LIPSCOMB UNIVERSITY
INSTITUTIONAL REVIEW BOARD
POLICIES AND PROCEDURES MANUAL

The Lipscomb IRB would like to express gratitude to the Pepperdine Institutional Review Boards. Much of the content and structure of the Pepperdine IRB manual was adopted in the writing of this policies and procedures manual.

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The Lipscomb University Institutional Review Board

The role of the Institutional Review Board (IRB) is to review all proposed research involving human subjects to ensure that subjects are treated ethically and that their rights and welfare are adequately protected. The IRB performs these reviews in compliance with The Code of Federal Regulations, Title 45, Public Welfare, Department of Health and Human Services, Part 46, Protection of Human Subjects (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html).

The IRB is composed primarily of faculty members from disciplines in which research involving human subjects is integral to that discipline's work, researchers whose primary interests are non-scientific, as well as members from the community. The human subjects review process is administered through the Office of Sponsored Programs.

All faculty and staff (both full-time and part-time) using human subjects or identifiable, private information about human subjects to conduct research within the course and scope of their duties are required to have prior approval from the IRB before research is initiated. Projects must be approved regardless of whether or not the research is funded and regardless of the source of funds. This policy also applies to students whose research is conducted under the advisement of a faculty member. All research proposals must be reviewed by the IRB and no individual, other than the IRB Chair, or the Chair's designee, may verify a proposal as a study exempt from federal regulations or outside the regulations' scope. Research that is conducted without IRB approval is not in compliance with Lipscomb University policy and federal regulations. In these circumstances, a non-compliance report will be sent to the Office of the Provost for further action.

It is the policy of Lipscomb University that all research involving human subjects must be conducted in accordance with accepted ethical and professional standards for research and that all such research must be reviewed and approved by the Lipscomb IRB. The Lipscomb IRB is charged with monitoring the ethical propriety of all research involving human subjects conducted under Lipscomb University's auspices. It is further charged with insuring that all such research is conducted in compliance with federal regulations regarding research with human subjects outlined by the federal guidelines of Department of Health and Human Services (DHHS) regarding the health, welfare, safety, rights, and privileges of human subjects; specifically, 45 CFR 46, 50, and 56. It is the policy of Lipscomb University that the IRB have the authority to approve, require modifications in, or disapprove any research involving human subjects conducted under Lipscomb University's auspices.

The primary goal of the IRB is to protect human subjects. A secondary goal of the Lipscomb IRB is to assist investigators in conducting ethical research that is in compliance with DHHS regulations. Thus, when a faculty member, student, and/or employee of Lipscomb University wishes to conduct research involving human subjects/participants her/his research proposal must be reviewed by the Lipscomb IRB.

The Lipscomb IRB falls under the authority of the Office of the Provost, which is ultimately responsible for the oversight of research and IRB functions within Lipscomb University. It is the Office of the Provost that has the legal authority to act and speak for the

institution, and ensures that the institution can effectively fulfill its research oversight function.

How to use this Manual

Lipscomb University's *Institutional Review Board Policies and Procedures Manual* is a reference book for investigators that outlines the policies, regulations, and procedures governing research with human participants and subjects, and the requirements for submitting research proposals for review by the Lipscomb University Institutional Review Boards (IRB). This manual describes the application and review process, as well as applicable regulatory requirements. It is important for investigators to thoroughly familiarize themselves with the contents of this manual before completing and submitting proposals to the IRB. Although this manual contains the most current information for potential investigators, sections of the manual are subject to change as new or amended policies and procedures are developed. The Lipscomb IRB will keep the Lipscomb University research community informed of such developments/changes. Members of the Lipscomb IRB also available to consult with investigators who have questions about the application process.

IRB Composition

In accordance with federal regulations governing the composition of the Institutional Review Board for research utilizing human subjects (21 CFR 56.107) the Lipscomb IRB is composed of at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted at Lipscomb University. It is made up of persons of diverse gender, racial and ethnic backgrounds, and includes at least one member whose primary concerns and training are in the nonscientific areas (e.g., lawyers, clergy, ethicists, etc.), as well as at least one member who is not otherwise affiliated with Lipscomb University (nor part of the immediate family of a person affiliated with Lipscomb University). It should be noted that 21 CFR 56.108(c) does not specifically require the presence of a member not otherwise affiliated with the institution to constitute a quorum; however, at Lipscomb, the non-affiliated member is expected to regularly attend IRB meetings. Members possess expertise on vulnerable populations, or will seek the assistance of an outside consultant if this expertise is not present in an IRB reviewing an application regarding a vulnerable population.

The Provost (or the Provost's designee) will make any appointments to the IRB, which are for a term of two academic years. The terms of members' appointment to the IRB shall be staggered such that the IRB is divided into two classes of as nearly equal size as possible. Upon expiration of a member's term, the member shall either roll off of the IRB or , upon the determination of the Provost (or the Provost's designee), be appointed for another two-year term. There shall be no limit to the number of successive terms that a member may serve on the IRB. To the extent possible, a sizable portion of the members of the IRB should have lengthy tenure on the IRB to ensure that individual members and the IRB as a whole have a working understanding of the IRB to provide effective support and expertise to the IRB. The Provost (or the Provost's designee) may remove a member of the IRB with cause.

Every two years, the Provost (or the Provost's designee) shall designate and appoint a chairperson of the IRB. The Provost (or the Provost's designee) may also designate and appoint a co-chairperson of the IRB, as deemed necessary or appropriate. The Provost (or the Provost's designee) may remove a chairperson and/or co-chairperson with cause. The service of the co-chairperson will be required in cases in which there is a conflict of interest (e.g., when the IRB chairperson is also the chairperson or faculty advisor of a student's research project; when the IRB chairperson is submitting an application for his/her own research). In such cases, the IRB co-chairperson will preside over the review of the student's/chairperson's work, will be responsible for notifying the student/chairperson of the outcome, and will be the person listed on the informed consent form as the agent representing the IRB. The chairperson and co-chairperson, as applicable, shall serve for a term of two years, or as otherwise indicated by the Provost (or Provost's designee). The chairperson or co-chairperson, as applicable, may call meetings of the IRB that are not regularly scheduled, shall set the agenda for each meeting, and shall preside at all meetings of the IRB.

Current IRB members include:

Term Ends May 31, 2025
Megan Parker Peters, Education, Chair
George Goldman, Bible & Ministry
Jaimie Beth Colvin, Library
Jeanne Fain, College of Education
Roletha Pillow, College of Health Sciences
Tim Creel, College of Business
Ann Toy, College of Health Sciences
Alice Nie, College of Education
Kim Robertson, Community Member

Term Ends May 31, 2024
Emily Mofield, Education
Damian McClintock, Graduate Counseling
Dodd Galbreath, Leadership and Public Service
Ken Mayer, School of Computing
Lonnie Cochran, Education
Andrew Mauldin, College of Health Sciences
Ben Gross, Pharmacy/Health Sciences
Pat Cole, Community Member

Conflicts of Interest

No member of the IRB may participate in an initial or continuing review of a project in which the member has a conflicting interest, except to provide information requested by the IRB. According to the federal regulations, members with a conflict of interest should be absent during discussion and voting. Should the quorum fail during a meeting, no further votes can be taken unless the quorum can be restored.

