

LIBERTY UNIVERSITY

INSTITUTIONAL REVIEW BOARD HANDBOOK



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Liberty University Mission Statement

Philosophy of Education

Liberty University is a Christian academic community in the tradition of evangelical institutions of higher education. As such, Liberty continues the philosophy of education which first gave rise to the university, and which is summarized in the following propositions.

God, the infinite source of all things, has shown us truth through scripture, nature, history, and above all, in Christ.

Persons are spiritual, rational, moral, social, and physical, created in the image of God. They are, therefore, able to know and to value themselves and other persons, the universe, and God.

Education as the process of teaching and learning, involves the whole person, by developing the knowledge, values, and skills which enable each individual to change freely. Thus it occurs most effectively when both instructor and student are properly related to God and each other through Christ.

Statement of Mission and Purpose

Maintaining the vision of the founder, Dr. Jerry Falwell, Liberty University develops Christ-centered men and women with the values, knowledge, and skills essential to impact the world. Through its residential and online programs, services, facilities, and collaborations, the University educates men and women who will make important contributions to their workplaces and communities, follow their chosen vocations as callings to glorify God, and fulfill the Great Commission.

Liberty University will:

1. Emphasize excellence in teaching and learning.
2. Foster university-level competencies in communication, critical thinking, information literacy, and mathematics in all undergraduate programs.
3. Ensure competency in scholarship, research, and professional communication in all graduate programs and undergraduate programs where appropriate.
4. Promote the synthesis of academic knowledge and Christian worldview in order that there might be a maturing of spiritual, intellectual, social and physical value-driven behavior.
5. Enable students to engage in a major field of study in career-focused disciplines built on a solid foundation in the liberal arts.
6. Promote an understanding of the Western tradition and the diverse elements of American cultural history, especially the importance of the individual in maintaining democratic and free market processes.
7. Contribute to a knowledge and understanding of other cultures and of international events.
8. Encourage a commitment to the Christian life, one of personal integrity, sensitivity to the needs of others, social responsibility and active communication of the Christian faith, and, as it is lived out, a life that leads people to Jesus Christ as the Lord of the universe and their own personal Savior.

A. INTRODUCTION

Pursuant to the National Research Act (P.L. 93-348§212a) and 45 CFR 46.103, Liberty University (LU) maintains an Institutional Review Board (IRB) and has created policy to govern its actions. At Liberty University, the IRB is charged with assuring the protection of the rights and welfare of human participants involved in research. Therefore, the IRB is required to review all research involving human participants prior to the conducting of any research.

A.1 General Distribution of Responsibility

Any undertaking in which a University faculty member, staff member, or student investigates or collects information on living humans for research may be considered as “involving human participants.” It is the responsibility of each investigator to seek review by the IRB for any study involving human participants prior to beginning the project.

As previously noted, the University’s IRB is responsible for the review of research involving human participants. The respective authorities and duties of the IRB are described in this policy manual. Members of the IRB are nominated by their respective departments due to their expertise and ability to serve on the committee, or at the request of the IRB Chair using the same criteria. The IRB Chair is appointed by the Research Officer and is responsible for the general conduct and operation of the IRB.

The IRB Coordinator assists the IRB Chair and is responsible for coordinating and implementing this policy. This includes the application review process, assisting in liaison with Federal agencies, regulations, record keeping and reporting, managing human participant’s research training, and assisting with assurance of compliance with federal regulations.

A.2 Abbreviations and Definitions Used in Policy and Procedures

Federal regulations and University policy use the following abbreviations:

CFR: Code of Federal Regulations

FDA: Food and Drug Administration

DHHS: Department of Health and Human Services

OHRP: Office for Human Research Protections

NIH: National Institutes of Health

IRB: Institutional Review Board

RO: Research Officer

PI: Principal Investigator

Federal regulations and University policy define various terms in regard to protection of human research participants. 45 CFR 46, also known as the Common Rule, is the body of regulations promulgated by DHHS. Most projects at the University fall under these regulations. 45 CFR 46 includes the following definitions:

A.2.1 Definitions used by the Department of Health and Human Services

(1) *IRB* means an institutional review board established in accord with and for the purposes expressed in 45 CFR part 46.

