investigator (PI) is required to **close-out the exempt project** (see page 15) when it is completed or if she/he leaves CBU. Faculty mentors responsible for overseeing student research projects must ensure these studies are completed and closed-out in an appropriate manner before the students leave CBU.

IF Not Exempt Research – Any research failing to conform to the characteristics cited in one of the previous six categories is ***not*** exempt and, therefore, must seek either an expedited review or a full review by the convened IRB, options which are explained beginning on the next page.

PROCESS TO FILE <u>EXEMPT</u> STATUS WITH THE IRB:

IMPORTANT: The final decision on whether or not a study involving human subjects is exempt may ***<u>not</u>*** be made by the Principal investigator (PI) or anyone participating in the research in any role. Professors requiring their students to complete course-based exempt research must file an *Exempt Student Research Declaration* form ***prior*** to allowing the students to begin data collection. The steps listed on the next page are required.

Please complete:

1) The appropriate CBU form to request **exempt** status (forms are shown in the Appendices and are available on the OIRPA/IRB website or InsideCBU):

   - *Exempt Student Research Declaration* ("2" below is not required; Appendix C)
   - Form A – *Exempt Research Project* (Appendix D)
   - Form C – *Outside Research Project* (for non-CBU persons) (Appendix F)

2) A *Research Project Description* (see Appendix B) as well as all other documentation listed on the application form.

Submission and Review: Once a *complete* application is submitted via e-mail (IRB@calbaptist.edu) and received by the IRB, an IRB representative reviews the application and required documentation. Normally within 5-10 working days the PI (or Professor in cases dealing with classroom-based student research) receives an e-mail either approving the research as exempt and granting permission to begin data collection, or the logic for withhold approval along with further instructions.

Exempt research may be approved by the IRB Chair or by the Chair's designee. Exempt approvals may be also reviewed by the IRB at their regular meetings.

EXPEDITED IRB REVIEW

Required form: *Form B – Expedited or Full Review Research Project* (Appendix E)

Expedited Review ("expedited" does NOT mean quick or accelerated review) **–** Research activities that (A) present no more than minimal risk (see *Glossary*) to human subjects, and (B) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review

procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed do not necessarily constitute minimal risk simply because they are included on this list. Inclusion on this list merely means the activity is *eligible* for review through the expedited review procedure.

Research Categories Eligible for an Expedited Review – The eight categories listed here generally qualify for an expedited review. For further explanation, see http://www.hhs.gov/ohrp.

(1) Data collected from voice, video, digital, or image recordings made for research purposes.

(2) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

(3) Data collected through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

(4) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

(5) Clinical studies using drugs and medical devices when either an investigational new drug application or an investigational device exemption application is not required. Consult the Office of Human Research Protection for specifics; http://www.hhs.gov/ohrp.

(6) Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as per federal guidelines.

(7) Prospective collection of biological specimens for research purposes by noninvasive means, e.g., hair and nail clippings, excreta, skin swab, etc.

(8) Continuing review of research previously approved by the convened IRB:

   A. When . . .

      a. the research is permanently closed to enrolling new subjects;

      b. all subjects have completed all research-related interventions; and

      c. the research remains active only for long term follow-up of subjects; or

   B. When no subjects have been enrolled and no additional risks have been identified; or

   C. When the remaining research activities are limited to data analysis.

If the IRB approves the expedited application, approval is for **one year**, as noted on the e-mail approval notification. If the research is not completed within one year, the PI must submit a **renewal request** (see Page 12). The PI must file a ***Research Study Closure Report*** (see Page 12) when the research concludes.

IMPORTANT:

(1) All research involving subjects who are potentially vulnerable to coercion or undue influence—including minor children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons—***requires a full IRB review***.

(2) The IRB has the authority to not approve, suspend, or terminate research not conducted in accordance with the IRB's requirements and/or is associated with unexpected harm to subjects (45 CFR 46.111).

The process for requesting an expedited IRB review is provided on the next page.

PROCESS FOR REQUESTING AN EXPEDITED IRB REVIEW

Please complete and submit to the IRB via e-mail at IRB@calbaptist.edu, the following**:**

1) The appropriate CBU form for an **expedited review** (forms are shown in the Appendices and are available on the OIRPA/IRB website or InsideCBU):

   - Form B – *Expedited or Full Review Research Project* (Appendix E)
   - Form C – *Outside Research* (for non-CBU persons) (Appendix F)

2) A *Research Project Description* (see Appendix B) as well as all other required documentation listed on the application form.

Applicants can expect to receive a response from the IRB in 10-15 or fewer working days. In cases where this timeline cannot be achieved, the applicant is contacted by the IRB and told when to expect a response.

Expedited research may be approved by the Chair of the IRB or by Chair's designee. Approvals under expedited procedures are reviewed at regularly-scheduled IRB meetings.

FULL IRB REVIEW

Required form: *Form B – Expedited or Full Review Research Project* (Appendix E)

Criteria – Research involving more than minimal risk, sensitive topics, invasive medical/physical protocols, or is not covered by the exempt or expedited categories, requires full review by the convened IRB.

Research on Vulnerable Populations – All research that involves vulnerable populations (e.g., fetuses, pregnant women, prisoners, or groups who may have diminished capacity to provide consent or other persons who may be high risk) ***must*** undergo a full review by the convened IRB. See 45 CFR 46.201 - 207, pregnant women; 46.300-306, prisoners; 46.401 - 409, children and minors (except as included under exempt and expedited categories).

