Institutional Research Board (IRB) Handbook

Individual forms and current policies are available on the Provost Tab of InsideCBU.
https://insidecbu.calbaptist.edu/ICS/Provost/Research__Scholarship/Institutional_Review_Board.jnz

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Dear Researcher,

We are so glad you have decided to start or continue your research program, asking and answering important and interesting questions about being human in the many diverse ways we do that here at California Baptist University (CBU). This IRB Handbook has been prepared to help you prepare and submit your proposed research to the Institutional Review Board (IRB) since IRB approval is required before any human participant research activities may begin. The IRB committee reviews proposed research projects from an ethical perspective, paying particular attention to protecting potential participants. This handbook compiles the most up-to-date policies and procedures together (you can check the table of contents to see when a policy was last updated). IRB forms are available on the InsideCBU IRB page linked on the handbook cover.

As you prepare your IRB application, please remember that *this is your professional work*. Successful applications demonstrate an understanding of and commitment to the ethical principles of research and the specific CBU processes for research (e.g., the procedures outlined in this Handbook). Remember that the IRB needs sufficient details, presented clearly and consistently, to fully understand the nature and scope of potential participants' interaction in this research. As a multidisciplinary committee, all proposed projects must be presented in an accessible, professional, and non-jargon-filled way. Please also keep in mind that the review of applications *takes time.* We want to serve you in your research goals while, at the same time, serving the participants by ensuring the guidelines for ethical research are met or surpassed. To prevent any stress for your research deadlines, we encourage you to submit early and consider the IRB process an essential part of your research process. If engaged thoughtfully, the IRB process can help you refine your thinking as you evaluate your research questions and the strength of your design in answering IRB questions. This is relevant to and an essential part of the IRB's evaluation of the scientific merit of your project against potential risks—even if small—to your participants and the extent to which you have mitigated those risks.

We look forward to serving you and answering your questions as you prepare to engage in human participant research.

On behalf of the IRB,

Erin I. Smith, Ph.D.
Chair, Institutional Review Board
IRB@calbaptist.edu

An Introduction to Human Participants* Research at CBU

Research involving human participants requires review by an interdisciplinary board, the Institutional Review Board (IRB), before carrying out the project. IRBs are designed to review research proposals to ensure that the proposals meet federal standards for conducting ethical research with human participants. Although these federal regulations apply to federally supported research (45 CFR 46.103), here at CBU, we desire to achieve or exceed these standards in all of our research. As such, the procedures we apply to our federally funded research apply to all research submitted to the IRB. The policies in this Handbook reflect the procedures CBU has adopted to satisfy the federal guidelines outlined in the Revised Common Rule (HHS, 2018). The Revised Common Rule (the section of federal regulations published by Health and Human Services regulating research) updated the Common Rule (published in 1991) and can be viewed here. This Final Rule is effective as of January 20, 2019. These federal codes and regulations will be referenced throughout this Handbook so readers can determine what code is relevant to which IRB process (e.g., the 45 CFR 46.103 reference above refers to the Revised Common Rule regulation stating that federally supported research must comply with these standards). Researchers should refer to articles in this handbook as posted online to ensure they use the most up-to-date version available.

In determining whether your research is "human participant research" requiring an IRB application, two relevant federal definitions are considered: a definition for *human participant* and a definition for *research*. For research that qualifies, the IRB will assess the proposed research as related to potential risks and benefits to participants, the extent to which risks have been mitigated/participants are fully informed, and the scientific merit of the research. Please note that not all scholarship will meet the definitions for *human participant research.* This is not an indication of the quality of your research; it is only an indication that your proposed project does not satisfy these federal definitions and is thus not regulated by IRB principles. Other ethical principles relevant to your field and scholarship will still apply.

CBU encourages its members to conduct scholarly research on campus and/or in collaboration with other agencies. Although the University respects academic freedom, the procedures outlined in this Handbook reflect a firm adherence to the basic ethical principles underlying what is acceptable practice in conducting research involving human participants at CBU and by CBU-affiliated researchers. The IRB is the committee tasked with ensuring these principles are reflected in research design prior to the research being conducted.

**Note:* Although individuals participating in research may be called human subjects or human participants, many professional organizations have adopted the nomenclature of "participant," emphasizing the individual's active involvement in the research process. Consistent with this practice, the term "participant" is used in this Handbook unless "subject" is required or quoted from federal guidelines.

The Institutional Review Board (IRB)

An IRB is a diverse, multidisciplinary committee (45 CFR 46.107) charged with the review of proposals for research with human participants. The primary role of the IRB is to assess the potential risks of the proposed study, examine steps that the research team has taken to mitigate these risks/protect potential participants), and weigh these risks against the benefit of the research (in general and/or to specific participants) (45 CFR 46.108, 46.109, 46.111)

A successful IRB application is supported by three kinds of expertise:

- *The research team – content and methodology experts*
- *The dean –signature indicates review of research content (e.g., approval of research at CBU)*
- *The IRB -approval indicates that the necessary protections are in place for human participants and consistency with the Revised Common Rule.*

Although the function of the IRB is not to review and critique research design, regulations 45 CFR 46.111(a)(1) indicate that risks to participants are minimized "by using procedures that are consistent with sound research design" or that involve "procedures already being performed on the subjects for diagnostic or treatment purposes." Thus, the IRB will comment on the proposed research design when it is relevant to the potential risks and anticipated benefits to participants (45 CFR 46.111(a)(2) or as a measure of professional courtesy. *IRB approval is not the same as endorsement of the research project. IRB approval is a statement by the IRB that if the project is completed according to the approved protocol, then human participants have been adequately protected and can provide researchers and investigators with protection from research-related liability.*

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."* A revision to this rule was adopted January 19, 2017 (effective 1/19/2019; see http://www.hhs.gov/ohrp/; 45 CFR 46 and 'Final Revisions to the Common Rule' for additional details). All institutions requesting and receiving funds from a federal agency for research involving humans are required to have IRB review, according to the Common Rule. CBU has elected to apply the policies of the Common Rule to all human participant research regardless of funding source. The documents available on the IRB website describe the procedures IRB uses to fulfill the expectations of these policies.

The regulations are based on three internationally recognized ethical principles 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 participants).

Belmont Report: *Ethical Principles and Guidelines for the Protection of Human Subjects*: http://ohsr.od.nih.gov/mpa/belmont

CBU's Institutional Review Board (IRB)

The IRB is a division of CBU's Office of the Provost and is responsible for the review of all applications to conduct human participant research by or with CBU personnel (students, staff, and faculty). The IRB's role is to ensure that all research adheres to the Federal Policy for the Protection of Human Participants (the "Revised Common Rule"). These regulations are based on the ethical principles established in the Belmont Report (1979).