Determining If IRB Review is Needed

Any research activity involving human subjects conducted by faculty, staff, and students must be reviewed and approved for compliance with regulatory and ethical requirements before the study or activity begins. These activities include a wide variety of procedures from collection of data through surveys or observation and interventions in school classrooms all the way across the spectrum to use of investigational drugs or devices and/or randomized clinical trials. Other examples of studies include research on medical records, research using existing pathological specimens, discarded tissue or secretions, and research requiring standardized tests from the fields of education, psychology or human performance.

Certain studies involving human subjects may be exempt from IRB review. Exempt projects fall into defined categories (see, Categories for Exempt Research) set forth in the Code of Federal Regulation, part 43, 45. Verification of a project's exempt status must be verified by a designated official of the IRB.

Definitions

Most federally funded research with human subjects is governed by federal regulations embodied in Title 45 Code of Federal Regulations Part 46 (45 CFR 46). It should be noted that Lipscomb's IRB follows federal and state regulations to review all University affiliated human subject research, ***regardless of funding***, to ensure the rights, welfare, and protection of all participants and subjects. Thus, investigators should understand the federal definitions of "research" and "human subjects" in order to help determine whether their proposed studies require IRB review. These regulations define research and human subjects as follows:

The regulatory definition of **human subjects research** is as follows: "A *systematic* investigation, including research development, testing and evaluation, designed to develop or to contribute to *generalizable knowledge*, **or** work that is intended to fulfill requirements for a master's thesis, doctoral dissertation, or other research requirement of the University."

Human subject is defined as: "A living individual about whom an investigator conducting research obtains

1. data through intervention or interaction with the individual, **or**
2. identifiable private information."

Intervention "includes both physical procedures by which data are gathered or manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communications or interpersonal contact between investigator and subject."

Interaction "includes communication or interpersonal contact between the investigator and subject."

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

Individually identifiable means the "the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects."

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."

NOTE: The FDA additionally defines a human subject as an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. Because the above definition excludes non-living humans, research that uses autopsy materials or cadavers is not 'human subjects research' and therefore is exempt from review.

Non-Research Activities ---*IRB Review is Not Required*

Examples of activities that typically are considered non-research activities by the IRB include:

- Biographies
- Oral histories that are designed solely to create a record of specific historical events
- Service or course evaluations, unless they can be generalized to other individuals
- Services, courses, or concepts where it is not the intention to share the results beyond the internal community
- Classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices
- Quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the university community

Class Projects and Coursework: class research assignments that involve the use of human subjects do not require IRB review if they are not going to be published and have no connection with research conducted or presented outside the classroom. Course instructors are responsible for ensuring that class projects do not propose more than a minimal risk to participants and must make sure their students understand and abide by ethical obligations in carrying out their class research assignments. We suggest that, at a minimum, students be required to complete the training modules available through the Collaborative Institutional Training Initiative (CITI).

Additionally, instructors are responsible for reviewing student class research assignment proposals and should review research methods and procedures to ensure they are ethical and appropriate. Course instructors are responsible for monitoring student research activities to ensure the rights and welfare of human subjects are adequately protected. Instructors who have any questions are encouraged to consult with the IRB Chair.

For more information on student research, please read the section entitled "Student Research Projects Requiring IRB Review Section" in this manual.

Protecting Human Subjects: Goals

In July 1974, the National Research Act (Public Law 93-348) was signed into law and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created. In fulfillment of their charge to identify basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human participants, the Commission created the Belmont Report. The Belmont Report forms the basis for 45 CFR 46 and defines three important principles considered basic to the protection of human subjects: 1) respect, 2) beneficence, and 3) justice.

The Lipscomb IRB is guided by the ethical principles set forth in the Belmont Report. Investigators need to be familiar with these principles in designing and implementing their research projects.

1. **Respect**

Respect for persons subsumes two ethical beliefs: (1) that individuals should be treated as autonomous agents, and (2) that persons with diminished autonomy are entitled to protection. It is imperative that an individual's decision to voluntarily participate in a research study is based on his/her ability to make a knowledgeable and informed assessment of the risks and benefits of the research. Investigators can help ensure that this principle is upheld by seeking voluntary, written informed consent with potential participants. The informed consent process should provide adequate information about the study and emphasize the voluntary nature of study participation so that potential participants can intelligently decide whether they wish to be involved in the research. This information should be provided in language that is easy for potential participants to understand.

Respect for persons also means honoring the privacy of individuals and maintaining their confidentiality. Individuals' privacy rights must also be protected in research conducted at certain heath and mental health organizations involving personally identifiable health information by the federal law, the Health Insurance Portability and Accountability Act of 1996, known as HIPAA or the Privacy Rule.

When individuals have diminished autonomy (e.g., minors, mentally disabled persons) investigators must take special care to protect them in research studies. In some cases this may mean excluding immature or incapacitated individuals from research activities that may harm them. The extent of protection depends on the risk of harm and

the likelihood of benefit. Judgments that any individual lacks autonomy should be periodically re-evaluated and will vary in different situations.

2. Beneficence

The principle of beneficence embodies the idea that research investigators should seek to secure the well being of their study participants by trying to maximize the potential benefits to the participants and minimize the potential risks of harm. If there are risks resulting from participation in a research study research, then there must be benefits. These may be direct benefits to the subjects, or benefits to humanity or the larger society in general.

3. Justice

The principle of justice means that the selection of research participants is fair and that the risks and benefits of research are equitably distributed. Investigators should not select research participants simply because of their ease of availability, their compromised position, their manipulability, or because of social, racial, sexual, economic, or cultural biases institutionalized in society. The selection of research participants should be based on factors that will most effectively address the research problem.

Human Subjects Research Training

All Lipscomb faculty, students and staff involved with research activities must complete training on the federal guidelines for the protection of human participants/subjects. Members of the IRB also need to complete additional training (see below). If a research project is covered under the federal law, HIPAA, then HIPAA training is also required (e.g., CITI's "Information Privacy & Security" training). Investigators, students and staff must complete such education before submitting an IRB application, and before working on a research project in any capacity. Documentation of the completion of training must be submitted with the IRB application in order to demonstrate an investigator's basic knowledge of human subjects protection policies. All members of a research project (e.g., research assistants) need to submit certificates of completion with the IRB application. If new members join the project after approval is granted, the investigator must make certain that they complete the education requirements and send in their certificates to the appropriate IRB.

Education for investigators and research staff on protections for (1) research with human subjects and (2) HIPAA must be received through approved methods.

The following training programs for human subjects protection are approved for use by Lipscomb investigators:

- Completion of the online tutorials for investigators found at: https://about.citiprogram.org
- Completion of off-campus workshops or conferences on the topic of human research protections if prior approval has been granted by the appropriate IRB chairperson.

- Human subjects protection education completed at another institution in the preceding year also may be acceptable for completing the educational requirement for investigators. Individuals with questions regarding education programs completed prior to their arrival at Lipscomb should contact their IRB chairperson.
- CITI training certificates must be updated every three years.

Researchers Required to Submit IRB Research Proposals

Who Needs to Apply

In accordance with federal regulations (45 CFR 46.112), Lipscomb University requires that all research involving human subjects conducted under Lipscomb University's auspices must be prospectively reviewed and have the continuing approval of the Lipscomb IRB. The Lipscomb IRB is charged with protecting the rights and welfare of all research subjects, not just those subjects who participate in federally funded projects. Lipscomb University pledges that *all research irrespective of funding:* (1) involving human subjects; (2) using records gathered on human subjects; or, (3) involving human tissue, will receive IRB review prior to initiation.