Sensitive Topics Requiring Full Board Review:

1. Sexual orientation, attitudes, preferences, or practices
2. Illegal or punishable conduct, including use of alcohol, drugs, or other addictive products
3. Information that could damage an individual's financial standing, employability, or reputation
4. Information (usually in medical records) that could lead to social stigmatization or discrimination
5. Psychological well-being or mental health, including physical or mental abuse
6. Incest, rape, date rape, or sexual molestation
7. Genetic information

8. Religious orientation or views
9. Veteran or wartime experiences

If the IRB approves the full-review application, approval is for **one year**, as noted on the e-mail approval notification. If the research is not completed within one year, the PI must submit a **renewal request** (see Page 13). The PI must file a ***Research Study Closure Report*** (see Page 13) when the research concludes.

PROCESS FOR REQUESTING AN IRB FULL REVIEW

Please complete and submit to the IRB via e-mail at IRB@calbaptist.edu, the following**:**

1) The appropriate CBU form for requesting a **full review** (forms are shown in the Appendices and are available on the OIRPA/IRB website or InsideCBU):
   - Form B – *Expedited or Full Review Research Project* (Appendix E)
   - Form C – *Outside Research Project* (for non-CBU persons) (Appendix F)
2) A *Research Project Description* (see Appendix B) as well as all other required documentation listed on the application form.

An IRB review application needing full review necessitates a convened IRB meeting called for that purpose *or* the application is reviewed at the next IRB meeting immediately following the date the *complete* application is submitted to the OIRPA/IRB. Applicants may expect to receive notification within 10 to 15 working days following a *complete* submission; the IRB does everything possible to achieve the minimum response time.

III. INFORMED CONSENT

No investigator may involve human beings as subjects in research covered by CBU policies unless the investigator first obtains legally effective informed consent from the subjects or the subjects' legally authorized representative/guardian, unless an exception to this policy is warranted based on criteria set forth in this section. For more information, consult 45 CFR 46.116.

Basic Elements of Informed Consent (See Appendix G – *Informed Consent Check List*)

(1) A statement that the study involves research, an explanation of the research **purposes** 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 a 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 subjects' rights, and who to contact in the event of a research-related injury to the subject;

(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) Informed consent must be documented by the use of a **written consent form** and signed by the subject or the subject's legalized representative. A copy is given to the person signing the form;

(10) The name, address, and telephone number of the principal investigator of the research project, and his/her affiliation with California Baptist University. If the principal investigator is a student, the name and telephone number of the faculty advisor is also required;

(11) A statement informing the subject that inquiries regarding the nature of the research his/her rights as a subject, or any other aspect of the research as it relates to his/her participation as a subject can be directed to the Office of Institution Research, Planning, and Assessment (OIRPA) at California Baptist University; IRB@calbaptist.edu.

(12) **Bill of Rights or Research Participants** (Appendix H) – This additional document is included with the consent form if human subjects are involved in an experimental procedure.

(13) **Authorization for Use of Private Health Information** (Appendix I) – Required if personal information considered "Protected Health Information" is used in the study.

Additional Elements for Informed Consent – When appropriate, one or more of the following information elements shall also be provided to each subject:

(1) A statement explaining the particular treatment 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 participating in the research;

(4) The potential consequences, if any, resulting from a subject's decision to withdraw from the research plus the orderly process by which a subject terminates her/his participation;

(5) A statement explaining that any significant new findings developed during the research which may relate to the subject's willingness to continue participating will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

Assent from Minors – If research subjects are minors (less than 18 years old in California), their parents or guardians must give consent and assent must be secured from the children. Consult 45 CFR 46.408 for specifics on this requirement. Provisions for a waiver to this requirement are contained in 45 CFR 46.116.

Waiving the Consent Requirement – Based on justification provided by the PI in the *Research Project Description* (Appendix B), the *IRB may potentially waive the requirement* to obtain formal consent from some or all adult (age 18 or above) research subjects if:

(1) The research is "exempt" (must be confirmed by the IRB) and there is no more than minimal risk to subjects, and involves no procedures for which written consent is normally required outside the research context, ***or***. . .

(2) The only record linking a subject with the research is the consent document and the primary risk is potential harm resulting from a breach of confidentiality. If such risk is present, each subject must be asked whether she/he wants documentation linking her/him to the research; each subject's wishes must be honored.

Documentation for Informed Consent - Informed consent shall be documented by using a written form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy must be given to the person signing the form. The consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by 45 CFR 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or. . .

(2) A short written consent document stating that the elements of informed consent required by 45 CFR 46.116 is presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. (See 45 CFR 46.117 for additional requirements related to this option.)

IV. RESEARCHERS' CONTINUING RESPONSIBILITIES:

Continuing Responsibilities – Once a research project is approved by the IRB, the PI and all associated researchers must adhere to the approved protocol and any additional IRB instructions. Likewise, continuing responsibilities listed below are mandatory:

1. Recruit and enroll only subjects who meet the PI's (IRB approved) inclusion and exclusion criteria;
2. Properly obtaining and documenting informed consent;
3. Obtaining prior approval for any deviation from the approved protocol;
4. Keeping accurate records;
5. *Promptly* reporting to the IRB any unanticipated problems involving risks to subjects or others.

Request for Change or Modification – The PI must submit requests (IRB@calbaptist.edu) in writing for any change or modification to the approved research protocol to the IRB ***before*** the change(s) is/are put into effect. No particular form or format is required, but the request must include the assigned IRB Number, a complete description of the change(s) or modification(s), plus the PI's dated signature. The document is reviewed by an IRB representative and a response sent to the PI. A copy of the request is placed in PI's IRB file.