Membership – CBU follows the guidelines set forth in 45 CFR 46.107 that require the IRB to have at least five (5) members with varying backgrounds and experience, including diversity in race and sex. 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(c)).

Upon appointment, all IRB members must complete the CITI online tutorial/training for the protection of human participants. Certificate completions are available to the IRB Chair and are to be updated according to the expiration dates dictated in the CITI program. A current IRB membership roster can be found on the IRB website on InsideCBU.

Functions and IRB Operations – As provided in the Faculty Handbook, faculty members are appointed to the IRB yearly by the Provost in collaboration with the University's deans and IRB Chair. The IRB reviews proposed research at convened meetings (at least monthly) throughout the typical 9-month academic calendar. IRB meetings are held during the summer, as needed. At meetings in which a majority of the members are present, including at least one member whose primary concerns are in nonscientific areas, research requiring full board review is reviewed. For the research to be approved, it must receive approval from a simple majority of those members present at the meeting (45 CFR 46.108 (b)). Research can only be disapproved by the convened IRB.

Research reviewed and approved via expedited procedures are discussed at meetings of the full board (45 CFR 46.110(c)).

IRB Responsibilities—In general, the IRB is responsible for determining if ***all*** the following requirements are satisfied in research with human participants falling under its authority:

1. The welfare and rights of human participants are adequately protected and informed consent is given and documented.
2. Human participants 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 participants.
4. The researcher(s) is/are qualified to conduct research involving human participants.
5. The selection of the participants is equitable.
6. The research plan makes adequate provision for monitoring the data collected to ensure the safety of the participant.
7. Adequate provisions have been made to protect the privacy of participants and to maintain the confidentiality of data.

The IRB is also responsible for conducting the continuing review of research covered by this policy at intervals appropriate to the degree of risk (at least once a year; 45 CFR 46.109 (e)). Exempt research (45 CFR 46.104) and minimal risk approved with expedited procedures are not subject to continuing review (45 CFR 46.109(f)(1)(i)). Research that was subject to continuing review but has progressed to involve only data analysis (45 CFR 46.109(f)(1)(iii)(A) or accessing follow-up clinical data (45 CFR 46.109(f)(1)(iii)(B), will no longer require continuing review as noted by the IRB.

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

The IRB notifies the investigators in writing (e-mail) of its decision after proposal review. The IRB may approve, disapprove, or request clarifications/modifications to the proposal before approval. If the application is disapproved, the IRB notification includes the reasons. It allows the investigator(s) to respond in writing, address the issues, and resubmit the application for a second review (45 CFR 46.109 (d)).

Human Participant* Research: Defined

HUMAN PARTICIPANTS DEFINED – According to the Revised Common Rule (45 CFR 46.102(e)), a *human participant* is a living individual about whom an investigator (whether professional or student)…

(i) Obtains information or biospecimens through *intervention* or *interaction* with the individual, and uses, studies, or analyzes the information or biospecimens

or

(ii) Obtains, uses, studies, analyzes, or generates identifiable *private information* or identifiable biospecimens."

Intervention includes the procedures for gathering the information or biospecimens and a research-initiated manipulation of the participant's context/environment (45 CFR 46.102(e)(2)).

Interaction refers to communication or interpersonal contact between a researcher and a participant ((45 CFR 46.102(e)(3)).

"Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonable expect will not be made public (*e.g.,* a medical record)." (45 CFR 46.102(e)(4)).

As provided by the *General Rule at CBU*, set forth herein, if the definition of a human participant has been met *and* the study also satisfies the federal definition of research, then institutional IRB approval is required.

As indicated in Introduction to Human Participant Research at CBU, ***research*** *with* ***human participants*** *that is for a thesis/dissertation or research that qualifies as a pilot study, even if not intended for publication, requires IRB approval.*

Additionally, some forms of secondary data may require IRB review. Many, but not all, forms of secondary data qualify for exemption; a determination is made by the IRB after the correct "exempt status" IRB applications are completed, submitted, and reviewed by the IRB as described below. Additionally, the use of non-public data that is identifiable, including information or biospecimens previously collected for other purposes, requires IRB review and approval. Please see IRB Review Categories of Human Participant Research for additional clarification on the difference between exempt research and research approved via expedited or full board review procedures.

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 for the purposes of pedagogy, satisfying the requirements of a specific, non-thesis/dissertation course; see *Research Defined*), and/or anyone conducting research identified in any way with or at the University (e.g., collected on campus or in collaboration with an individual affiliated with CBU), ***must*** seek appropriate approval from the CBU IRB (See Conducting Research at CBU).

ANIMAL RESEARCH – Proposed research using animal (non-human) subjects requires review by the Institutional Animal Care and Use Committee (IACUC). Information on these processes can be found by contacting the IACUC Chair (iacuc@calbaptist.edu).

**Note:* Although individuals participating in research may be called human subjects or human participants, many professional organizations have adopted the nomenclature of "participant" emphasizing the individual's active involvement in the research process. Consistent with this practice, the term "participant" is used in this Handbook unless the term "subject" is required pursuant to federal guidelines.

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 [l]). 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.

A research project that fails to meet the federal definitions for *research* and *human participants* is outside the purview of the IRB. This does not mean the project is not valuable research and scholarship, but simply that the project is not regulated by the federal codes that apply to "human subject research."

CLASSROOM-BASED PROJECTS – Classroom-based activities intended for general instruction in research processes and principles (e.g., not for generalization) are not subject to IRB review and approval. Instructors who require their students to engage in work that would qualify as human-participant research outside the classroom are expected to know and practice the applicable federal and CBU policies and procedures for protecting the rights and welfare of human research participants, even though the class projects are not reviewed by the IRB. In this way, instructors are encouraged to serve the same essential functions as an IRB to ensure that students understand all aspects of the research process. Instructors should pay careful attention that students are not engaging in course-based projects that may involve more than minimal risk to potential participants in the project. It should be true that "the probability of magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (45 CFR 46.102(j)).

Research conducted for the completion of a master's or a doctoral degree that is human participant research requires IRB approval.

Research conducted as a "pilot study", a small-scale study used to develop, refine, or contribute to larger-scale research projects, requires IRB approval.

Note this exception: students who may want to use the data from their projects for some other purpose (e.g., generalization or dissemination) are required to seek approval via standard IRB application processes *before* collecting any data. The IRB does not consider this secondary data and will not provide an exempt determination or approval after data have been collected.