For this reason, all proposed research in which a faculty member, student, or employee of Lipscomb University is the principal or co-principal investigator and that involves either direct or indirect contact with human subjects must submit an application to one of the Lipscomb University IRB. Investigators are welcomed and encouraged to contact IRB chairpersons and members with any questions.

Alumni and Adjunct Researchers

If a student starts a research project as a Lipscomb student and then graduates, but wishes to continue the research study post-graduation, the alum must notify the IRB office. If the student's faculty advisor is still actively working with the student as a collaborator on the study, the IRB protocol can be modified so that the principle investigator on record is the affiliated faculty member. The alum can be listed as a co-investigator on the protocol. However, if the faculty supervisor is no longer actively working with the student as a collaborator on the study, and the student is not affiliated with Lipscomb, Lipscomb's IRB is no longer responsible for continuing oversight of the student's research study and the IRB can close the student's study.

If an alum is affiliated with another institution and is collaborating with an investigator affiliated with Lipscomb, the alum must 1) submit an application to their home institution's IRB for review and submit those approvals to Lipscomb's IRB, or 2) the IRB and the alum's institution's IRB can enter into a cooperative agreement with Lipscomb (see **Collaborators from Other Institutions** in the following section).

If an alum's research study involves the use of Lipscomb University resources, and they are not collaborating with an affiliated Lipscomb investigator, the alum is considered an outside researcher and is required to follow the procedures outlined for non-Lipscomb affiliated investigators.

The Lipscomb IRB can review research studies of adjunct faculty members who have no primary affiliation with another university and who plan to conduct research and represent themselves as Lipscomb faculty. If an adjunct faculty member's primary affiliation is not with Lipscomb University, but with another institution, they must obtain IRB approval from their home institution first before submitting a research proposal form to the Lipscomb IRB.

An adjunct faculty member whose primary affiliation is with another University who plans on using Lipscomb University resources is considered an outside researcher and is required to follow the procedures outlined for non-Lipscomb affiliated investigators.

Collaborators from Other Institutions

Lipscomb investigators who are working with researchers from another institution must also ensure that IRB approval is obtained from the other institution before the research project can commence.

According to the federal regulations (§46.114), cooperative research projects are projects that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. In some circumstances, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort. In cases when a Lipscomb researcher is collaborating with a member or members of another institution, a formal letter of cooperation written and signed by an authorized member of that institution must be submitted with the research proposal form.

Students working with a faculty member who has IRB approval may submit an amendment or modification to the existing protocol. Personnel and funding may be added to faculty projects, and any procedural changes should be described in detail.

Non-Lipscomb Affiliated Investigators

Investigators not affiliated with Lipscomb University must first partner with a Lipscomb faculty researcher before submitting a research proposal form (note: partnerships between Lipscomb faculty members and outside researchers need to be approved by the Lipscomb faculty member's Dean). If a researcher is unable to form a partnership with a Lipscomb for whatever reason, he or she may contact the IRB Chair directly to discuss possible alternative paths to submitting a research proposal.

Accessing Lipscomb Student Emails

The Lipscomb IRB does not have access to a directory of student email addresses. If researchers would like to gain access to student email addresses, they may contact Lipscomb's Office of the Registrar to request permission to access student email addresses.

Student Research Projects Requiring IRB Review

Research projects involving human subjects conducted by any Lipscomb undergraduate or graduate student with the intent to contribute to generalizable

knowledge, such as theses, dissertations, and independent research projects, must be supervised by a Lipscomb faculty member and reviewed by the IRB. Because such directed or independent research projects employ systematic data collection from human subjects and a plan to publicly disseminate research findings, they must be submitted to the IRB for review.

It is the responsibility of the faculty member supervising the research to ensure that approval of the Lipscomb IRB is obtained. By signing as a sponsor of a student project, faculty advisors take the responsibility for ensuring that all research procedures comply with federal, State and University policies pertaining to the protection of human subjects.

Classroom research projects that are intended to contribute to generalizable knowledge (e.g., through publication or presentation) are subject to the federal regulations and are required to undergo IRB review. The category of review (i.e., exempt, expedited, or full review) depends on the type of activity being proposed, the subject population, and the level of risk to the subject.

Review may also be required if an instructor is not prepared to insure the ethical propriety of a student's project. If the instructor has concerns or questions concerning a particular project, review by the IRB is required.

Because some classroom research assignments could place subjects at risk, the Lipscomb IRB may require some or all classroom projects to be reviewed. Be sure to consult the IRB regarding its requirements. The following categories which might trigger IRB review are provided here for your reference only:

- The project involves more than "Minimal risk" (the probability and magnitude of harm that is normally encountered in the daily lives of healthy individuals).
- The project is not limited to surveys/questionnaires/interview procedures, observation of public behavior, or standard educational exercises directly related to the topic(s) being studied in an official University course.
- Surveys/questionnaires/interviews, if used, contain sensitive personal questions (e.g., questions about alcohol/drug use, sexual behavior/attitudes/orientation, criminal activity, suicidality/self-injurious behavior, violent or aggressive behavior, medical history, grades/test scores) or other personal information that could "label" or "stigmatize" an individual.
- The participants are from a special population that requires extra protections (e.g., pregnant women, prisoners, children under age 18, cognitively impaired individuals).
- Information recorded with direct or indirect (code number) identifiers linking the participant to his/her data when the questions being asked could reasonably harm the participant's reputation, employability, financial standing, and/or place the participant at risk of criminal or civil liability.

- The project includes deception. Individuals must be fully informed and given the opportunity to voluntarily consent to participation.
- The results of the classroom assignment either leave the University. Or, if the project involves gathering data from or about a company, agency, or organization and the data/results are shared with others *beyond that company, agency, or organization.*

Projects Not Requiring IRB Review

Class Research Projects

A number of schools and departments offer courses that may have a research component or constitute training in research methodology. Such classes require students to undertake projects in which other people are interviewed, observed, or otherwise serve as participants. The purpose of these course projects is to train students and provide them with greater understanding of social, educational, business, psychological, or biomedical processes, and an opportunity to practice various research methods. Such projects are conducted primarily for instructional purposes within the context of a formal class and are not designed to contribute to general knowledge (e.g., through conference presentations, journal publications, etc.). Therefore, the IRB does not consider them to be research. Thus, IRB review and approval are not required, provided the instructor is prepared to accept professional and ethical responsibility for all research projects conducted in conjunction with the class.

Under these conditions, it is the instructor's responsibility to monitor the ethical propriety of the projects, applying the criteria listed in this document. Furthermore, students should be required to complete human subjects research training before beginning any class research projects with human subjects. Time spent between instructors and students discussing matters such as confidentiality and avoidance of unnecessary discomfort or invasion of privacy will be time well spent. When assigning class research projects, instructor responsibilities include: communicating to students the ethical principles for the protection of human subjects, reviewing student classroom research projects, and monitoring their activities and consent procedures. All adverse incidents with participants involved in class research projects must be reported to the IRB for review.

Although the IRB does not review class projects, instructors and students are encouraged to follow federal guidelines and University policy when designing and conducting class projects with human volunteers. The explicit recognition of the existence of the IRB at all educational institutions, and discussion of their goals and concerns, should be an integral part of introducing students to research methodologies.

When in doubt, it is wise to have a research project reviewed. The category of review (i.e., exempt, expedited, or full review) depends on the type of activity being proposed, the subject population, and the level of risk to the subject.