(2) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(3) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the DHHS to whom authority has been delegated.

(4) *Department or Agency* means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

(5) *Institution* means any public or private entity or agency (including federal, state, and other agencies).

(6) *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program considered research for other purposes. For example, some demonstration and service programs may include research activities.

(7) *Human subject/participant* means a living individual about whom an investigator (whether professional or student) conducting research obtains

- (a) Data through intervention or interaction with the individual, or
- (b) Identifiable private information.

- *Intervention* includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes (e.g., cognitive experiment).

- *Interaction* includes communication or interpersonal contact between investigator and human subject (e.g., a telephone interview).

- *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 which has been provided for specific purposes by an individual and which he or she can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator) in order for the obtaining of the information to constitute research involving human participants.

(8) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated for participants 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.

(9) *Vulnerable population* means children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, individuals who are unable to give informed consent due to a physical or mental condition, or individuals whose circumstances may make them especially vulnerable to coercion (e.g., probationers).

(10) *Prisoner* means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. Prisoners receive additional protections under 45 CFR 46, Subpart C.

(11) *Child* means a person who has not yet attained the age of consent to treatments or procedures involved in the research under the applicable laws of the jurisdiction in which the research will be conducted. Children receive additional protections under 45 CFR 46, Subpart D.

(12) *Parent* means a child's biological or adoptive parent.

(13) *Guardian* means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

(14) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(15) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(16) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(17) *Adverse effect* means an undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (e.g., subject becomes upset following completion of a depression questionnaire, or subject experiences intestinal bleeding associated with aspirin therapy) that is directly or indirectly due to participation in a research study.

Some studies may fall under the regulations promulgated by the FDA (21 CFR 50). These will generally be studies that involve the testing of an investigational medication or a medical device. Refer to 21 CFR 50 for specific definitions regarding these studies. Some FDA definitions differ from the above DHHS definitions.

A.2.2 Definitions used by Liberty University

In addition to definitions promulgated by federal agencies, the University policy uses the following definitions:

(1) *Research* defined herein is similar to that used by DHHS. It is generally defined as systematic investigation—including research development, testing, and evaluation—designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)).

Systematic Investigation is further defined as any activity that utilizes scientific methods (either quantitative or qualitative) in an orderly, iterative process of data gathering. These methods may be experimental, quasi-experimental, or pre-experimental in nature and may or may not involve random selection and/or random assignment. In general, they follow an orderly plan of the investigator's design or adoption.

Generalizable Knowledge is further defined as any information generated from data collected to describe, inform, generate or test hypotheses that will be shared with others in any public or semi-public venue other than closed meetings and/or the classroom setting. This may include dissemination of information through more traditional, formalized means such as journal publications or conference presentations. It also includes dissemination through things like local or state newsletters or posting on the Internet such that a wider audience could access the information freely.

(2) *Principal Investigator* is the person who leads the project and is ultimately responsible for all aspects of it.

(3) *IRB Committee Member* is a current member of the IRB who often serves as a reviewer on Expedited and Full Review proposals. Committee members may consist of academicians with scientific training, clergy, medical doctors, persons without scientific training, students, former students, and consumers.

(4) *IRB Alternate Committee Member* is a member who substitutes for a regular IRB committee member of similar qualifications when the regular member is unavailable for proposal reviews.

(5) *Student class project* means a study in which a student investigator (individually or as part of a group) gathers or analyzes information in a systematic manner primarily for the learning experience (pedagogical purposes). It is not intended to contribute to generalizable knowledge and is not to be presented outside the class in which the research is being done or published/disseminated (including publication on the Internet) in any way, presented, archived, or compiled with similar research for later publishing or presentation. Human subjects research conducted for a senior project, master's thesis, seminar project, or dissertation does not fall under this definition and must be reviewed by the IRB.