Under this definition, projects conducted for the completion of a master's or doctoral degree *that satisfy the federal definitions for human participant research* (and thus require IRB oversight) do *not* qualify as a classroom-based activity, even if the result is not intended for publication. These projects require review and approval from the IRB via appropriate application channels. Additionally, research that constitutes "pilot studies", small-scale studies that are used to develop, refine, or contribute to larger-scale research projects, still require IRB approval. A good rule of thumb is that if the product will be used for scholarly purposes/to contribute to knowledge, even if ultimately unpublished, then IRB approval is required *prior* to data collection.

Conducting Research at CBU

WHO MAY CONDUCT RESEARCH AT CBU?

Generally, CBU faculty, 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-participant 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 IRB. The Principal Investigator (PI) is *required* to apply for and secure approval *before* recruiting participants and collecting data.

In some circumstances, the IRB may accept the application and approval from the IRB of another institution with an IRB registered with the Office of Human Research Protections (OHRP) in the Department of Health and Human Services (DHSS) and/or with a Federalwide Assurance (FWA) registration number. Researchers with approval from a qualifying institution may submit an *External IRB Approval Form*. If the CBU IRB does not accept the sponsoring institution's approved IRB review, the CBU faculty member shall submit all the items listed on the CBU IRB application and subsequently receive CBU's approval before beginning sample selection and data collection at CBU.

For example, a faculty member completing research as part of their doctoral degree may submit an External IRB Approval Form after receiving IRB approval from their doctoral institution, if that institution has an FWA.

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, so long as such activities are legal and comply with stated CBU policies. Faculty members are considered "employees" and "agents" of the University and, therefore, may expect University support and assistance in the event they are sued for professional activities performed within the course and scope of their employment. IRB approval indicates that the proposed research has met the standards set out by the Revised Common Rule for protecting human participants (see section of this Handbook "Institutional Review Board").

Outside Researchers – CBU desires to create an atmosphere of collaboration. In some cases, the CBU IRB may permit an external researcher to conduct research on the CBU campus among CBU employees and/or students. An external researcher is a person not employed by, enrolled as a student at, or affiliated with CBU. If such IRB permission is granted, the external researcher is not deemed an agent of CBU.

Without exception, the external researcher must seek and secure CBU IRB approval before engaging in research at CBU. As part of the application process, the external researcher must

identify and secure approval from a qualified CBU employee (e.g., a faculty member) to serve as their Campus Liaison. The Campus Liaison may or may not assist with the actual research, but the Campus Liaison must agree to represent the external researcher/research project at CBU, assisting the external research, as needed, to comply with all CBU policies and procedures. Note that applications to the IRB must be submitted by a CBU-affiliated member (e.g., the Campus Liaison). External researchers must complete and submit the *External Researcher IRB Application Form*.

The CBU IRB's approval of an external research IRB application does not obligate CBU or the IRB in any way, including in the conduct of the research/recruitment of potential participants. (see Other Research Restrictions/Considerations below pertaining to CBU's restrictions on recruiting students as participants).

Research with Controlling Agencies – A controlling agent is an individual in charge of an organization from which a researcher hopes to recruit participants. As such, the term "controlling agencies" refers to anyone who serves in a gatekeeping function for the intended participants of the proposed research, whether the relationship is collaborative (e.g., they are working with you on the research project) or not. When conducting research in a context in which your access to potential participants is subject to the approval of a controlling agent, documentation of the approval of this controlling agent is required in the IRB application in the form of a *research agreement.*

For example, research that intends to actively recruit potential participants from *campus-based events* (e.g., club events, classrooms) requires a signed research agreement from the individual in charge (e.g., club advisor, course instructor). In the case of *classroom recruitment*, faculty need to specify whether course/extra credit will be offered and, if so, that they understand they are required to offer an equitable, non-research assignment of equal value. In some cases of classroom participation (e.g., faculty posting an announcement to Blackboard on behalf of a PI), a research agreement may not be required. In the case of research with *commercial organizations*, the research agreement should include all the above information plus specific terms relating to additional aspects of the research project including accountability, intellectual property, and liability issues defined for all participating parties. Prior to implementation, all agreements shall be reviewed and are subject to alteration by CBU's legal counsel.

> *A <u>research agreement</u> should be a form/letter signed by the proper individual at a controlling agency indicating*
> *...that the PI has permission to access to the research populations.*
> *...they understand the research procedure, potential risks, benefits, and the nature of participants' involvement.*
> *...any conditions of this approval.*

See the "Research Agreement" examples for additional details.

Research Agreement

The purpose of a Research Agreement is to document the relationship between a PI and a controlling/cooperative agency in the research process. The Research Agreement should indicate that the controlling agency/entity/individual (1) understands the research process and all that it entails and (2) agrees to allow the PI to recruit and engage in the research activities as described in the IRB application. Sometimes, controlling agencies want to see IRB approval prior to agreeing. If that is the case, you may submit your IRB application which, once approved, would be approved *contingent* on the furnishing of a signed Research Agreement.

Contingent Approval—If an organization/entity wants IRB approval prior to signing a Research Agreement, then the PI should specify this in their application. Approval for the application may be issued contingent on the receipt of a signed Research Agreement. After approval, the PI can receive the signed Research Agreement, and then submit the Research Agreement to the IRB. Once the Research Agreement is in the PIs file, they may conduct the research as approved in the organization from whom they have a signed Research Agreement.

Case Example: A PI wants to recruit members of a church to participate in their research study. Prior to recruiting individuals from this church, whose information is not publicly available, permission from the Pastor must be received as the Pastor is considered the "controlling agency" for the members of his/her congregation.

Case Example: A PI wants to recruit faculty from college campuses to participate in his/her research study. Since e-mail contact information for these faculty are freely available online, recruitment through e-mail would not require IRB approval. If, however, the PI wanted to visit campuses to recruit, this would require permission from individual campus' IRBs, as they are considered the "controlling agency" for all research activities on their campus

Example Research Agreement, on CBU letterhead:
To: Institutional Review Board, California Baptist University
Re: Consent to recruit from school/organization

To Whom It May Concern:

I, Name of controlling agent, agree to allow [Principal Investigator/Researchers] to recruit participants from [Organization] for the study entitled "[Study Name]." I understand the benefits, risks, and time involved in participation in this study. I understand that individual participation is contingent upon voluntary and informed consent. I am fully aware of the procedure and agree to allow interviews to be conducted in the manner approved by CBU's IRB (as described in the protocol). Please contact me if you have any further questions.

Sincerely,
[Signature and date]

In cases of single site IRB reliance requests, please contact the IRB.

CBU RESEARCHERS AT OTHER INSTITUTIONS

CBU's IRB is registered with OHRP (http://ohrp.cit.nih.gov/search/search.aspx) and our Federalwide Assurance (FWA) #FWA00025340 (expires 01/13/2027).