Program Evaluations and Administrative Review Projects

Program evaluations and administrative review projects need not be reviewed by the IRB if the results will not be distributed outside the institutional setting, or if they are used solely to evaluate or review a program in order to build a better program. If, however, the results of the project will be published or otherwise distributed to an audience outside the institution, the project must be reviewed by the IRB.

When in doubt, it is wise to have a research project reviewed. The category of review (i.e., exempt, expedited, or full review) depends on the type of activity being proposed, the subject population, and the level of risk to the subject.

Pilot Studies and Focus Groups

A pilot study is a preliminary investigation of the feasibility of a study, usually done on a small scale (usually fewer than 10 subjects/participants) and exploratory in nature. A focus group is defined as a small, targeted group of consumers, led by a moderator, whose opinions and perceptions on a certain topic are elicited. Both procedures are typically designed to help the investigator refine data collection procedures and instruments or prepare a better, more precise research design. At the point of academic discussions, (e.g., "how could this survey question be misunderstood?") such studies would not contribute to generalizable knowledge and therefore are not considered research and do not require IRB review.

However, the IRB has encountered cases in which information derived from pilot studies and focus groups have been considered or used for research purposes (e.g., publication or presentation). The IRB urges investigators preparing pilot studies to weigh the likelihood that the pilot data will actually be used for research purposes. In those instances, IRB review and approval is required before pilot study data collection commences. Such studies often involve an application for expedited review but may require full IRB review.

International Research

Investigators conducting studies internationally should be aware of the laws and regulations governing human research protections in those countries. The Office of Human Research Protections (OHRP) has compiled a list of national policies which can be found on OHRP's website at http://www.hhs.gov/ohrp/international/. Investigators are responsible for identifying and abiding by the laws, regulations, and human subjects research protections in those countries where the research will be conducted. It is the investigator's responsibility for providing the IRB with the necessary information to adequately review the study.

Investigators are required to obtain and submit IRB approval (or equivalent), if available, from the foreign institution and submit those approvals to Lipscomb's IRB for review. If the foreign institution does not have an IRB (or equivalent), documentation granting approval to conduct research at the foreign institution/research site from that

institution/research site's official must be submitted to the IRB prior to approval and study commencement.

Investigators should check the U.S. Department of State's Travel Advisory Warnings at http://travel.state.gov/ when submitting an application to the IRB. Research studies conducted in a country(ies) listed on the travel advisory list may have to be reviewed at the full convened IRB meeting. The investigator should consult with the Chairperson(s) of the IRB prior to submitting an application for review.

When to Submit a Research Proposal

Determining when to submit a proposal depends upon when a researcher would like to begin data collection. To improve the chances that a project receives IRB approval by the planned data collection start date, researchers should submit their research proposal form and all required materials and documents as early as possible. The more time between the date that a research proposal is submitted and the planned data collection start date, the greater the chances the project will not be delayed by the IRB review process.

Usually, exempt and expedited proposals are approved in 2-4 weeks. The approval timeline for exempt and expedited reviews could be longer if research proposal materials are missing (e.g., letters of cooperation, informed consent forms, etc.) or if proposals are submitted over the summer or holiday breaks.

When a research proposal requires a full committee review, the approval timelines are longer. The IRB recommends that researchers consider the following timeline when submitting research proposals requiring full committee review:

- **90 days prior to data collection = excellent chance of IRB approval**
- **60 days prior to data collection = good chance of IRB approval**
- **30 days prior to data collection = fair chance of IRB approval**

For a research proposal to have any chance of being reviewed by the full committee, it must be submitted 10 days before the end of the month; depending on the volume of submissions, a research proposal requiring full-review submitted at this time may be reviewed at the following month's IRB meeting. Submission deadlines apply to applications seeking full review of either archival and prospectively conducted research projects. Applications seeking confirmation of exempt status or expedited review of either archival or prospectively conducted research projects may be submitted at any time. Provided the research proposal is in order and contains no need for revisions, the approval process generally takes three to four weeks.

The IRB makes every attempt to review all applications submitted for a particular month. Applications will be reviewed in the order in which they were submitted to IRB administrative personnel. Because IRB meetings not only include reviews of new applications, but also reviews of re-submitted applications, discussion of amendments to approved projects, adverse event reports, etc. it may not be possible for the IRB to review all applications submitted during a particular month. Because many funding agencies

require proof of IRB approval prior to the award of grants, investigators should take care to submit their IRB applications concurrently with submissions for funding.

Student submissions to the IRB may be subject to additional requirements by school/department within the University. It is the responsibility of all faculty members supervising student projects to review and co-sign their students' IRB applications. For example, there may be timing requirements for each program or department. Thus, students should check with their department/program to determine if there are any formal requirements that must be fulfilled prior to submitting an IRB application.

Contacting the IRB

The primary means of contacting the IRB is through the IRB email address: irb@lipscomb.edu. The names and contact information of the IRB chair and individual IRB members is available on the https://www.lipscomb.edu/irb website.

The IRB Review Process

The IRB reviews three types of human subjects research proposals: exempt, expedited, and full-review. Although researchers identify the research proposal type on the research proposal form, it is ultimately the decision of the IRB to decide if a research proposal is exempt, expedited, or full-review. A detailed description of these three types of research proposals is available on the IRB website (https://www.lipscomb.edu/irb). The U.S. Department of Health & Human Services (HHS) has also created charts to help researchers know when IRB review is required and what type of research is being conducted (https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c2).

Meetings of the IRB normally occur on the first or second Thursday of the month, depending on holidays and the academic calendar. IRB meeting proceedings include review of full-review research proposals and discussion of exempt and expedited proposals as needed. Policies and procedures of the IRB may also be a discussion topic in monthly IRB meetings; additionally, a scheduled review of IRB policies and procedures occurs each September. In order for the proceedings of monthly IRB meetings to be valid, a quorum must be met; a quorum includes a majority of IRB members including at least one member whose primary interest and training is in a non-scientific discipline (e.g., law, religion, business, etc.).

IRB Meeting Schedule

The IRB most often meets on either the first or second Tuesday of each month. The current IRB meeting schedule can be found here:

https://docs.google.com/document/d/1H1xCZsh8_vvkaKRAdsNF2jDg1L1ZDl2oKZJ385PWMj0/edit?usp=sharing

Exempt Research Proposals

Exempt research proposals fall into one of six categories:

1. Research conducted in educational settings involving normal educational practices or that which compares or tests the effectiveness of educational techniques.
2. Research using educational tests, surveys, interviews, or observation of public behavior unless the information being gathered is particularly sensitive. Information is considered sensitive if it is either directly or indirectly identifiable or if it is reasonable to assume that the disclosure of the information could lead to negative effects on a subject's life (e.g., criminal prosecution, civil liability, interpersonal conflict, psychological distress).
3. When human subjects are elected or appointed public officials, research using educational tests, surveys, interviews, or observation of public behavior that is identifiable and/or sensitive is considered exempt; however, this public official exception does not apply if a federal statute requires information be kept confidential before, during, and after the research process.
4. Research involving the collection or study of existing data if these data are publicly available or if the information is recorded by the researcher in a way that does not allow the subjects to be directly or indirectly identified (i.e., de-identified data).
5. Research subject to the approval of department or agency heads designed to 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
    d. Possible changes in methods or payment for benefits or services under those programs
6. Taste and food quality evaluation and consumer acceptance studies if the food consumed is wholesome with no additives or proven to be safe by the Food and Drug Administration, Environmental Protection Agency, or the Food Safety and Inspection Service of the U.S. Department of Agriculture

In the case of research proposals identified as exempt by the researcher, the role of the IRB when reviewing these proposals is to confirm that the project does indeed fall into the exempt category.