Renewals for Continuing Research – If needed, one year from the date the original IRB application was approved via *expedited* or *full review* (not exempt research), the PI must submit a request to the IRB (IRB@calbaptist.edu) seeking approval to continue the research. Depending on the degree of risk involved, more frequent reporting may be requested by the IRB (45 CFR 46.109.e). For research that initially required a **full IRB review**, the renewal request and report is considered by the full, convened IRB. If the initial approval was based on an **expedited review**, only the IRB Chair (or designated IRB member) reviews the renewal request/report. For either type renewal, please provide the following items:

1. A cover letter stating specifically what is requested; include the assigned IRB number, project title, principal investigator, date of last IRB approval
2. A copy of the previously approved IRB application and documents
3. A status report on the progress of the research, including:
   A. The number of subjects studied thus far;
   B. A summary of adverse events, if any, and any unanticipated problems involving risks to subjects or others and any subjects withdrawing from the research or complaints about the research since the last IRB approval or review;
   C. A summary of any relevant interim findings and amendments or modifications to the research since the last review;
   D. Any other relevant information, especially information about any new risks associated with the research; and
   E. A copy of any newly proposed consent documentation, if any.

Research Study Closure Report – Upon completing a research study previously approved, the PI must submit the following *written* Closure Report to the IRB via e-mail, irb@calbaptist.edu:

1. Assigned IRB number, project title, principal investigator, date of last IRB approval
2. The number of subjects studied
3. Summarize the following ***since the initial approval or last IRB review***:
   A. Any adverse events and any unanticipated problems involving risks to subjects
   B. Any subjects withdrawing from the research
   C. Any complaints about the research
   D. A brief summary of the research findings
4. The PI's electronic signature (name, title, college/school, contact information)

V. RESEARCH MISCONDUCT

Professional self-regulation depends on conscientious community participation. Consequently, individual researchers must assume responsibility for their own actions, take misconduct seriously, and report apparent misconduct by other researchers. CBU Students, faculty, staff, and others conducting research at or under CBU identity are subject to the definition of research misconduct set forth in this section.

Research Misconduct Defined – Research misconduct is the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- **Fabrication** is making up data or results and recording or reporting them.
- **Falsification** is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- **Plagiarism** is the appropriation of another person's ideas, processes, results, or works without giving appropriate credit.

To be considered research misconduct, actions must:

- Represent a "significant departure from accepted practices";
- Have been "committed intentionally, or knowingly, or recklessly"; and
- Be "proven by a preponderance of evidence".

Reporting Misconduct and Subsequent Action -- Persons observing or suspecting research misconduct at CBU must submit, in writing, detailed allegations with supporting evidence to the Associate Provost for Institutional Research, Planning, and Assessment, who also serves as CBU's Research Integrity Officer (RIO). The Associate Provost is obligated to pursue the allegations in a manner dictated by the CBU governing document, *Research Misconduct: Definitions, Policies and Procedures,* available on the Office of Institutional Research, Planning, and Assessment (OIRB) website or via InsideCBU under the "Inst Research" tab.

VI. THE INSTITUTIONAL REVIEW BOARD (IRB)

The CBU Institutional Review Board (IRB) is a function of the Provost's Office and is facilitated by the Office of Institutional Research, Planning, and Assessment (OIRPA), supervised by the Associate Provost for Institutional Research, Planning, and Assessment.

Membership – CBU follows the guidelines set forth in 45 CFR 46 that require the IRB to have at least five members with varying backgrounds and experience, including diversity in race and gender. The IRB is also comprised of at least:

- One scientist,
- One non-scientist, and
- "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" (45 CFR 46.107[d]).

In addition to the five-member board, two alternate faculty members and two alternate community members are appointed to assure adequate representation at scheduled monthly meetings. Prior to or immediately upon being appointed to the IRB, all members and alternate members must complete the protecting human subjects online training provided by the National Institutes of Health. Certificates of completion are placed on file in the Office Institutional Research, Planning, and Assessment (OIRPA).

Functions and IRB Operations – Faculty members are appointed to the IRB yearly by the Provost in collaboration with the College and School Deans, as stipulated in the Faculty Handbook. The IRB reviews proposed research at convened meetings (at least monthly) at which a majority of the members are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research

to be approved, it must receive approval from a majority of those members present at the meeting (45 CFR 46.108).

IRB Responsibilities:

In general, the IRB is responsible for determining if ***all*** the following requirements are satisfied in human-subjects research falling under it authority:

1. The welfare and rights of human subjects are adequately protected and informed consent given and documented.
2. Human subjects are not placed at unreasonable physical, mental, or emotional risk as a result of research
3. The importance of the research outweighs the risks to the subjects.
4. The researcher(s) is/are qualified to conduct research involving human subjects.
5. The selection of the subjects is equitable.
6. The research plan makes adequate provision for monitoring the data collected to ensure the safety of the subject.
7. Adequate provisions have been made to protect the privacy of subjects and to maintain the confidentiality of data;
8. Conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year (45 CFR 46. 109; 116; 117).

IMPORTANT

Federal regulations (45 CFR 46.109) grant the CBU IRB the authority to approve, require modifications (in order to secure approval), or disapprove all research activities conducted at or with CBU or by CBU faculty, staff, and students. Furthermore, research approved by the CBU IRB may be subject to further appropriate review and approval or disapproval by CBU officials.