In the case of conducting research at other institutions, please review their IRB requirements.

OTHER RESEARCH RESTRICTIONS/CONSIDERATIONS

In an effort to protect the rights and welfare of CBU personnel and students, all research conducted at CBU is required to comply with the following restrictions:

1. Student e-mails will not be provided by CBU for participant recruitment. Generally, CBU-affiliated and external researchers may *not* use the CBU e-mail system to recruit participants or collect data (e.g., mass invitations to students to participate in research are not permissible). Only the CBU President or the Provost may suspend this policy and utilize the CBU e-mail system to collect data directly supporting administrative or academic purposes. Exceptions to this policy require prior written approval from the Provost. In their applications, PIs should be explicit regarding how potential participants are recruited/the use of student e-mails.
2. If course/extra credit is offered for student participation in a research project, an equitable alternative (in terms of time, difficulty, access, etc.) to earn course/extra credit must be offered to those students declining to participate. The onus is on the PI to demonstrate that research participation is voluntary and not the result of coercion.
3. In order to avoid any perceived coercion to participate, full-time and adjunct faculty members may recruit students in their courses to participate in research in which they serve as PI or Co-PI *only* (a) when there are alternatives to the instructor's research (other research participation/non-research options), (b) when the faculty member is sufficiently naïve to student identities, and (c) when the research occurs outside of class time (exceptions to this may apply in the case of some exempt category educational research). Ultimately, approval of the recruitment of students enrolled in the researcher's classroom is at the discretion of the IRB.

All PIs, faculty advisors, and research assistants associated with a project must have a valid, non-expired CITI Human Subjects Research certificate (Biomedical Researchers or Social-Behavioral-Educational Researchers, Basic or Refresher Course) at the time of application. A copy of the certificate is required with the application. The IRB may accept a different ethics training certificate with an explanation, including the demonstration of equivalent training.

Cooperative Research: Single IRB Reliance

CBU faculty, staff, and enrolled students are encouraged to engage in collaborative research with other universities and organizations, but the CBU Principal Investigator (PI) is required to secure IRB approval prior to undertaking the joint research. The IRB approval process for collaborative research is the same as CBU campus-based research, with additional information on the collaborating organization provided in the Research Description. A written and signed research agreement should be submitted with the IRB application and is required prior to IRB approval.

When a researcher seeks to conduct research in partnership with another institution, CBU may accept the other institution's IRB determination when the IRB approval is given by an FWA-holding institution. In order to request the acceptance of another IRB's review, the CBU-affiliated researcher should complete and submit the *External IRB Approval Form*. Such applications also require approval of the appropriate CBU dean. Official CBU IRB acceptance of the other institution's determination is required prior to the commencement of research activities.

A similar approval process with a single IRB can be determined with the execution of an IRB Authorization Agreement (IAA). The use of a single IRB for review of multi-site projects will be required for all funded research by January 20, 2020 according to the regulations at 45 CFR 46.114.

Steps for Submitting an IRB Application

PRELIMINARY STEPS

1. Determine whether your project qualifies as *research (Research Defined).*
2. Determine whether your project includes *human participants (Human Participant Research Defined).*
3. Complete/Renew IRB-required CITI *Human Subjects Research* Certificate. An equivalent certification may be substituted, at the discretion of the IRB.
4. Develop a well-designed research project. The IRB application shall include a review of the *entire protocol* from start to finish. The IRB does not approve "general research ideas."

> When thoughtfully developed, the IRB process can improve a research project. A well-written proposal requires considering every detail of the protocol (e.g., the recruitment script, the protocol, the hypotheses to test, etc.) and making important research-related decisions relative to these details. Additionally, a successful IRB application requires the ability to communicate the details about the project to a multidisciplinary group of scientists and non-scientists who may or may not have knowledge of your area of research. The IRB can be a great ally to your research. Please remember that we are your colleagues and want to see your research be as successful as possible!

FUNCTIONAL STEPS

1. Download the most current forms for the necessary application (submission on old forms will be returned for correction). Refer to this handbook for the selection of the correct Review Category. Complete all application sections and secure all necessary signatures.
2. Email the completed application as a word document, attaching any additional items (e.g., research agreement, informed consent document, instrumentation or measures) not already embedded within the application. Note that incomplete, inaccurate, or improperly formatted applications cannot be reviewed and will be returned to the PI for correction.
3. Submit the application to IRB@calbaptist.edu. Please indicate in the subject line some basic information about your submission (e.g., whether it is an exempt, expedited, or full board application; whether it is a new submission, a request for renewal or amendment, etc.). Only e-mailed applications are accepted. You should receive an email notice of receipt of the application within three (3) business days of submission.
4. IRB applications are reviewed according to their research category (exempt, expedited, full board). Please note that the research categories do not necessarily indicate the amount of time for review; **a <u>minimum</u> of three weeks should be expected for any category**. Protocols with more risk to participants may involve longer periods of review. Note that the IRB may not convene during CBU holidays and, as such, additional time may be required. After review, the researcher will receive notification of one of the following responses:

a. Research approved as submitted.
b. Research requires revision prior to approval. Revisions are reviewed by the IRB Chair or the Chair's designee.
c. Deferral of application. When extensive revisions are required, applicants may be asked to revise and resubmit the application. Review of the revised application will be conducted by the original reviewers/full board, as deemed necessary by the IRB.
d. Research disapproved. This disapproval shall only result after a full IRB review. Researchers may resubmit a disapproved application once. Such re-submittal shall include a letter by the researcher addressing the IRB concerns specified in the original disapproval.

5. **Applications requiring revision will be given four (4) weeks to submit the revisions**. If revisions are not received within four (4) weeks, the application will be closed and the PI must resubmit a new application if they wish to pursue the project (e.g., the application will be assigned a new IRB number).

POST-IRB APPROVAL

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. In order to ensure continuing compliance, researchers must adhere to the following regulations:

1. **Recruit and enroll** only participants who meet the IRB approved inclusion and exclusion criteria.
2. Obtain and document **informed consent** properly, according to the approved protocol and procedures outlined in these documents/the Final Rule (45 CFR 46.117).
3. **Submit any changes to study protocol** *(including the addition of researchers or research assistants)* to the IRB (IRB@calbaptist.edu) with the completion of an *Amendment to Research Protocol Form*. All changes to research protocols *must* be approved by the IRB *prior* to implementation. The form is reviewed by the IRB Chair or designated IRB representative and a response is sent to the PI. Upon receipt by the IRB, a copy of the request and approval shall be placed in the PI's IRB file.
4. **Keep accurate records**. Note that data forms (consent forms, data, etc.) must be retained for three (3) years unless otherwise approved or mandated by statute or a granting agency.
5. Report any experience of an **unanticipated risk** or **adverse event** by a participant to the IRB *immediately*, using the *Unanticipated Risk/Adverse Event Form*.
6. Plan for **continuing review**, as appropriate. Exempt and (most) expedited protocols are not subject to continuing IRB review (45 CFR 46.109 (f)). Functionally, this means that there is no expiration date for these projects. However, changes to the protocol that impact potential risks (including changes to the informed consent) should be submitted to the IRB in order to determine whether the initial designation/approval

remains unchanged (see #1 above). Additionally, unanticipated risk/adverse event reports are required even without continuing review (see #2, above).