Expedited Research Proposals

Review of expedited research proposals may be completed by the IRB chair or an experienced member of the IRB. Although the chair of the IRB or an experienced member of

the IRB may approve expedited proposals, disapproval of a research proposal must come after review of the full committee.

Expedited research proposals describe research activities that have the following characteristics:

1. Research procedures present no more than a minimal risk to human subjects. Procedures of minimal risk are defined as those that offer no greater risk than what one would expect from activities of everyday life, a routine physical examination, or psychological examinations or tests.
2. The risks to subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge to be gained.
3. Selection of subjects is equitable and non-coercive and informed consent is obtained and documented.
4. The research plan makes adequate provision for monitoring data collected, ensuring the safety of subjects, and securing data and maintaining the confidentiality of human subjects.
5. Characteristics of expedited research activities, design elements, and participants commonly include:
    a. Collection of hair and nail clippings in a non-disfiguring manner
    b. Collection of excreta and external secretions.
    c. Collection of data from subjects 18 years of age or older using non-invasive procedures routinely employed in clinical practice.
    d. Anonymous voice recordings made for research purposes such as investigations of speech defects.
    e. Moderate exercise by healthy volunteers age 18-60.
    f. Study of existing data, documents, records, pathological specimens, or diagnostic specimens.
    g. Research on individual or group behavior or characteristics of individuals such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate the subject's behavior and the research will not involve stress to subjects.
    h. Research involving manipulation of the subject's behavior which does not involve stress or risk.
    i. Clinical studies of drugs and medical devices for which an investigational new drug/device application (21 CFR Part 312, 21 CFR Part 812) is not required or when the medical device is cleared/approved for marketing and being used in accordance with the labeling.

j. Collection of blood samples by stick (i.e., finger, heel, ear, or venipuncture) when:

i. Subjects are healthy, nonpregnant adults weighing at least 110 lbs.

ii. Blood drawn does not exceed 550 ml over an 8-week period

iii. Blood collection does not occur more than 2 times per week

Full-Review Research Proposals

Full-review research proposals are those that present more than minimal risk to subjects and/or may also involve vulnerable populations (e.g., children, prisoners). These proposals are reviewed by the full IRB in regularly scheduled monthly meetings.

Full-review research proposals are reviewed in the order that they come in. Depending on the volume of research proposals, submission of a proposal by the deadline (i.e., 10 days prior to the last day of the month) does not guarantee that a proposal will be reviewed at the next regularly scheduled IRB meeting.

Characteristics of full-review research activities, design elements, and participants commonly include:

a. Maximal exercise by healthy volunteers

b. Institutionalized persons (e.g., prisoners, patients in long-term care facilities)

c. Persons lacking the capacity to consent (e.g., people with disabilities and developmental delays)

d. Deception in the experimental design

e. The administration of drugs or other substances where an IND/IDE is required

f. Subjects with life-threatening physical conditions

g. Activity inducing a significant level of psychological or physical stress

h. Sensitive topics that could put subjects at risk for legal or civil liability or those that may invade a subject's privacy in regard to high-risk aspects of his or her behavior (e.g., illegal conduct, drug use, sexual behavior, alcohol use, etc.) when there is a possibility that the subject could be identified

i. Research involving waivers of any HIPAA regulations

Issues Considered in an IRB Review

I. **Study Design & Methods:** The IRB will review the design of a study with the aim of determining if it adversely impacts the rights and welfare of the human subjects. It is also considered unethical by the IRB to subject human

subjects to a study that is so methodologically flawed that little to no reliable information is likely to result. Additionally, the IRB will not approve a study that claims to be gathering information that is not consistent with a study's methodology. In some cases, it may be necessary for the IRB to consult with an outside expert to determine whether a study's design places participants at unnecessary risk. Information should also be included in the application about how the study plans to address adverse events (e.g., what will happen if preliminary results show that the protocol is harmful or injurious?).

Examples of methodological flaws that would prevent the IRB from approving a proposal include:

a. Statistical analyses are not consistent with a researcher's claims to participants (e.g., cause/effect).

b. Sample size is not sufficient to support a researcher's claims to participants of the potential applications of project findings (e.g., generalizability).

c. Selection bias in the sample contradicts a researcher's claim of generalizability of study findings.

d. Measurement error (e.g., poorly designed questionnaires) will prevent a researcher from accomplishing study objectives.

Study designs involving deception or withholding of information can be approved by the IRB under the Federal regulations if such strategies are justified and the protocol provides for a post-study debriefing of the subjects. A waiver of the debriefing requirement may be granted by the IRB (via a consensus vote) if the debriefing may be harmful to the subjects.

II. **Investigator Qualifications:** The IRB will examine the qualifications of students, faculty, and/or staff investigators. Procedures requiring special skills on the part of the investigators, licensure, accreditation, and/or experience in qualifying the investigator for the performance of the proposed procedures are reviewed by the IRB. In addition, the IRB will consider the facilities and equipment used to conduct the research and maintain the rights and welfare of the subjects.

III. **Selection of Subjects:** It is important that selection of subjects be equitable and free of coercion. In order to evaluate this, the IRB will take into consideration where and for what purposes the research is being conducted, and will carefully review research involving vulnerable subject populations, including children, individuals with cognitive disorders, educationally or economically disadvantaged subjects, pregnant women, and prisoners. Thus, it is important that investigators explain in their IRB application how the appearance of coercion in the recruitment of subjects will be avoided, and

what steps will be taken to safeguard the rights and welfare of subject populations.

When young children are being recruited as human subjects, researchers should provide a script they will use to recruit their participants in order to show that their selection procedures are free of coercion.

IV. **Risks and Benefits:** IRB applications will be reviewed to determine if risks posed to subjects are reasonable in relation to any anticipated benefits to subjects. Consideration will also be given to the importance of the knowledge that may be expected to result from the research. Because the federal regulations do not allow the IRB to evaluate potential long-range effects of applying knowledge gained through research (e.g., possible effects of research on public policy), the IRB considers only those risks and benefits that may directly result from the research.

The IRB also reviews any possible benefits a subject may derive from participating in research, and considers benefits of new knowledge that may justify asking a person to undertake the risks of the study. Investigators should note that paying subjects for their participation in research is NOT considered a benefit.

V. **Informed Consent Process:** The proposed informed consent process will be carefully reviewed by the IRB to determine that it is appropriately obtained and documented. For information on what an informed consent form should include, see the Appendices for an informed consent template. Note that the IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in the informed consent template or waive the requirements to obtain informed consent provided the IRB finds and documents that:

a. the research involves no more than minimal risk to the participants;

b. the waiver or alteration will not adversely affect the rights and welfare of the participants;

c. the research could not practicably be carried out without the waiver or alteration; and

d. whenever appropriate, the participants will be provided with additional pertinent information after participation.

VI. **Confidentiality and Privacy:** The IRB application will be reviewed to ensure that the research plan makes appropriate provision for protecting the privacy of subjects and maintaining the confidentiality of data in all stages of the research.