The IRB notifies the investigators and the OIRPA in writing (e-mail) of its decision to approve or disapprove the proposed research, or if modifications are required in order to secure IRB approval. If the application is disapproved, the IRB notification includes the reasons and gives the investigator(s) an opportunity to respond in writing and/or address the issues and resubmit the application for a second review.

VII. FEDERAL RESOURCES

U. S. Department of Health and Human Services, Office of Human Research Protections; http://www.hhs.gov/ohrp

U. S. Department of Health and Human Services, Office of Research Integrity; http://ori.hhs.gov

U. S. Department of Education; http://www2.ed.gov/about/offices/list/ocfo/humansub.html

U.S. Food and Drug Administration; http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm118862.htm

VIII. GLOSSARY

Assent: In addition to parental or guardian permission, an appropriate process to secure a child's (under legal age) affirmative agreement to participate in research.

Assurance: A written, binding commitment filed with a Federal agency by an institution wanting to conduct human research. The institution promises to comply with the applicable regulations governing human subject research and stipulates the procedures through which compliance is achieved.

Child or Children: Persons who have not attained the legal age for consent to treatments or procedures involved in research under the applicable law of the jurisdiction in which the research is conducted. Special rules and protections govern the participation of children in research. In California, the legal age for consent is 18 years old.

Exempt Research: Research exempted from formal IRB review. The six federal exemption categories are listed in this document.

Expedited Review: Human subjects are involved with no more than minimal risk, and/or minor changes are made during the (one year or less) for which approval is authorized.

Review of proposed research is completed by the IRB Chair or a designated voting member or group of voting members rather than the entire IRB. Approved expedited proposals are later reviewed by the full IRB Committee.

Full Review: A review of the research proposal by a 5-member IRB committee who hold IRB certification. In order to approve the research proposal, the IRB shall determine that all relevant criteria for approval are satisfied and must receive the approval of a majority of the members present at the meeting.

Informed Consent: Obtaining from potential human subjects or their legal representatives, using appropriate documentation, their willingness to participate in the clearly explained research.

IRB Approval: The Institutional Review Board (IRB) reviews the IRB application and determines the research may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

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 physical or psychological tests.

Parent: A person's biological or adoptive parent. In conducting research with minors (under 18 years of age in CA), parental permission is nearly always required.

Permission: The parents(s) or guardian(s) agree to allow their minor child or ward to participate in the research.

Principal Investigator: The scientist or scholar with primary responsibility for designing and conducting the research project, including preparing the research protocol.

Protocol: The specific research objective, design, methods, statistical analysis, and organization—includes any amendments made to the original document. The research plan must include provisions for the adequate protection of prospective subjects' rights and welfare, and ensure that pertinent laws and regulations are observed.

Research Misconduct: Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

Vulnerable Populations: Individuals or groups who by reason of disability, illness, age, other status exhibit diminished personal autonomy. Neither the federal regulations nor ethical codes proscribe inclusion of vulnerable person as research subjects. However, DHHS regulations mandate special justification for research involving fetuses, pregnant women, and human in vitro fertilization; prisoners; and minor children.

IX. APPENDICES

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All documents listed and shown in the Appendices are available on the OIRPA/IRB website

California Baptist University
INSTITUTION REVIEW BOARD
STEPS IN SUBMITTING AN APPLICATION FOR IRB REVIEW

PRELIMINARY STEPS

_____1. Develop a well-designed research project. In specific, the IRB assumes the Principal Investigator (PI) understands the requirements for protecting the rights and welfare of human research subjects.

_____2. Determine if the proposed research is eligible for (a) exempt status, (b) expedited review, or (c) full review by the convened IRB. Assistance in determining submission status is available in the *IRB Handbook* (Pages 4-10) or on the OIRPA/IRB website or *InsideCBU*.

FUNCTIONAL STEPS

_____3. Depending on the application category (exempt student research, exempt, expedited, full review, or outside research), acquire a copy of the appropriate IRB application form; copies are available on the IRB subpage on the OIRPA website, www.calbaptist.edu/irb, or the *Inst Research* tab in *InsideCBU*.

_____4. Complete all application sections and secure the necessary signatures. *Incomplete or inaccurate applications cannot be reviewed and are returned to the PI.*

_____5. Compile all the documents required when submitting a review application to the IRB:

A. The appropriate, completed application form (consult the *IRB Handbook*)
B. A Research Project Description* (See Appendix B, *IRB Handbook*)
C. A copy of the consent document(s)*
D. If used, a copy of the subject recruiting flyer or brochure*
E. A copy of any instruments used (questionnaire, interview protocol, standardized test, etc.)
F. If appropriate, a copy of the written and signed research agreement between the CBU researchers and the other collaborating organization(s) engaged in the research (see Page 5)

_____6. Submit the application and all supporting documents to IRB@calbaptist.edu. *Only e-mailed applications are accepted.* In some cases the PI may find in necessary to create and send a PDF file.

***** Not required with an *Exempt Student Research Declaration* submitted by a CBU faculty member.

APPENDIX B

California Baptist University
INSTITUTIONAL REVIEW BOARD

Research Project Description

All **exempt** (*excluding* course-based exempt student research), **expedited**, or **full review** IRB review applications are required to include, in writing, the information identified below along with the appropriate IRB application form. Brief, complete statements are expected. Failure to provide the required information results in delaying the IRB approval process.

The Research Project Description is submitted as part of an original new IRB application. The description should not exceed 3-4 pages and include ***all*** the information identified below*. Avoid technical jargon; by law the IRB must include members who may not be specialists in your academic discipline.