For expedited protocols deemed more than minimal risk and applications approved under full IRB review procedures, a researcher must submit a *Continuing Research—Renewal Request Form* if the PI would like to continue their research project beyond the expiration of approval noted in their original application. Please allow sufficient time for review of Continuing Research requests; full board applications submitted for renewal need to be considered by the full board (45 CFR 46.109(e)), according to the meeting schedule/submission deadlines, unless expedited categories 8 or 9 apply. (Please see Categories of Expedited Research for details and complete the Continuing Research Renewal Request appropriately.) Protocols that expire before renewal has been approved will be closed and subject to review as a new application. During periods of no IRB approval, all research activities must cease. Although the IRB intends to remind the PIs of the upcoming expiration deadlines, it is the PI's responsibility to complete the appropriate form and prevent a study from expiring.

Research that was approved with a condition of required continuing review may submit a Continuing Review Release Request Form, requesting the cessation of continuing review, if one or both of the following conditions are true:

(a) "Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
(b) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care." (45 CFR 46.109 (f)(3)(iii)(A-B))

Research activities that are not subject to continuing review may continue in the fashion outlined and approved in the original IRB application until a *Study Closure Report* has been submitted.

7. At the conclusion of a project (exempt, expedited, or full board review), researchers are to submit a ***Study Closure Report Form*** to the IRB (via email at IRB@calbaptist.edu).

IRB Review Categories for Human Participants Research

The Final Rule has 3 categories of IRB review: (i) Exempt (45 CFR 46.104), (ii) Expedited (45 CFR 46.110) and (iii) review by the Full Convened Board (45 CFR 46.109). Functionally, the differences between these categories describe the:

1. Policies for review (e.g., by the IRB Chair or Chair's designee (45 CFR 46.110(b)(2)) or at a convened meeting satisfying quorum requirements (45 CFR 46.108(b));
2. Degree of risk involved in the study procedures to participants.

Federal guidelines outlined in the Final Rule (45 CFR 46) identify three levels of review. The Principal Investigator (PI) is responsible for understanding the difference between these types of reviews so that they submit appropriately. However, the final designation of research category is determined by the IRB.

Although differences in these review policies and degree of risk may impact the length of time required for IRB review, the terms "exempt", "expedited" and "full board" do not refer to time (e.g., expedited does not mean "quicker"; rather it refers to a review process and a specific category of risk to participants). Well-formed, thoughtful, and clear IRB applications are generally reviewed faster than applications that are poorly conceptualized and articulated. If the length of IRB review time is of concern, the IRB recommends that researchers submit their applications early and spend sufficient time preparing the necessary documents, fully and clearly addressing the questions and anticipating potential questions that may be raised by IRB review.

Exempt research is research defined by the Final Rule as exempted from formal IRB review. Because the CBU IRB does not have paid administrators, the process for the review of exempt research is not substantially different than the review of expedited research. Although the Final Rule offers 8 categories of exempt research, the CBU IRB permits 6 (45 CFR 46.104(d)(1-6). Categories 7 and 8, which involve *broad consent* (45 CFR 46.116(d)) and *limited IRB review* as a condition of exemption (45 CFR 46.104(7) and 45 CFR 46.104(8)(iii)) are not accepted categories at CBU.

Thus, there are six (6) accepted federal exemption categories (listed below). Exempt research requires IRB review for the purposes of determination of exempt status. In some cases, research that qualifies as exempt but fails to conform to expected standards of research at CBU (e.g., having all elements of informed consent *or* providing justification within the application for the exclusion of these elements) will be returned to the PI for revision prior to issuing the exempt determination. Exempt status applications still require all appropriate documentation for the proposed research (e.g., consent forms) with all necessary items included. Exempt research applications are reviewed by the Chair or designated IRB member(s) to determine whether the PI's determination of exempt status is appropriate and whether all items necessary for review are included. Exempt research is not subject to continuing review and is thus not issued an expiration date. However, researchers are required to submit a research closure report once the project is complete (see Post IRB Approval under "Steps for Submitting an IRB Application above). Exempt IRB Applications are submitted with the standard *IRB Application* form.

Expedited research involves no more than minimal risk (45 CFR 46.102(j)) and meets the requirements for at least one of the eight (8) criteria for expedited review (listed below). According to federal guidelines, minimal risk means that "the probability of magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." Expedited research proposals are reviewed by the IRB Chair and/or designated members of the committee, a review which is discussed by the convened IRB during scheduled meetings. The individual members of the committee reviewing expedited research have all the power of the full committee, except for disapproving research, which can only be done by the full committee (45 CFR 46.110). Expedited IRB Applications are submitted with the standard *IRB Application* form.

Full Committee Review involves research that does not meet the requirements for exempt or expedited research. This research requires review by the full convened board. According to 45 CFR 46 Subparts B (pregnant women, fetuses, neonates), C (prisoners), and D (minors), research involving protected populations requires review by the convened board. Currently, CBU's IRB is unable to review research proposals with prisoner populations (Subpart C). If researchers wish to conduct research with prisoners, external IRB approval will be required.

Additionally, CBU's IRB takes special consideration of research involving vulnerable populations not otherwise protected in Subparts B, C, and D, including participants who may be "vulnerable to coercion or undue influence, such as…individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons" (45 CFR 46.107(a)).

Finally, CBU defines additional topics (see below) that may be sensitive as requiring full IRB review. Applications requiring full IRB review require a simple majority (more than 50%) of the IRB to be present (e.g., a minimum of 5-members, including one non-scientist member) to review the application. Recommendations will be made according to vote, with approval requiring a simple majority of the members present at the meeting. Full Board IRB Applications are submitted with the standard *IRB Application* form.

> Please keep in mind that the review time frame for exempt/expedited/full convened IRB review may not differ substantially (see review processes below). PIs are encouraged to submit their applications well in advance of when they hope to start data collection. Approval is required *prior* to the start of data collection. IRB approval is never granted after the data has been collected.