Applicants should understand the difference between anonymity and confidentiality. Anonymity can be defined as when a person is not named or

identifiable in any manner. Confidentiality may be defined as when personally identifiable and private information is entrusted to an investigator to not disclose it. Thus, routine practices for assuring confidentiality include: substituting codes for identifying information; removing cover sheets (containing names and addresses); limiting access to identified data; and storing research records in locked cabinets and/or encrypted drives. Even signed consent forms are records that contain confidential information and these should be secured according to state and federal standards. None of the above examples involve anonymous data because each involves some way of linking a person to the data.

Requirements of IRB Approved Research

In order for the IRB to approve a research proposal, the board must determine that all of the following requirements are satisfied:

I. Risks to the subjects are minimized and are reasonable in relation to anticipated benefits of the research;

II. Selection of subjects is equitable given the purposes and the setting of the research;

III. Appropriate informed consent will be sought from each subject or the subject's legally authorized representative, and such consent will be appropriately documented;

IV. The research plan makes appropriate provision for monitoring the data collected to insure the safety of subjects;

V. Appropriate provisions are made to protect the privacy of subjects and to maintain the confidentiality of data;

VI. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, appropriate additional safeguards have been included to protect the rights and welfare of these subjects.

Status of Research Review

After IRB review, researchers will receive a status letter informing them of the decision of the IRB. The following are the various responses of the IRB:

I. **Research approved:** IRB approval lasts for one year from the date of approval. Researchers who receive approval are free to proceed with data collection.

II. **Conditional approval:** If conditional approval is granted, researchers are allowed to proceed with data collection provided that the required modifications (listed on the letter) are in place. Within 30 days of receipt of conditional approval, researchers will need to submit a revised ***Research Proposal Form*** (i.e., one that documents the required modifications) with the

Request for Amendment to Approved Research box checked on the first page.

III. **Committee requests further information:** There are times when the IRB needs further information in order to make a decision about the status of a review. The request for additional information will be made directly to the researcher via email.

IV. **The proposal has been denied:** The IRB will provide a brief description of the reasons a research proposal was not approved directly to the researcher via email.

If an approved study continues unchanged for longer than one year, the principal investigator will need to submit another ***Research Proposal Form*** with the ***Project Continuation*** box checked on the first page. If an approved study continues for more than one year and there are changes to the research design or data that is collected, the principal investigator will need to submit another ***Research Proposal Form*** with the ***Request for Amendment to Approved Research*** box checked on the first page. The IRB reserves the right to observe, review, and evaluate a study and its procedures at any time.

Right of Appeal

It is the policy of Lipscomb University that the final decision regarding approval or disapproval of all proposals rests with the IRB. No research involving human subjects may be conducted under Lipscomb University's auspices without the prior and continuing approval of the IRB. Any investigator who disagrees with a decision of the IRB may request a hearing of appeal at any duly convened meeting of the IRB, during which relevant arguments and/or witnesses may be presented on behalf of the investigator. The final decision, however, rests with the IRB.

Provost Review of Research Involving Lipscomb Faculty, Staff, and/or Students

In order to ensure the rights, welfare, and protection of Lipscomb-affiliated participants, the Office of the Provost may also review research proposals that include members of the Lipscomb faculty, staff, and/or students as human subjects.

How to Submit a New Research Proposal

I. Complete the Research Proposal Form. Please note that researchers fill out the columns on the left side of this form. Institutional Review Board members fill out columns on the right side of this form (highlighted in purple). This document needs to be completed using Microsoft Word. Here is an example of how it should be saved:

IRB-Doe-John-MM-DD-YY

II. Attach the Research Proposal Form and any other associated materials to an email to the IRB at irb@lipscomb.edu. On the subject line enter the first and last name of both the investigator and the faculty research advisor and the date.

a. All advisors of student research must hold a CITI certificate of completion, showing that they understand the protection of human subjects in research. Certificates for advisors must be included in research proposal submissions.
b. When a research proposal is submitted to the IRB email address, the advisor must be included in the submission email string to show that they are aware of the proposal being submitted. If this does not occur, the proposal will not be considered.
c. These new specifications add some greater responsibility on the research advisor, but they will resolve some major issues that have arisen over the course of the last year.
d. Please pass this information on to research advisors and students.

Adverse Event Reporting

Investigators must report adverse events that occur during the course of their research with human subjects to the IRB in a timely fashion. An adverse event, as defined by the Department of Health and Human Services, is "an undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (e.g., headache following spinal tap or intestinal bleeding associated with aspirin therapy)." An adverse event in non-medical research can include an undesirable and unintended consequence of, or reaction to, procedures. An unanticipated adverse event can also be defined as any adverse experience whose nature, severity, and frequency of risk were not described in the information provided for IRB review or in the consent form.

Adverse events/experiences include, but are not limited to:

I. Problems related to the safety of subjects such as injury, life threatening events, or events that require or prolong hospitalization, produce a disability, result in a congenital anomaly/birth defect, or require medical evaluation (such as additional laboratory testing) and/or medical treatment.

II. Incidents or serious problems involving the conduct of the study or subject participation, such as, problems with recruitment and/or the consent process.

III. Issues of noncompliance.

IV. Major unresolved disputes between a research investigator and a research subject or between research investigators (including research staff) involved in the conduct of the research study,

Only unanticipated adverse events that are associated with a research intervention must be reported to the IRB. An adverse event is considered to be associated with a research intervention if there is a reasonable possibility that the reaction may have been caused by the research intervention (i.e., a causal relationship between the reaction and research intervention cannot be ruled out by the investigator(s)).

All adverse reactions and unexpected events should be reported as soon as possible to the IRB Chairperson (via email at irb@lipscomb.edu) no later than 96 hours from the time the investigator became aware of the problem. All fatal or life-threatening events MUST be reported to the IRB within 48 hours after discovery. Investigators should file such reports in writing, using the "Adverse Event Report Form" available online and contained in the appendices. of this manual. All relevant documents and supporting material should be included with the Adverse Event Report Form. When attaching supporting material and consent forms, participants' personal identifiers (e.g., name, social security number) should not be included.

In some instances, a serious or unexpected adverse event may necessitate an immediate change in protocol to relieve an apparent immediate hazard to research participants. In such situations, the principal investigator may implement a change in protocol in order to protect the welfare of the research participants. Investigators should be certain to describe such changes in protocol in the Adverse Event Report Form.

When the IRB receives an Adverse Event Report Form, the information will be reviewed to determine:

I. Whether the IRB requires additional information;

II. Whether further action (e.g., modification) is required regarding the protocol and/or consent form;

III. If current participants need to be informed of adverse event;

IV. If the study is to be monitored for a specified period of time;

V. Whether the research activity should be temporarily suspended;

VI. If actions taken by the investigator adequately addressed the adverse event or whether further actions to be administered by the investigator are required; and/or

VII. If the study is to be permanently discontinued.

The investigator will be informed in writing of the findings of the IRB review. When necessary, the IRB will also promptly report to appropriate institutional officials, any supporting agency or department heads, and the U.S. Department of Health and Human Services' Office for Human Research Protections (OHRP) any

a. Unanticipated problems involving risks to subjects or others;

b. Any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and

c. Any suspension or termination of IRB approval. If the adverse incident appears to constitute scientific misconduct it must be referred to the Office of the Provost.