(6) *Institutional research* is a study that is designed to obtain information to assist in the administration of the University. Institutional research provides information for administrative planning, policy making, decision making, and includes examinations of institutional effectiveness. Institutional research is specifically defined as those data collection and

interpretation efforts that: (a) will not be shared outside of the University environment; (b) will not be disseminated to other professionals or the public in any forum; (c) presents no more than “minimal risk” (as defined by Federal regulation); (d) is not intended to produce “generalizable knowledge”; and (e) contains no identifiers in the data that might compromise an individual’s confidentiality. Institutional studies meeting this definition are not subject to the IRB policy and procedures.

(7) *IRB Appointed Consultant* is a person whom the IRB feels has appropriate expertise to assist in the review of an IRB application. An example might include a person with the appropriate cultural background or expertise to assist in reviewing projects involving this particular culture.

(8) *Training* refers to a process approved by the University and required by federal regulations, to instruct investigators or IRB committee members/alternate members in the ethical conduct of research involving human participants.

A.2.3 General Principles

All of the University’s human subject activities and all activities of the IRB are guided by the basic ethical principles that underlie the conduct of biomedical and behavioral research involving human participants set forth in the report of the *National Commission for the Protection of Human Participants of Biomedical and Behavioral Research, The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Participants of Research*, regardless of funding source. The three basic principles contained in The Belmont Report central to the ethics of research involving human participants and guiding the IRB in assuring that the rights and welfare of participants are protected include: [respect for persons, beneficence, and justice](#).

Respect for persons requires that potential participants be given the opportunity to choose what will or will not happen to them and is the principle upon which obtaining informed consent and the consent process (including information, comprehension and voluntariness) is based. Respect for persons also provides additional protections for potentially vulnerable participants.

Beneficence is exemplified in the expressions of “do no harm” and “maximize possible benefits and minimize possible harms” both on the individual investigator and societal levels as they extend both to particular research projects and to the research enterprise as a whole, respectively.

Justice requires that there be fair procedures and outcomes in the selection of participants, both individually (by offering potentially beneficial research to all who might benefit) and socially (based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons).

While not explicitly stated in the Belmont Report, an additional principle of **Scientific Integrity** also guides the IRB in its actions. This principle requires clarity around research processes sufficient to allow for an adequate evaluation of the impact the research may have on human participants and right conduct on the part of those implementing the research to assure ethical behavior.

A.3 General Information on the IRB

The following information provides a brief sketch of IRB activities. These activities will be described in further detail in later sections of this handbook.

Principal Investigators (PIs) are responsible for the preparation of applications and for the content therein. Applications are reviewed by one or more IRB committee members or alternate members depending upon the specific classification of the research application (See Section F for a detailed description of the IRB review process). Typically, the IRB will communicate with the PI regarding clarifications or revisions needed in the application. The PI then responds with revisions and updates. If approved, the IRB Chair, IRB Coordinator, or other appropriately trained IRB personnel will notify the PI of the Board's disposition.

Approvals are for a one year period, unless a shorter interval is specified by the IRB. For projects in which data collection lasts longer than one year, an Annual Review Form (See Appendix B for a link to this form) must be submitted electronically to the IRB at irb@liberty.edu. It is the PI's and faculty sponsor's responsibility to turn in this form by the end of 11 months of the project's start date in order for review to take place for continued data collecting.

Previously approved projects may be modified by the PI by submitting a Change in Protocol Form (See Appendix B for a link to this form) electronically to the IRB with a detailed description of the modifications/changes being made. If the IRB Chair determines that the changes to the application significantly impact the risk/benefit ratio, he/she may require the PI to submit an entirely new application for review. If the risk/benefit ratio remains relatively unchanged, the IRB Chair or designated substitute can approve such changes without further committee review.

Reports of adverse events must be reported within 48 hours via phone, email, or in person to the IRB. A written report of the adverse event must then be submitted to the IRB Chair shortly thereafter. See Section H for details on deadlines for written report submissions.