FEDERAL GUIDELINES FOR RESEARCH CATEGORIES

The following sections describe the federal guidelines for determining whether research is exempt, expedited, or requiring full IRB review. HHS decision trees developed to help determine review category can be found here:
https://calbaptist.box.com/s/zvgbnag1wrg4jn1rf3wi8d8hdvpllf3u

EXEMPT REVIEW

The federal regulations, 45 CFR 46.104(d), identifies six exempt research categories accepted by CBU (1-6). Under some circumstances, exempt research may include protected populations under subparts B, C, and D (45 CFR 46.104(b)):

- *Subpart B:* Pregnant women, human fetuses, and neonates may be included in any exempt research categories, so long as the conditions of exemption have been met.
- *Subpart C:* Prisoners are not included in research exempted by these policies, except in the condition in which a prisoner population is not the intended population of the research (e.g., the research is "aimed at…a broader subject population that only incidentally includes prisoners" 45 CFR 46.104(b)(2)).
- *Subpart D:* Minors may be included in research that satisfies specific exemption criteria, including the exemptions (1), (4), (5), and (6). They may be included in research involving educational tests or the observation of public behavior in which the investigator does not participate (exemption 2), so long as the information cannot be linked to the participant's identity ((d)(2)(i)) or if the information, if released, would not be damaging to the participant's reputation, educational advancement, employability, or financial standing ((d)(2)(ii)). Minors may not participate in research that is exempt under (d)(2)(iii).

Categories of Exemption – 45 CFR 46.104(d)

(1) **Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.** This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) **Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording)** if at least one (1) of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

(3) **Benign behavioral interventions**

i. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
   A. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
   B. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
   C. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, ***and*** an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

ii. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

iii. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) **Secondary research for which consent is not required**: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

i. The identifiable private information or identifiable biospecimens are publicly available;

ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch

activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

(5) **Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads** (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

i. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(6) **Taste and food quality evaluation and consumer acceptance studies**:

i. If wholesome foods without additives are consumed, or

ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

If your research qualifies for Exempt Status Review, please complete the Exempt Qualification Section (Section B1) of the IRB Application. Note that the PI is required to specify which criteria (e.g., number of exemption) is met in the submission of their exempt application.

EXPEDITED REVIEW

The Office for Human Research Protections (OHRP) published 9 categories of research considered to be minimal risk (1998). These are "research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories". Research that meets these criteria may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 (and 21 CFR 56.110, FDA).

Research that is "*minimal risk"* means that the "probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (45 CFR 46.102(j)). Although the activities included on this list are meant to constitute minimal risk, under some circumstances these activities may constitute more than minimal risk. If this is deemed to be the case, the rationale for not considering the research under expedited review processes must be documented by the IRB, including the rationale for continuing review, as applicable (45 CFR 46.115(a)). Note that "expedited" does NOT mean quick or accelerated review.

Other Considerations: The categories in this list apply regardless of the age of the participants, except as noted, and the standard requirements for informed consent (or its waiver, alteration, or exception) apply under expedited (as with convened) IRB review.

Research Categories Eligible for an Expedited Review* – The following nine (9) activities describe types of research considered to be minimal risk by the HHS Secretary. Categories 1-7 apply to initial and continuing IRB review. For further explanation, see http://www.hhs.gov/ohrp.
**Source: 63 FR 60364-60367, November 9, 1998. Content last reviewed by OHRP March 21, 2016*

1. **Clinical studies of drugs and medical devices** only when condition (a) or (b) is met.
    a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
    b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:**
    a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an eight (8) week period and collection may not occur more frequently than two (2) times per week; or
    b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the

lesser of 50 ml or 3 ml per kg in an eight (8) week period and collection may not occur more frequently than two (2) times per week.

3. **Prospective collection of biological specimens for research purposes by noninvasive means.** *Examples:*
    a. hair and nail clippings in a nondisfiguring manner;
    b. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
    c. permanent teeth if routine patient care indicates a need for extraction;
    d. excreta and external secretions (including sweat);
    e. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
    f. placenta removed at delivery;
    g. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
    h. supra- and subgingival dental plaque and calculus, provided that the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
    i. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
    j. sputum collected after saline mist nebulization.

4. **Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice**, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) *Examples:*
    a. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
    b. weighing or testing sensory acuity;
    c. magnetic resonance imaging;
    d. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
    e. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. **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).**
    NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects (45 CFR 46.101(b)(4)). This listing refers only to research that is not exempt.

6. **Collection of data from voice, video, digital, or image recordings made for research purposes.**

7. **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.**

   NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects (45 CFR 46.101(b)(2) and (3)). This listing refers only to research that is not exempt.

8. **Continuing review of research previously approved by the convened IRB as follows**:
   a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   b. where no subjects have been enrolled and no additional risks have been identified; or
   c. where the remaining research activities are limited to data analysis.
      Note: Expedited 8c now qualifies for transition to no continuing review. If your project has progressed to the stage of data analysis *only*, you may request transition to no continuing review by submitting the Continuing Review Release Request Form, which will be reviewed using expedited procedures.

9. **Continuing review of research, not conducted under an investigational new drug application or investigational device exemption** where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Unless otherwise documented in the approval letter to the researcher(s), IRB approval of an expedited application does not have an expiration date (i.e., no continuing review required). The PI must file a completed *Study Closure Report Form* when the research concludes. See Post IRB Approval (under "Steps for Submitting an IRB Application" above) for more information.

If your research qualifies for Expedited Status Review, please complete the Expedited Review Section (Section B2) of the IRB application. Note that the application will require the PI to specify which criteria is met to make this expedited review.

Important note:
Research involving participants who are potentially vulnerable to coercion or undue influence—including minor children (anyone under the age of 18 in the state of California), prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons—***requires a full IRB review*** unless explicitly exempted. Additionally, some topics which may fall under expedited categories are considered *sensitive topics* at CBU and require additional review by the full convened board.

REVIEW BY THE FULL CONVENED BOARD

Research involving more than minimal risk, sensitive topics, invasive medical/physical protocols, or that 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).

Federal definitions and requirements for research involving prisoners requires IRB expertise that is currently not available to the CBU IRB. Thus, we cannot serve as the IRB of record for research involving prisoners. Details on these policies are available on HHS (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/prisoner-research/index.html). Researchers looking to conduct research with prisoners may secure appropriate IRB elsewhere and complete an External IRB Approval form to the IRB.

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, if released.
4. Information (usually in medical records) that could lead to social stigmatization or discrimination, if released.
5. Traumatic experiences, including physical, emotional, or sexual abuse and veteran/wartime experiences.

Why sensitive topics?