Research Noncompliance

All investigators are required to conduct their studies in compliance with the IRB-approved protocol as well as comply with Lipscomb's IRB and University policies, state and local laws, and federal regulations related to the rights and welfare of human subjects research. If any allegations of noncompliance are made to the Lipscomb IRB or the Office of the Provost, those allegations must be investigated and it must be determined whether the allegation has a basis in fact or not. If the noncompliance appears to constitute scientific misconduct it must be referred to the Office of the Provost.

Investigators are required to self-report to the IRB any instances of noncompliance that involves potential risk to subjects or involves significant failure to comply with federal regulations, state laws, University policies, and/or IRB requirements. Lipscomb personnel, including investigators, research team, faculty, staff, administration, or students are also responsible for reporting to the IRB suspected or actual noncompliance. Reports of suspected noncompliance may also be reported to the IRB or the Office of the Provost by research subjects, subject's family members and others external to the University, including regulatory agencies. These reports may be in the form of complaints and may also be made anonymously.

IRB Review in Emergency Situations

Federal regulations do not permit human subject research activities to be started, even in an emergency, without prior IRB review and approval (see 45 CFR 46.103[b] and 46.116[f]). For example, if an investigator provided emergency medical care to an individual without prior IRB review and approval, the individual may not be considered a research subject under 45 CFR Part 46. The federal guidelines make clear that an investigator (e.g., physician) can provide emergency medical care to an individual when such care is warranted without regard to IRB review and approval, but also clearly state that such emergency care may not be claimed as research. Furthermore, any data regarding such care cannot be included in any report of a prospectively conceived research activity. More simply stated, federal regulations for the protection of human subjects do not permit research activities to be started, even in emergency, without prior IRB review and approval. If the emergency care involves drugs, devices, or biologics that are considered to be investigational by the Food and Drug Administration (FDA), then it may be necessary to meet FDA requirements to use the investigational article for emergency purposes.

Records

Investigator Records

Record retention requirements vary with the type of research conducted and the provisions of the investigator's funding source. Therefore, investigators must understand and follow any record retention requirements of their sponsor, department, or field of research. In addition, Lipscomb University and OHRP guidelines require that investigators maintain research records for at least three years after completion of the research. HIPAA related research records must be retained for at least 6 years. Furthermore, all records must be accessible for inspection and copying by authorized representatives of the IRB,

department or agency supporting the research. Conditions for maintaining confidentiality of the subjects and the research records are required for the life of the data. These rules apply equally to research conducted by students and/or staff. Protocols conducted with FDA regulated articles must be kept in accordance with current FDA regulations.

Current FDA policy states that investigators are required to maintain records for the longest of either:

I. A period of at least two years following the date on which the results of the clinical investigation are submitted to the FDA in support of an application for a research Investigational New Drug Number or Investigational Device Exemption or marketing permit; or

II. A period of at least two years following the date on which an application for research or marketing permit (in support of which the results of the clinical investigation were submitted to the FDA) is approved by the FDA; or

III. Two years after the investigation is discontinued and FDA is notified.

IRB Records

Documentation of IRB activities is maintained for at least three years (or at least 6 years for HIPAA related protocols) following the completion of research and includes the following (**§**46.115):

I. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects;

II. Documentation of actions taken through procedures of exempt and expedited review in the IRB minutes and in other appropriate files;

III. Minutes of IRB meetings in sufficient detail to show attendance; actions taken; vote on these actions including the number of members voting for, against, and abstaining; basis for requiring changes in or disapproving research; length of approval granted for projects; and a written summary of the discussion of controverted issues and their resolution;

IV. Records of continuing review activities;

V. Copies of all correspondence between the IRB and the investigators.

VI. A roster of IRB members. IRB may also keep on file a copy of each member's professional vitae; and

VII. Written operating procedures for the IRB.

VIII. Statements of significant new findings provided to subjects.

All records shall be accessible for inspection and copying by authorized federal representatives at reasonable times and in a reasonable manner.

Appendices

Appendix A: Helpful Links

Human subjects research trainings.

Collaborative IRB Training Initiative (CITI): https://about.citiprogram.org

Code of federal regulations.

45 CFR 46: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.103(b)

Office for Human Research Protections.

Frequently Asked Questions: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/index.html

Appendix B: IRB Research Proposal Information Sheet

IRB Research Proposal Information Sheet

Research Requiring IRB Review

- A detailed description of research requiring IRB review is available here: https://www.lipscomb.edu/irb
- Any research activity involving human subjects conducted by faculty, staff, and students must be reviewed and approved for compliance with regulatory and ethical requirements before the study or activity begins.
- Class research assignments that involve the use of human subjects do not require IRB review if they present only minimal risk to participants, they are not going to be published, and they have no connection with research conducted or presented outside the classroom.

Submission Due Dates

https://docs.google.com/document/d/1H1xCZsh8_vvkaKRAdsNF2jDg1L1ZDl2oKZJ385PWMj0/edit

- Specific research proposal submission due dates are listed here: https://www.lipscomb.edu/irb
- Expedited and exempt proposals are accepted whenever they are submitted and are usually approved within 2-4 weeks of the submission date.
- Research proposals requiring a full review are due 10 days prior to the next scheduled IRB meeting

Approval Delays and Full Review Timelines

- It is not uncommon for the approval of research proposals to be delayed due to missing information or issues with the research proposal itself. Some of the most common reasons for a delay include:
    - Missing CITI (or NIH) certificates of completion for the researcher and/or faculty advisor.
    - Missing cooperation letters from institutions participating in the research project.
    - Research procedures are not clearly described (e.g., recruitment, obtaining consent, data storage, etc.).
    - The informed consent is missing key components (e.g., risks & benefits, contacts, etc.).
    - Informed consent and/or assent forms and other written materials are not written at the appropriate reading level of participants.
- For full review proposals, we highly suggest considering the following timeline in order to avoid delaying the desired data collection start date:
    - **90 days prior to data collection = excellent chance of IRB approval**
    - **60 days prior to data collection = good chance of IRB approval**
    - **30 days prior to data collection = fair chance of IRB approval**

Helpful Link

- How to submit a research proposal to the IRB

Appendix C: IRB Research Proposal Form

https://drive.google.com/file/d/1CffQkzSI2BAq1CUsmx4mpYLUib45X1bO/view

Appendix D: IRB Research Study Multimedia Release Form

https://www.lipscomb.edu/sites/default/files/2019-01/Multimedia%20Release%20Form.docx

Appendix E: Adverse Event Report Form

https://drive.google.com/file/d/17iP6hqcI_evfqCs5f2L7w1t16D_mlrUD/view?usp=sharing

Appendix F: Informed Consent Template

Lipscomb University IRB Consent Template

Researchers, please use this document as guidance when creating consent forms for your research. The black text should remain in place. You may modify the red text to fit the needs of your proposal. See the completed example consent form later in this document.

INFORMATION AND CONSENT FORM

Introduction:

You are invited to be in a research study (state what is being studied). Principal Investigator's Name, a graduate student in the College Name at Lipscomb University under the supervision of Advisor's Name, a faculty member in the Department/ College Name will lead this study. We asked you to be in this study because (state how and why the subject was selected). Please read this form and ask questions before you agree to be in the study.

Background Information:

The purpose of this study is to (state what the study is designed to observe, measure, discover, or establish). We expect about XX people to participate in this research.

Procedures:

If you decide to participate, we will ask you to…. (Using bullets, in a step-by-step fashion, describe all steps and procedures you will follow, including their purposes, how long each step will take, and any repetitions.). This study will take about (Indicate the length of time the subjects will be participating in the study. If the study has multiple parts, indicate the expected time of each interval).