1. State the research/project title.
2. Provide a brief abstract: 3-4 sentence statement summarizing the project.
3. List the research question(s), hypotheses, and/or goals.
4. Describe the intended population and sample: number, age, sex, criteria for selection, method of recruiting, inducement to participate (if any) ***OR*** data source if not directly from live participants (e.g., a pre-existing database), indicating whether or not data are de-identified. See **CBU Research Restrictions** on Page 5.
5. Identify the procedures for obtaining consent from the agency controlling access to potential participants (if any) and from participants and/or their legally responsible representatives, **OR** a request, with justification (see 45 CFR 46.116), for waving the requirement for informed consent.
6. If the research project is conducted in cooperation with another university or organization, explain the collaborative relationship. Attach the written and signed research agreement.
7. Indicate whether or not deception is used. If yes, explain how and when subjects are informed about the research's true purposes.
8. Describe the treatment and/or manipulated independent variable(s), if any.
9. Identify the data-gathering instruments and procedures.
10. Outline the plan to ensure the subjects' privacy and confidentiality, including data protection.
11. Identify foreseeable risks or distress to participants during treatment or data-gathering; if none, so state.
12. Explain follow up procedures, if any, including services provided to subjects who potentially experience anxiety, stress, physical harm, etc. plan
13. Very briefly, provide the plans for data analyze and disseminating the research results.

NOTE:** ALL 13 description elements ***must be addressed, even if only to declare an element does not apply.

If you are a CBU faculty or staff member pursuing an advanced degree at another institution and want to collect data from CBU students, faculty, or staff, PLEASE see *Faculty Research to Complete a Graduate Degree* on Page 5.

APPENDIX C
(For reference only, use the actual form available
on the OIRPA/IRB website or InsideCBU)

CALIFORNIA BAPTIST UNIVERSITY
Institutional Review Board

EXEMPT STUDENT RESEARCH DECLARATION

Instructions: A CBU Faculty Member who requires students in her/his course to complete a research project to satisfy course requirements must complete and file an *Exempt Student Research Declaration* with the Office of Institutional Research, Planning, and Assessment (OIRPA) *prior* to the students undertaking the research. One (1) Declaration submission is required for *each project, in each* course (excluding multiple sections), *each* semester or academic year, as appropriate.

Faculty Member's Name: Enter name here

CBU E-mail and Telephone Extension: Enter e-mail and telephone here

School/College/Department: Enter name here

Academic Program: Enter name here

Course Number/Name: Enter number/name here

Semester/Year: Enter semester/year here

Number of Students: Enter number here

Briefly describe the required, course-based student research (type of research, purpose, subjects, sampling methods, research methods, etc.): Enter description here text.

Course-based student research projects do not require IRB review if the following six criteria are ***all*** met:

1. Takes place with the course instructor's instruction, supervision, and assessment.
2. Occurs in a classroom, department, student housing, or other campus setting, or in a public setting with generally unlimited public access, such as a shopping center, park, or street.
3. Involves learning research techniques and is *not* intended for generalization (e.g., publication).
4. Involves **no** more than minimal risk to the subjects/participants.
5. No deception takes place.
6. Data are recorded anonymously by the students (i.e., no subject names or any other information or codes that can link subjects to a list of names and/or do not identify subjects through their behavior).

As the course instructor, I certify that all the basic conditions governing exempt student research listed above accurately depict the required student research in the identified course.

Signature (your typed signature is sufficient): Type signature here Date: Enter date here.

- ✓ Save a completed copy of this form on your computer and then e-mail a copy to IRB@calbaptist.edu
- ✓ An IRB representative reviews the form and either sends a confirmation or further instructions.

APPENDIX D
(For reference only, the actual form is available on the OIRPA/IRB website or InsideCBU)

INSTITUTIONAL REVIEW BOARD (IRB) REVIEW APPLICATION

FORM A – Exempt Research Project

Instructions: Use this form if the proposed research is "exempt" based on criteria set forth in 45 CFR 46.101. For assistance, consult the *IRB Handbook* or the OIRPA/IRB website.

Date: Enter date here **IRB NUMBER** (assigned by the IRB)**:** Enter number here

Research Project Title: Enter title here

Principal Investigator (PI)**:** Enter name here **School/College/Dept:** Enter name here

Phone: Enter number here **Email:** Enter address here

Co-Principal Investigator: Enter name here **School/College/Dept:** Enter name here

Phone: Enter name here **Email:** Enter name here

Faculty Advisor (if appropriate)**:** Enter name here **School/College/Dept:** Enter name here

Campus Phone: Enter number here **Email:** Enter address here

Type of Research (please check one):

☐ Master's capstone or thesis ☐ Faculty or staff research project

☐ Other (Please specify): Enter text here

Submission Type (please check one):

☐ New ☐ Renewal ☐ Addendum (change in protocol)

☐ Other (please specify): Enter text here

Exempt Qualification - Enter the number, between 1 and 6, which corresponds to the appropriate 45 CFR 46.101 exempt category (see *IRB Handbook*, Page 5): Enter number here

Exempt Status Checklist - *<u>All</u> items listed below must apply to the research and be checked*:

☐ The research *does not* involve subjects who are prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults.

☐ The research *does not* involve collecting or recording behavior which, if known outside the research, could reasonably place subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

☐ The research does *not* involve collecting information regarding sensitive aspects of subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

☐ The research does *not* involve subjects under the age of 18.

☐ The research does *not* involve deception.