In addition to the federally protected classes/vulnerable populations, the IRB at CBU considers research on sensitive topics as requiring full board review to ensure the adequate protection of potential participants.

If researchers are unsure about whether their proposed project involves one of the preceding sensitive topics, they are encouraged to reach out to the IRB for preliminary guidance prior to submitting an application.

If the IRB approves the Full Board Review Application, such approval is for **one (1) year** or as otherwise noted on the e-mail approval notification. If the research is not completed within one (1) year, the PI must submit a Continuing Research Renewal Request *allowing for sufficient time for review and approval of the request*. The PI must file a completed *Study Closure Report Form* when the research concludes. See "Post-IRB Approval" above for more information.

If your research requires review by the full convened board, please complete the Full Board Review Section (Section B3) of the IRB Application Form to submit your IRB application.

Informed Consent

Informed consent refers to the process by which human participants agree (consent) to participate in a research project. Participants' consent should be informed, evidenced by the fact that they express that they *know and understand* the relevant elements of the research prior to their participation. All human participants research must include an informed consent from the human participants or, if the participant is a minor, from their legal representative/guardian. (Minors provide assent; their guardians provide consent.) There are a limited number of circumstances in which a waiver of documentation of consent or the informed consent process may be obtained, discussed below. Please also visit https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/ for more information.

Keep in mind that although an informed consent document is a critical legal document, it is the PI's responsibility to ensure that the informed consent document *clearly informs potential participants about the research.* The informed consent should be easily readable (e.g., free from jargon, use age-appropriate language) and fully descriptive of the relevant pieces of information as participants consider whether they would wish to participate. Moreover, researchers should take steps to ensure that consent is provided voluntarily, free from duress, and without coercion (real or perceived).

One important change to the informed consent document in the Final Rule is the clear and concise presentation of *key information* relevant to the decision to participate at the beginning of the document (45 CFR 46.116(a)(5)). This key information includes:

- That consent is being sought for research and that participation is voluntary
- The purposes of the research, including the expected duration of participation and procedures
- The reasonable forseeable risks or discomforts
- The benefits to participants or others that are reasonable expected
- Any alternative procedures that are available that may be advantageous to the prospective participant

The IRB will review the presentation of this key information in light of the full research proposal and evaluate whether the information that a "reasonable person" would want to have prior to participating has been clearly and adequately communicated (45 CFR 46.116(a)(4)).

In addition to this key information, there are nine (9) basic elements of consent that should be addressed, as applicable:

Basic Elements of Informed Consent (45 CFR 46.116(b)(1-9))

These elements should be elaborated after the summary of the key information described above. In some cases, these items may be satisfied *by* their inclusion in the key information. (This will be research-specific. Keep in mind that clarity usually involves minimal redundancy in relatively

straightforward projects.) If an element does not apply, it does not need to be included in the informed consent.

1. A statement that **the study involves research**, an explanation of the **purposes** of the research, the **expected duration** of the participants' participation, a description of the **procedures** to be followed, and identification of any procedures that are experimental;
   Note: Introducing the study as research should also entail some explanation of your connection to CBU (e.g., "this is a research project conducted by John Doe (undergraduate student) and Jane Roe (Associate Professor of Kinesiology at California Baptist University").

2. A description of any **reasonably foreseeable risks or discomforts** to the participant;
   Note: Sometimes research risks are communicated most clearly by comparing it to other risks likely encountered by participants. For example, for a college athlete, the risks associated with research on weight training may not be substantially different than the risks associated with their athletic training more generally. These statements depend on the participants and the particularities of the proposed research.

3. A description of **any benefits** to the participant or to others that 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 participant;
   Note: If participants are recruited as part of a course requirement or for extra credit, the consent form needs to indicate this and be explicit about the alternative assignments offered to fulfill these requirements/extra credit options. Alternative assignments should be equitable (time and effort) to that of the research to avoid making research participation coercive.

5. A statement describing the extent, if any, to which **confidentiality of records** identifying the participant will be maintained;
   Note: Confidentiality concerns the extent to which the information provided by a participant will not be disclosed without permission or beyond what is stipulated by the informed consent. Anonymity is an extension of confidentiality which removes the possibility of connecting participant identities to data.

6. For research involving more than minimal risk, an explanation as to whether any **compensation** and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

7. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and **whom to contact** in the event of a research-related injury to the participant;

   Note: The name and contact information of the PI of the research and faculty advisor (if applicable) should be included. Since most participants do not know what an IRB is, the following statement may be useful to include/modify in the consent form: "The IRB is a committee tasked with the review of research and the protection of human participants. If you should have any questions about the nature of the research, about your participation, or your rights as a research participant, please contact the IRB via email at IRB@calbaptist.edu."

8. **A statement that** participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant 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; and

9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

   i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or the legally authorized representative, if this might be a possibility; or

   ii. A statement that the participant's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Best practices suggest that, if possible, an informed consent should be limited to a single-page document with all the necessary information. Researchers may choose a format that best communicates the relevant information (e.g., as a letter to potential participants, as a question/answer document, etc.). Examples of consent forms may be found on the IRB website. Consent forms should indicate the availability of a Bill of Rights for Research Participants available on InsideCBU. Providing this Bill of Rights directly to participants is not required.

Tips for formatting an informed consent…

- Start with the essential information that a reasonable person would want prior to deciding if they will participate in the research or not.
- Use reader-friendly font (e.g., Arial, 12-point) with spacing between boldface headers and 1-inch margins, keeping the document to 1 page, if possible.
- Directly address the potential participant (e.g., with a question and answer format)
- Use clear and concise language at approximately the 8th grade level, avoiding scientific jargon or long/complex sentences.
- Avoid the use of "research subject", keeping with best practices to recognize participant autonomy. Use the word "participant" instead.
- Introduce yourself early in the document (if a student, also indicate your faculty advisor)
- Identify why the individual participant is being invited to participate (e.g., eligibility requirements), as appropriate.
- Recognize that even minimal risk *is* risk; for research on CBU's campus students should be given the contact information for the Counseling Center or Health Center (as appropriate) should an unforeseen risk arise.

Additional Elements for Informed Consent (45 CFR 46.116(c)(1-9) – *When appropriate*, one or more of the following information elements shall also be provided to participants:

1. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) that are currently unforeseeable;

2. Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

3. Any additional costs to the participant that may result from participation in the research;

4. The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
   Note: This needs to be addressed when course/extra credit is offered in exchange for participation.

5. A statement that significant new findings developed during the course of the research that may relate to the participant's willingness to continue participation will be provided to the subject;

6. The approximate number of participants involved in the study;

7. A statement that the participant's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants and, if so, under what conditions; and

9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Additionally, if the researchers intend to share the data once de-identified (e.g., via Open Science Framework or in a research database), the process for the de-identification and sharing needs to be made clear to the participants.