The IRB is responsible for the following activities:

- Conduct initial and continuing review of research with human participants and report the findings and actions to the PI in writing;
- Determine whether any given project requires more than an annual review. Considerations used in making these determinations include the absolute risk to the subject, whether the risks outweigh the benefits, and prior conduct of the investigator(s) regarding the protection of human research participants.
- Review proposed significant changes in research activities to ensure that the protection of human research participants is maintained.
- Collaborate with the Research Officer and appropriate Liberty University departments to investigate any actual or suspected adverse event or incident of noncompliance.
- Observe project activities at any point to ascertain whether human subject protections are implemented so as to reduce the likelihood of an adverse event or noncompliance.

B. RESPONSIBILITIES AND ACTIONS OF THE INSTITUTIONAL REVIEW BOARD

B.1 Composition of the IRB and Appointment of Members

Federal regulations require that the IRB must be composed of at least five (5) members (45 CFR 46.107). The Liberty University IRB shall be composed of at least nine (9) members.

Representation will include members whose primary concerns are in scientific areas, such that social and behavioral sciences, education, and biomedical sciences are represented. The IRB has at least one member whose primary concerns are in non-scientific areas and a community representative who is not otherwise affiliated with the University nor a member of the immediate family of a University employee. At least one member (or alternate) must be able to act as an advocate for “vulnerable populations,” by virtue of experience and education. At least one member shall have expertise in both qualitative and quantitative research methods. In addition, the membership shall include men and women, as well as representation of racial and ethnic minority groups reflective of the composition of the University, when at all possible.

If a member goes on sabbatical or other leave for a semester, then an alternate will take his or her place from the department they represent. If a member or alternate leaves the University or goes on leave for one year or more, then the Research Officer, in concert with the IRB Chair, will appoint a replacement.

The IRB Chair will be appointed by the Research Officer. If either the IRB Chair takes a sabbatical, other leave of absence, or leaves the University, the Research Officer shall appoint a replacement. The new Chair will serve during the previous Chair’s absence.

B.2 Responsibilities and Actions of the IRB Chair

The Chair of the IRB is ultimately responsible for the conduct of the Board. The Chair:

- Monitors changes in federal regulations and guidelines and consults with the Research Officer in proposing policies and procedures to the IRB;
- Oversees initial training and continuing instruction of IRB members, University administrators, and any other personnel for whom federal regulations and University policy requires training regarding policies and procedures;
- Provides that research covered by the regulations will be reviewed, approved, and subjected to continuing review by the IRB;

B.3 Responsibilities and Actions of the IRB Coordinator

The IRB Coordinator manages the logistical side of the Institutional Review Board. This person

- Assists the IRB Chair in the on-going development of IRB systems to enhance the efficiency and functioning of the IRB committee;
- Interacts with faculty, researchers, staff, students, and pertinent federal institutions regarding IRB functioning at LU;
- Maintains awareness of the latest changes in federal regulations related to IRB functioning;
- Arranges for regular meetings, keeping their minutes;
- Organizes orientations and appropriate training for Board members, staff, and faculty;

- Consults with PI's, the IRB Chair, Associate Research Officer, and Research Officer as needed about current or prospective applications;
- Organizes and catalogs IRB submissions and approvals;
- Maintains/updates the IRB website, SharePoint site, and other IRB databases;
- Assists in overseeing continued compliance with federal guidelines regarding IRB policies;
- Develops training materials and leads/assists in IRB educational activities;
- Provides a list of IRB members to OHRP and the FDA, identified by the requirements contained in 45 CFR 46.103(b)(3).

B.4 Meetings and Quorums

A quorum is required to convene a meeting of the IRB. A quorum consists of at least a majority of members (or their alternates) present at the meeting, either in person, via conference call, Skype, or other appropriate technology. When members or alternates are associated with a project being reviewed, they are ineligible to vote on the project. However, the IRB may ask them to provide information about the project to enhance its review. The IRB will excuse the researcher from the meeting during final deliberations on the project. Potential conflicts of interest should be noted in the IRB meeting minutes. Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests), the IRB may not take official votes until the quorum is restored. Alternate members of the Board may be invited to each meeting and may participate in the discussion of agenda items, including reviews, so as to enhance their education and development. If they are not serving in a member's place, they are not eligible to vote.