Checklist for Application Submission – *<u>All</u> items listed below must be checked and included along with this completed application form*:

☐ Research Description (See Appendix B in the *IRB Handbook*)

☐ Informed consent/assent forms (if appropriate) ☐ **NA**

☐ Outline or script used to recruit and secure subjects' consent to participate in the research

☐ Instruments(s), survey questionnaire, tests, and/or other materials

☐ PI's curriculum vitae (including all Co-PIs)

☐ Grant proposal (if applicable) ☐ **NA**

☐ All required signatures

Signatures (Typed signatures are sufficient; severe penalties are enforced when false signatures are typed by someone other than the named individual):

As the Principal Investigator(s), I/we certify this application and attachments are an accurate and complete description of the proposed research and, furthermore, agree to protect the rights and welfare of all human subjects involved in the research.

Principal Investigator: Type signature here **Date:** Enter date here

Co-Principal Investigator: Type signature here **Date:** Enter date here
If additional Co-PIs, attach a list providing the name(s), CBU ID number(s), signature(s), and date(s)

I agree to supervise this student's research and ensure the rights and welfare of all human subjects are protected.

Faculty Advisor (if appropriate)**:** Type signature here **Date:** Enter date here

I reviewed the proposed research and support this application for IRB review.

Dean: Type signature here **Date:** Enter date here
(Required for Faculty or Staff Research)

The IRB makes the final determination on whether or not the research project does in fact meet the criteria for at least one exempt category. If an exempt status is appropriate and confirmed, **no expiration date** is listed in the approval notice (e-mail) and exempt studies **do not require an annual review**.

Submit this completed form, along with attachments, via e-mail to the
Office of Institutional Research, Planning, and Assessment (OIRPA) at IRB@calbaptist.edu
Questions: 951-343-5070

IRB USE ONLY

Date exempt application received by the IRB: Enter date here

IRB determination: Enter text here

IRB Chair or Designee Signature: Type signature here **Date:** Enter date here

APPENDIX E
(For reference only, the actual form is available on the OIRPA/IRB website or InsideCBU)

INSTITUTIONAL REVIEW BOARD (IRB) REVIEW APPLICATION

FORM B – Expedited or Full Review Research Project

Instructions: Use this form if the proposed research requires an **expedited** or **full review** by the IRB, based on criteria set forth in 45 CFR 46 (*this form is NOT appropriate for **exempt** review; use Form A*). For assistance, consult the *IRB Handbook* or the OIRPA/IRB website.

Date: Enter date here **IRB NUMBER** (assigned by the IRB)**:** Enter number here

Research Project Title: Enter title here

Principal Investigator (PI)**:** Enter name here **School/College/Dept:** Enter name here

Phone: Enter number here **Email:** Enter address here

Co-Principal Investigator: Enter name here **School/College/Dept:** Enter name here

Phone: Enter name here **Email:** Enter name here

Faculty Advisor (if appropriate)**:** Enter name here **School/College/Dept:** Enter name here

Campus Phone: Enter number here **Email:** Enter address here

IRB Review Category (please check one): ☐ Expedited ☐ Full Review (by the convened IRB)

Type of Research (please check one):

☐ Master's capstone or thesis ☐ Faculty or staff research project

☐ Other (Please specify): Enter text here

Submission Type (please check one):

☐ New ☐ Renewal ☐ Addendum (change in protocol)

☐ Other (please specify): Enter text here

Funding: Is the research externally funded or potentially externally funded (check one)? ☐ YES ☐ NO

If yes, check the most appropriate category: ☐ Private ☐ State ☐ Federal

Agency: Enter name here **Grant Number:** Enter number here

Checklist for Application Submission – *All items listed below must be checked and included with this completed application form*:

☐ Research Description (See Appendix B in the *IRB Handbook*)

☐ Informed consent/assent forms

☐ Outline, script, brochure, etc., used to recruit and secure subjects' consent to participate in the research

☐ Instruments(s), survey questionnaire, tests, and/or other materials

☐ PI's curriculum vitae (including all Co-PIs)

☐ Grant proposal (if applicable) ☐ NA

☐ All required signatures

Signatures (Typed signatures are sufficient; severe penalties are enforced when false signatures are typed by someone other than the named individual):

As the Principal Investigator(s), I\we certify this application and attachments are an accurate and complete description of the proposed research and, furthermore, agree to protect the rights and welfare of all human subjects involved in the research.

Principal Investigator: Enter signature here **Date:** Enter date here

Co-Principal Investigator: Enter signature here **Date:** Enter date here

If additional Co-PIs, attach a list providing the name(s), contact information, signature(s), and date(s)

I agree to supervise this student's research and ensure the rights and welfare of all human subjects are protected.

Faculty Advisor (if appropriate)**:** Enter signature here **Date:** Enter date here

I reviewed the proposed research and support this application for IRB review.

Dean: Enter signature here **Date:** Enter date here
(Required for Faculty or Staff Research)

Submit this completed form, along with attachments, via e-mail to the Office of Institutional Research, Planning, and Assessment (OIRPA) at IRB@calbaptist.edu
Questions: 951-343-5070

IRB USE ONLY

Date exempt application received by the IRB: Enter date here

IRB determination: Enter text here

IRB Chair or Designee Signature: Enter signature here **Date:** Enter date here

APPENDIX F
(For reference only, the actual form is available on the OIRPA/IRB website or InsideCBU)

INSTITUTIONAL REVIEW BOARD (IRB) REVIEW APPLICATION

FORM C – "Outside" Research Project

Instructions: Use this form when the Principal Investigator is not a CBU student or member of the CBU faculty or staff. For assistance, consult the *IRB Handbook* or the OIRPA/IRB website.