Documentation for Informed Consent - Informed consent shall be documented by using a written form approved by the IRB and signed by the participant or the participant's legally authorized representative. "Written" includes digital signatures (45 CFR 46.103(m)). A copy (physical or digital) must be given to the person signing the form. The consent form may be either of the following:

(1) A written consent document that meets the requirements for informed consent outlined in 45 CFR 46.116 (see above). The participant/legally authorized representative should have sufficient time to read the informed consent before it is signed. The researcher may (but is not required to) read the informed consent aloud.

(2) A short, written consent document stating that the elements of informed consent required by 45 CFR 46.116(b)(2) (see above) were presented orally, with key information first, to the participant/ the participant's legally authorized representative. For use of the short form, the IRB approves the written summary of what is to be said to the participant/legally authorized representative and there shall be a witness to the oral presentation. The witness signs the short form and copy of the summary; the researcher obtaining consent signs a copy of the summary. The participant/legally authorized representative shall receive the summary and the short form.

Note that when informed consent is provided in a language other than English (which is appropriate for non-native English speakers), additional requirements may apply for approval (e.g., evidence of adequate translation). Please contact the IRB for additional details.

Note that federal guidelines permit research under the "exempt" category to deviate from these requirements. However, CBU's IRB requires that even exempt research includes high-quality

informed consent documents adhering to the standards laid out in this Handbook. If a researcher desires omission or alteration of some of the required elements of informed consent for an exempt research application, such request must be justified in the IRB application.

Informed consent templates and examples are available on the IRB webpage. If researchers use a provided template, care needs to be taken to ensure that all information in the form corresponds with their intended research plans, as described in their application.

Waiver of Informed Consent

Waiver of the Documentation of Informed Consent (45 CFR 46.117(c))

Under some circumstances, an IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all participants if it finds any of the following:

(i) That the only record linking the participant and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant (or legally authorized representative) will be asked whether the participant wants documentation linking the subject with the research, and the participant's wishes will govern;

(ii) That the research presents no more than minimal risk of harm to participant and involves no procedures for which written consent is normally required outside of the research context; or

(iii) If the participants or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to participant and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Note that even when the documentation of informed consent is waived, the researcher should still document that the process of informed consent has taken place and should provide research participants/legally authorized representatives with a written statement regarding the research (similar to the short form described above). The IRB may require this written statement be reviewed and approved by the IRB prior to use.

Waiver or Alteration of Informed Consent (45 CFR 46.116(e-j))

A *waiver* of informed consent (45 CFR 46.116(f)(1)) is when an IRB waives the requirement to obtain a signature documenting informed consent for research otherwise normally requiring it. A common example is the request to replace a signature with a check box asserting agreement to participate in an online study.

An *alteration* of informed consent (45 CFR 46.116(f)(2)) is when an IRB waives otherwise required elements of an informed consent. In other words, an alteration allows for the IRB to approve research with an informed consent that does not have all of the required information for an informed consent (as described above). Note that the alteration of informed consent does not permit the alteration of the general requirements for informed consent (including the provision of key information; 45 CFR 46.116(a)).

Conditions for Requesting a Waiver or Alteration of Informed Consent

The most common circumstance for requesting a waiver or alteration of informed consent will involve the waiver for the documentation of consent (see above). In other circumstances, research for which all the following statements are true may also be eligible for the waiver or alteration of informed consent:

1. The research involves no more than minimal risk to the participants;
2. The research could not practicably be carried out without the requested waiver or alteration;
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
4. The waiver or alteration will not adversely affect the rights and welfare of the participants; and
5. Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation. (45 CFR 46.116(f)(3)

Another circumstance in which a waiver or alteration of informed consent could be considered is research for which the following statements are true:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
    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; or
    d. Possible changes in methods or levels of payment for benefits or services under those programs; and
2. The research could not practicably be carried out without the waiver or alteration. (45 CFR 46.116(e)(3))

Finally, under some circumstances, the IRB will approve research involving screening, recruiting, or the determination of eligibility for participation without informed consent procedures from the participant/legally authorized representative. This will be considered when

1. The investigator will obtain information through oral or written communication with the prospective participant or legally authorized representative, or
2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

Informed consent requirements are not intended to preempt any applicable federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective. Neither is this policy intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under

applicable Federal, state, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe). (45 CFR 46.116(i-j))

Clinical trials have additional considerations regarding informed consent processes.
Please see 45 CFR 46. 116(h) for additional details.

Assent for Minors

If research participants are minors (less than 18 years old in California), their parents or guardians *must* give written consent; after consent has been received from the legally authorized representative, then verbal assent must be secured from the minor. For older minors, written consent may be appropriate. Consult 45 CFR 46.408 for specifics on this requirement. Provisions for a waiver to this requirement are contained in 45 CFR 46.116.

Keep in mind that the script used to obtain verbal assent should be appropriate for the participant but should also contain basic elements of the informed consent. For example, the researcher should introduce themselves, give a short explanation for the research, what their involvement will entail, and that they can choose not to participate.

Example assent script with a school-age child being interviewed:

Hi! My name is ____ and I work at California Baptist University. I'm hoping to understand more about ___. Your parent/guardian said that I could ask you some questions but, before I do, I wanted to make sure that was okay with you. It will take about ___ minutes and there are no right or wrong answers. You can skip any question you don't want to answer or stop answering questions at any time. I won't even ask you to put your name on the paper! Is it okay with you if I ask you a few questions now?

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 any element of force, fraud, deceit, duress, coercion or undue influence on the decision.

This document may also be found here:
https://oag.ca.gov/sites/all/files/agweb/pdfs/research/bill_of_rights.pdf

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 CBU's Research Integrity Officer (RIO), Dr. Elizabeth Morris, Associate Provost for Accreditation, Assessment and Curriculum and Professor of Education and Mathematics. The RIO is obligated to pursue the allegations in a manner dictated by the CBU governing document, Research Misconduct: Definitions, Policies and Procedures.

Additional Resources

CITI Information:

National Institute of Health Office of Extramural Research, Protecting Human Research Participants Tutorial: https://phrp.nihtraining.com/users/login.php *(paid service)*

CBU's Center for the Study of Human Behavior has an IRB section: https://calbaptist.edu/college-of-behavioral-and-social-sciences/center-study-human-behavior/research/

An excellent resource for faculty interested in conducting Research on Teaching and Learning: http://www.teachpsych.org/Resources/Documents/otrp/resources/martin14.pdf

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