The Chair will convene meetings of the board for review of new applications, modification requests requiring full review, and continuation requests requiring full review. The board carefully reviews these items. Suspension or termination of IRB approval, and Board procedural and educational issues may also be the focus of a convened IRB meeting.

The meeting schedule and past meeting minutes, along with any full review applications submitted for consideration, shall be distributed electronically to IRB committee members and alternates at least 5 business days prior to a convened IRB meeting. Past meeting minutes shall be reviewed and considered for approval during the convened IRB meeting. The committee may approve the minutes as presented, approve the minutes with requested revisions, or deny approval of the minutes. Any requested revisions will be noted and completed by the Coordinator or designee after the meeting. The Liberty University IRB will maintain approved meeting minutes electronically for a period of 7 years.

B.5 Review of Research

In conducting the review of research, the IRB shall follow the regulations as stated in 45 CFR 46.109, 21 CFR 50 (when research falls under FDA regulation), and LU's policy as described herein. One or more of the following parties may be involved in the initial review of the IRB Application:

- IRB Committee Member
- IRB Alternate Committee Member
- IRB Appointed Consultant

Each party above will be provided with the applicable documents for application review and may include the following:

- IRB Application completed by the PI
- IRB Committee Member Reviewer Worksheet
- IRB Application Supporting Documents (surveys, interviews, observation guides, school approval letters, etc.)
- IRB Change in Protocol Form completed by the PI
- IRB Annual Review Form
- Other pertinent documents as needed

B.6 Approval of Research

In accordance with 45 CFR 46.111, the following criteria are to be met for a research project to be approved by the IRB:

- Risks to participants are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and (ii) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). The IRB will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research benefits that fall within the purview of its responsibility.
- Selection of participants is equitable. In making this assessment the IRB takes into account the purposes of the research and the setting in which the research will be conducted and is particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative in accordance with 45 CFR 46.116.
- Informed consent will be appropriately documented in accordance with 45 CFR 46.117.
- The research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
- There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

Further, when some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards must be included in the study to protect the rights and welfare of these participants.

B.7 Actions and Authority of the IRB

Action on any of the options listed below requires a majority vote of the quorum. Action to require revision of an application may be initiated by any reviewing IRB member upon initial review of an application if the Board member determines that such revisions are (a) needed to determine the level of risk to participants and/or (b) needed to complete an application.

B.7.1 Actions Regarding Approval of Applications

The IRB may reach any of the following determinations with respect to any proposed project:

- Approve application as submitted.
- Issue a Conditional Approval.
- Require modifications and resubmission to the IRB. The IRB determines certain changes that are required for approval and these are communicated in writing to the PI. The PI submits the changes to the IRB Coordinator. At the IRB committee's discretion, the IRB Coordinator, IRB Chair, or designated IRB member(s) may approve the revised application on behalf of the IRB if the changes meet the requirements described in the written communication with the PI.
- Request IRB appointed consultant review. At any point, the IRB Chair or the IRB committee may determine that someone not on the IRB with relevant expertise needs to be consulted to address research issues as they relate to the protection of human research participants. For example, research projects involving multicultural contexts may lead to consultation with cultural experts. The consultant shall not be involved in the proposed project. In some cases, the identity of the consultant may need to remain confidential if there is any question that there could be problems should the PI know the identity of the consultant.
- Disapprove the application as submitted. When a project is disapproved, the PI may revise the proposal in accordance with IRB recommendations, discuss the project with the IRB Chair or respond in writing, or withdraw the proposal application.