Date: Enter date here **IRB NUMBER** (assigned by the IRB)**:** Enter number here

Research Project Title: Enter title here

Principal Investigator (PI)**:** Enter name here **School/College/Organization:** Enter name here

Contact Phone: Enter number here **Email:** Enter address here

Mailing Address: Enter address here

CBU Campus Liaison (required)**:** Enter name here **School/College/Dept:** Enter name here

Campus Phone: Enter number here **Email:** Enter address here

IRB Review Category (please check one): ☐ Exempt ☐ Expedited ☐ Full Review (by the convened IRB)

Type of Research (please check one):

☐ Master's capstone or thesis ☐ Doctoral dissertation ☐ Faculty/Professional research

☐ Other (Please specify): Enter text here

Submission Type (please check one):

☐ New ☐ Renewal ☐ Addendum (change in protocol)

☐ Other (please specify): Enter text here

Funding: Is the research externally funded or potentially externally funded (check one)? ☐ YES ☐ NO

If yes, check the most appropriate category: ☐ Private ☐ State ☐ Federal

Agency: Enter name here **Grant Number:** Enter number here

Explain why you are seeking to conduct research at CBU using CBU students, faculty, or staff:

Enter explanation here

Checklist for Application Submission – *All items listed below must be checked and included with this completed application form*:

☐ Research Description (See Appendix B in the *IRB Handbook*) OR a copy of the completed IRB application from the PI's sponsoring college, university, or organization.

☐ Informed consent form(s)

☐ Outline, script, brochure, etc., used to recruit and secure subjects' consent to participate in the research

☐ Instruments(s), survey questionnaire, tests, and/or other materials

☐ PI's curriculum vitae

☐ Grant proposal (if applicable) ☐ NA

☐ All required signatures

Signatures (Typed signatures are sufficient; severe penalties are enforced when false signatures are typed by someone other than the named individual):

As the Principal Investigator, I certify this application and attachments are an accurate and complete description of the proposed research and, furthermore, agree to protect the rights and welfare of all human subjects involved in the research; and abide by the IRB policies and procedures governing human subjects research at CBU.

Principal Investigator: Enter signature here **Date:** Enter date here

I agree to assist the named researcher and ensure she/he protects the rights and welfare of all human subjects, as well as comply with all IRB policies and practices governing human subjects research at CBU.

Campus Liaison (Required)**:** Enter signature here **Date:** Enter date here

Submit this completed form, along with attachments, via e-mail to the Office of Institutional Research, Planning, and Assessment (OIRPA) at IRB@calbaptist.edu
Questions: 951-343-5070

PLEASE NOTE:

1. Completing this IRB application does not constitute permission to conduct research at California Baptist University among its students, faculty, or staff. In 5-15 days the IRB reviews the application and notifies the PI as to the final determination. In cases were approval is granted, the PI is responsible to coordinate with the identified Campus Liaison in completing the research and comply with all CBU policies and procedures governing research at CBU and among its students and employees.

2. The CBU campus e-mail system may not be used to recruit subjects or collect data.

IRB USE ONLY

Date exempt application received by the IRB: Enter date here

IRB determination: Enter text here

IRB Chair or Designee Signature: Enter signature here **Date:** Enter date here

APPENDIX G
(For reference only, the actual form is available
on the OIRPA/IRB website or InsideCBU)

INSTITUTIONAL REVIEW BOARD

Informed Consent Checklist

When using humans as research subjects, the Principal Investigator (PI) must first obtain the subjects' informed consent. Use this checklist to create an informed consent form. See pp. 10-12 in the *IRB Handbook* (A blank sample consent form is provided in Appendix H) and 45 CFR 46.116, 117.

- ☐ A statement explaining the purpose of the research
- ☐ A statement setting forth the expected duration of the subject's participation
- ☐ A description of the procedures methods used in the research
- ☐ A description of any potential risk or discomfort to the subject, including invasion of privacy
- ☐ A description of any benefits resulting from the research, either to the subject or to others
- ☐ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- ☐ A statement informing subject about how his/her anonymity will be guarded; i.e., that their confidentiality will be protected by assigned code numbers, by limitations of who has access to data, by data storage in locked cabinets, by locked computer files, etc.
- ☐ A statement that the subject's participation is voluntary, that his/her refusal to participate results in 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.
- ☐ If research involves more than a minimal risk, explain whether any compensation or medical treatment is available if injury occurs and, if so, what they consist of, or where further information may be obtained.
- ☐ If written informed consent is required, a place for the subject to sign and date the form as well as a statement that a signed copy is given to the subject for his/her records.
- ☐ If the research subjects are minors, a statement of parental responsibility in consenting to the child's participation in the study with a place for the parent to sign and date the form, in addition to the under-age participant's signature. A separate assent form for the participant is also acceptable.
- ☐ The name, address, and telephone number of the principal investigator of the research project, and his/her affiliation with California Baptist University. If the principal investigator is a student, the name and telephone number of the faculty advisor is also required.
- ☐ A statement informing the subject that inquiries regarding his/her rights as a subject, or any other aspect of the research as it relates to his/her participation as a subject can be directed to the CBU IRB Chair, Office of Institutional Research, Planning, and Assessment (OIRPA).
- ☐ If there is more than minimal risk and/or it is medical/clinical research involving human subjects,
  1) A signed *Bill of Rights for Research Participants*
  2) A signed authorization for *Use of Private Health Information* (if medical research)
- ☐ Potential additional elements – please consult the *IRB Handbook* and 45 CFR 46.116, 117.