Risks and Benefits:

The study has several risks (instead of "several," use the word "minimal" if that is the case for your study. NOTE: All studies have some level of risk. You CANNOT say that the study has NO risks, nor can you say that the study has "no known risks." Describe studies of the lowest risk level as having a "minimal level of risk"). First, describe the most significant risk here. Second, describe any secondary risk here…(You must describe all risks. Indicate the likelihood of the risk with words such as "highly likely," "likely," "very unlikely" etc. Describe discomforts and any inconveniences the subjects may reasonably expect. If you tell the subjects of significant physical or psychological risks to participation, you must also say under what conditions the

researcher will terminate the study.)

The benefits to participation are (Describe any benefits. If there are no direct benefits to the subjects, state "There are no direct benefits to you for participating in this research." If applicable, describe appropriate alternative procedures that might be to the subject's advantage, if any. You must disclose any standard treatment that is being withheld. This wording typically is needed only for medical studies.)

Compensation:

If you are a part of this study, you will receive (Include payment or reimbursement information here. Explain when disbursement will occur and conditions of payment. Delete this section if it is not applicable).

(If this study involves a physically invasive procedure or an exercise component which may have even a slight risk of injury, you must include the following statement in the consent form. Omit this section if the study does not involve physical risk) In the event that this research activity results in an injury, we/I will help you by (give an example of a potential problem/injury and describe how you will assist them). Any costs for research-related injuries should be paid by you or your insurance company. If you think you have suffered a research-related injury, please let me/us know right away.

Confidentiality:

We will get your permission before sharing any information gained in connection with this research study that can be identified with you. We will keep your results confidential. If we present or publish information from this study, we will not use your personal information. Only group data will be presented. (If applicable, include ways in which you will maintain confidentiality, e.g. "No one in the daycare center will know your child's results," If you release information to anyone for any reason, you must state the persons or agencies to whom you will give the information, the nature of the information, and the purpose of the disclosure.)

We/I will keep the research results secure. Only I (or other researcher named in this form) and our/my advisor will have access to the records while we/I work on this project. We/I will finish analyzing the data by (specify the ending date of your research). We will delete your personal information that could be used to identify you from the research data collected for the study. (If you make photographs, audio or video recordings, explain who will have access to them, if you will present them for educational purposes, and when you will erase or destroy them. All multimedia data collected requires a separate multimedia release form. This form is available on Lipscomb's IRB website).

Voluntary Participation:

Participation in this research study is voluntary. You are free to stop participating at any time. (Explain here if monetary benefits will be adjusted if the subject withdraws early). Your decision whether or not to participate will not affect your current or future relations with (the name of any other cooperating institution or) Lipscomb University in any way.

New Information:

If during the research study we/I learn any information that might make you change your mind participating in the study, we/I will tell you. (This section is optional. Consult your advisor to decide if it applies to your study).

Contacts and Questions:

If you have any questions, please feel free to contact me, Principal Investigator Name, (or one of the researchers) at xxx-xxx-xxxx or xxxxx@lipscomb.edu (include a phone number and email address for each researcher). You may ask questions now or later and my faculty advisor, Faculty Advisor Name (phone number & email address), will be happy to answer them. If you have other questions or concerns about the study and would like to talk to someone other than the researcher(s), you may also contact Dr. Megan Parker Peters. Chair of the Lipscomb University Institutional Review Board at mparkerpeters@lipscomb.edu. (Be sure that you have a current copy of this template and that this contact information is up to date.)

You may keep a copy of this form for your records.

Statement of Consent:

You are choosing whether or not to participate. Your signature indicates that you have read this information and your questions

have been answered. Even after signing this form, you may choose to stop participating in the study at any time.

I agree to participate in the study. (If you are photographing, video- or audio-taping/recording your subjects, include a statement such as "and I agree to be videotaped" and have participants sign the multimedia release form available on Lipscomb's IRB website)

For electronic informed consent forms, in lieu of a signature, require participants to acknowledge reading and understanding the parameters of informed consent. This can be done with an electronic signature, checkbox, or similar method of documentation.

_____ _____

Signature of Participant Date

_____ _____

Signature of Parent, Legal Guardian, or Witness Date

_____ _____

Signature of Researcher Date

Appendix G: Minor Assent Template

CHILD VERBAL ASSENT (Younger than age 7)

When a study includes participants under the age of 7 who can reasonably be expected to understand verbal communication, obtaining verbal consent for research participation is ideal.

When submitting a research proposal that includes children who will provide verbal assent, please include a script that details what the researchers will say to the participants in recruitment and obtaining verbal assent.

CHILD ASSENT FORM (ages 7-12)

In order for minors (younger than 18 years of age) to participate in a research study, parental or guardian permission must be obtained. For minors 7-13, a child assent form, written in the following format is required. For minors age 13-17, language should be adjusted to be age appropriate for that group.

The child assent form must be brief and contain extremely simplistic language written at the appropriate age level. The heading for this form should be Child Assent Form.

The following elements need to be present on the child assent form:

1. a statement of the purpose of the research
2. a description of the research procedures involved in the study;
3. a description of the potential risks and/or discomforts associated with the research;
4. a description of any direct benefits to the minor;
5. a statement that the minor does not have to participate if he/she does not want to;
6. a statement that the minor is free to withdraw at any time;
7. a statement that the minor should discuss whether or not to participate with his/her parents prior to signing the form;
8. a statement that the parent(s)/guardian(s) of the minor will be asked for their permission on behalf of the minor;
9. an offer to answer all questions.

Only the minor and the investigator obtaining consent should sign the child assent form. The parent or legal guardian of the minor should be given a copy of the assent form.

The following is an example of a template that could be modified accordingly for other projects:

CHILD ASSENT FORM

I am [Insert Name] a graduate student from Lipscomb University. I am doing a study to figure out [explain in simple terms why you are conducting research]. I am asking you to take part in the research study because [explain why the child qualifies for the study].

For this research, I will [explain what child will be asked to do: e.g., ask you some questions about how you feel about school and how you get along with your classmates]. We will keep all your answers private, and will not show them to your teacher or parent(s)/guardian. Only people from Lipscomb working on the study will see them. [If this is not an accurate description of the use of their information, insert other description as applicable].

I don't think that any big problems will happen to you as part of this study, but you might [explain any risks which may result, e.g., you might feel sad when we ask about bad things that happen at school. You also might be upset if other kids see your answers, but we will try to keep other kids from seeing what you write].

[Describe direct benefits if applicable]. You can feel good about helping me to [explain any potential benefits to others].

You should know that:

- You do not have to be in this study if you do not want to. You won't get into any trouble with Lipscomb University, your teacher, or the [insert school/ organization name, if applicable] if you say no.
- You may stop being in the study at any time. If there is a question you don't want to answer, just leave it blank.
- Your parent(s)/guardian(s) were asked if it is OK for you to be in this study. Even if they say it's OK, it is still your choice whether or not to take part.
- You can ask any questions you have, now or later. If you think of a question later, you or your parents can contact me at [provide contact information for researcher(s), and advisor if graduate student].

Please sign this form only if you:

- have understood what you will be doing for this study,
- have had all your questions answered,
- have talked to your parent(s)/legal guardian about this project, and
- agree to take part in this research

Signature of Participant	Date
Signature of Researcher	Date