B.7.2 Additional Actions and Authority of the IRB

The IRB

- Consults with the Research Officer and/or Associate Research Officer concerning matters of development and implementation of policies and procedures regarding the protection of human participants,
- Consults with the Research Officer and/or Associate Research Officer concerning matters of training University employees and students regarding the conduct of research involving human participants,
- Monitors approved projects for adherence to an approved protocol,
- Suspends or terminates approval of research that is not being conducted in accordance with Federal Regulations and University policy or that has been associated with unexpected serious harm to participants.

C. RESPONSIBILITIES AND ACTIONS OF THE RESEARCH OFFICER

C.1 Administrative Responsibilities of the RO Pertinent to IRB Functions

The Research Officer (RO) is administratively responsible for the implementation of the assurance to the Secretary of Health and Human Services. Procedures and actions of the RO with respect to implementation of the assurance include, but are not limited to the following:

- Assure that sufficient provisions have been made for staff and space needs in order to support the IRB's functions;
- Assure prompt reporting to appropriate University officials, OHRP (or FDA, if appropriate), and any sponsoring federal department or agency head of any unanticipated injuries or problems involving risks to participants or others, any serious or continuing noncompliance with the regulations or requirements of the IRB, and any suspension or termination of IRB approval of research;
- Provide satisfactory written assurance to the Secretary of Health and Human Services that the institution will comply with the requirements as set forth in the applicable federal regulations.

C.2 Actions of the RO upon Receipt of Notice of IRB Action from the Chair

- For externally funded research projects approved by the IRB, the RO will determine appropriate University personnel to complete any documentation required by the funding agency, and delegate responsibility for who sends the documentation to the proper agency.
- For research projects determined by the IRB Chair to require Administrative Approval in addition to IRB approval, the RO or designated substitute (such as the Associate RO) will serve as the reviewer and will communicate an approval or denial decision to the IRB Chair or Coordinator. This approval or denial is separate from IRB approval, as the RO may not approve research that has not been otherwise approved by the IRB. See Section F for the Administrative Approval Procedures.

C.3 Revisions of Policies and Procedures

The RO or designated representative (such as the Associate RO), in consultation with the IRB Chair and Coordinator, may implement changes of policy and procedures for the review of research involving human participants as may be consistent with currently applicable regulations, institutional requirements, and IRB experience. As changes occur in 45 CFR 46 and applicable portions of 21 CFR 50, they will be incorporated into University policy and procedures by reference, without requiring separate action by the RO or Associate RO. When Federal agencies issue new or revised guidelines and regulations, the IRB Chair will consult with the IRB Coordinator and draft a recommendation to the RO or Associate RO regarding adoption. The RO will maintain a current master copy of University policy. Additionally, the RO or designee shall determine the appropriate method of dissemination of policy and procedural changes to the University community.

D. RESPONSIBILITIES AND RIGHTS OF THE PRINCIPAL INVESTIGATOR

D.1 Responsibilities

- The PI has primary responsibility for all aspects of the protection of human participants on a given project, including compliance with all Federal and University policies and procedures, and that all research associates involved in a PI's project also comply with said regulations, policies, procedures, and guidelines.
- **The PI must complete all IRB-related training required by LU.**

D.2 Rights

- Applications shall be reviewed by the IRB in accordance with the ethical principles described in the Belmont Report, federal regulations, and University policy.
- When protocols are submitted, the IRB shall review the application as specified in the policy, barring any unforeseen and/or insurmountable problems.
- All decisions of the IRB shall be conveyed to the PI in writing (electronically or otherwise).
- The PI may consult with the IRB Coordinator, Chair, or designee if the PI is unclear about the rationale for its decisions or if any questions arise at any time related to the application or approved protocol.

D.3 Responsibilities of the PI upon Leaving the University

When a PI plans to leave the University and continue the research activities at another institution, she or he must notify the IRB in writing. This will allow the IRB to close the active research file. The PI is responsible for obtaining IRB approval at the new institution. If the research project will continue at the University under another investigator, the PI must submit written notification of such changes, and the IRB will follow the review guidelines set forth in this policy.