APPENDIX H
(For reference only, the actual form is available
on the OIRPA/IRB website or InsideCBU)

CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT/PARTICIPANT

Date:

Principal Investigator(s): **E-mail and Telephone:**

College/School/Department/Program:

Research Project Title:

Study Purpose:

Procedures:

Potential Risks:

Benefits:

Compensation (if any):

Confidentiality: *I understand that I may refuse to participate or may withdraw from this study at any time without any negative consequences. Also, the investigator may stop the study at any time. I also understand that no information which identifies me will be released without my separate consent and all identifiable information will be protected to the limits allow by law. If the study design or data use are changed, I will be so informed and my consent re-obtained.*

I have read and received a copy of the Bill of Rights for Research Participants and this consent form.

Participant's Signature: _____ **Date:** _____

Participant's Printed Name: _____

Principal Investigator's Signature: _____ **Date:** _____

APPENDIX I
(For reference only, the actual form is available
on the OIRPA/IRB website or InsideCBU)

BILL OF RIGHTS for RESEARCH PARTICIPANTS

All persons asked to participate as a subject in a research project, before deciding whether or not to participate, have the right to:

1. Be informed about the nature and purpose of the research.
2. Be given an explanation of the procedures used in the research and, if appropriate, any drug or medical device utilized.
3. Be given a description of any attendant discomforts and risks reasonably expected from or during the research.
4. Be given an explanation of any benefits to subjects potentially resulting from research, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to subjects, and the potential related risks and benefits.
6. Be informed about medical or psychological treatment, if any, available to the subject if complications arise during or after the research.
7. Be given an opportunity to ask any questions concerning the research purposes and procedures.
8. Be told that consent to participate in the research may be withdrawn at any time and subjects may discontinue participation in the research without prejudice.
9. Be given a copy of any signed and dated written consent form related to the research.
10. Be given the opportunity to decide to consent or not consent to participate in the research without the any element of force, fraud, deceit, duress, coercion or undue influence on the decision.

I carefully read this Bill of Rights and fully understand my rights as a potential subject in a research project involving people as subjects. (Signatures required if the research involves medical experiments or if there is more than minimal risk associated with the research.)

Patient/Participant's Signature: _____ Date: _____

Patient/Participant's Printed Name: _____

AND (If the Patient/Participant is less than 18 years of age)/OR

Parent/Legal Guardian's Signature: _____ Date: _____

Parent/Legal Guardian's Printed Name: _____

Relationship to the Patient/Participant: _____

Witness' Signature: _____ Date: _____

Witness' Printed Name: _____

APPENDIX J
(For reference only, the actual form is available
on the OIRPA/IRB website or InsideCBU)

INSTITUTIONAL REVIEW BOARD

Authorization for Use of Private Health Information

OFFICE OF INSTITUTIONAL RESEARCH, PLANNING, AND ASSESSMENT
California Baptist University • 8432 Magnolia Avenue • Riverside, CA 92504
(951) 343-5070 • IRB@calbaptist.edu

Title of Research Study: **IRB Number:**

Principal Investigator: **e-mail:** **Telephone:**

Others who might have access to your information:

The study named above intends to use personal information related to your health status. National and international data protection regulations give you the right to control who uses your medical information. Therefore, by signing this form, you specifically authorize your medical information to be used or shared as described below.

The following personal information, considered "Protected Health Information" (PHI) is needed to conduct this study and may include, but is not limited to: Name, address, length and type of disability, any orthopedic injuries or cardiovascular disorders.

The individual(s) listed above will use or share this PHI in the course of this study to the Institutional Review Board (IRB) of California Baptist University, the sponsor of the study and its affiliates, government agencies such as the Food and Drug Administration (FDA), other research sites involved in this study, health care providers who provide services to you in connection with this study, central labs, central review centers and central reviewers.

The main reason for sharing this information is to be able to conduct the study as described previously in the consent form. In addition, it is shared to ensure that the study meets legal, institutional, and accreditation standards. Information may also be shared to report adverse events or situations that may help prevent placing other individuals at risk.

All reasonable efforts will be used to protect the confidentiality of your PHI, which may be shared with others to support this study, to carry out their responsibilities, to conduct public health reporting and to comply with the law as applicable. Those who receive the PHI may share with others if they are required by law, and they may share it with others who may not need to follow the federal privacy rule.

Subject to any legal limitations, you have the right to access any protected health information created during this study. You may request this information from the Principal Investigator named above but it will only become available after the study analyses are complete. The authorization expires upon the conclusion of this research study.

You may change your mind about this authorization at any time. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for this study. However, study personnel may continue to use the health information that was provided before you withdrew your permission. If you sign this form and enter the study, but later change your mind and withdraw your permission, you will be removed from the study at that time. To withdraw your permission, please contact the Principal Investigator listed above.

You may refuse to sign this authorization. Refusing to sign does affect the present or future service or care you receive at this institution and does not cause any penalty or loss of benefits to which you are entitled. However, if you do not sign this authorization form, you not permitted to take part in the study for which you are being considered.

……

I agree my personal health information may be used for the study purposes described on this form.

Patient's Printed Name: _____

Patient's Signature: _____ Date: _____

OR

Printed Name of Patient's Legal Representative: _____

Representative's Relationship to Patient: _____

Legal Representative's Signature: _____ Date: _____

Signature of Person Requesting this Authorization: _____

Printed Name: _____ Date: _____