E. PROCESS FOR IRB REVIEW AND APPROVAL OF RESEARCH

E.1 Levels of Review

Upon receipt of a new application, the IRB Coordinator, IRB Assistant Coordinator, or trained IRB Graduate Student Assistant (GSA) will review the application narrative using chart one of OHRP's decision chart series (Appendix A). By using the decision chart, IRB staff will confirm whether the application can be classified as human subjects research or if it is a project that does not fall under IRB jurisdiction. If the application is classified as human subjects research, the application will be further examined to determine whether it meets criteria for an *Exemption Certification*, or if the application must be reviewed under *Expedited* or *Full Review* procedures. In addition, the IRB Coordinator, Assistant Coordinator, or GSA will perform a preliminary review of the application.

During preliminary review the IRB Chair, Coordinator, Assistant Coordinator, or GSA will examine new applications to identify common errors that many applicants make in completing IRB research applications and to identify common ethical issues needing clarification. Once the PI corrects these errors and provides appropriate clarifications, the application will be passed on to other committee members for further review if needed (see Expedited and Full Review categories below). By addressing common errors/ethical issues in this manner, preliminary review permits other IRB committee members to focus their time more efficiently on key ethical aspects of the application.

E1.1 Exemption Certification Review

E.1.1.1 New Application

Upon confirmation that a new application is classified as human subjects research, the IRB Coordinator, Assistant Coordinator, or IRB GSA will use chart two through seven of OHRP's decision chart series (Appendix A) to determine whether the application is eligible to receive an Exemption Certification. Research activities in which the involvement of human participants constitutes no more than minimal risk and falls within one or more of the exempt categories described in 45 CFR 46.101, as outlined below, may be eligible for exemption. Research activities may be deemed exempt from this policy (but not from IRB review) if one of the following is true:

- Research is to be conducted in established or commonly accepted educational settings, involving normal educational practices, such as
 - (i) research on regular and special education instructional strategies, or
 - (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- Research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - (i) information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and
 - (ii) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

- Research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt if:
 - (i) the human participants are elected or appointed public officials or candidates for public office; or
 - (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- Research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.
- Research and demonstration projects to be conducted by or subject to the approval of Official Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
 - (i) Public benefit or service programs;
 - (ii) procedures for obtaining benefits or services under those programs;
 - (iii) possible changes in or alternatives to those programs or procedures; or
 - (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- 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.

E.1.1.2. Preliminary Review and Certification Determination

Only the IRB may certify that the proposed research meets the exemption criteria outlined above. The IRB Chair, Coordinator, Assistant Coordinator, or GSA will make this determination during its preliminary review process. Exempt proposals not requiring special expertise will be reviewed by the IRB Chair, Coordinator, Assistant Coordinator, or trained IRB GSA. Additional IRB committee members, alternates, or consultants may be asked for input on an Exempt proposal when special expertise is needed to review the proposal properly. After preliminary review, the IRB may take one of the following actions:

- Certify the research project as exempt and requiring no further IRB review, unless modifications are proposed which are outside the exemption categories. The PI is sent an Exemption Certification notification by email.
- Require additional information or modification(s). The IRB Chair, Coordinator, or designee will contact the PI to request the required additional information or modification(s) if the information is needed to confirm the application falls under one of the exemption criteria. If, upon receipt of revisions and clarifications, the IRB Chair or Coordinator is satisfied and the protocol meets the exemption criteria, the research project is certified as exempt and an Exemption Certification notification is sent to the PI by email.

- Deny exemption certification. If the application does not fall within one or more of the exemption categories, as deemed by the IRB Chair or designee, the application is considered for expedited or full review.

E.1.1.3 Modification Request of an Exempt Study

If a study is certified as exempt, the PI must consult the IRB for any proposed modifications to the research project's protocol or informed consent or assent forms by emailing irb@liberty.edu with specific information on the proposed changes and how the participants will be affected by those changes. The IRB Chair, Coordinator, Assistant Coordinator, or GSA will assist the PI in determining whether the proposed changes will affect the study's current exempt status. If implementing the proposed changes will cause the study to no longer meet the exemption criteria, a new application must be submitted to the IRB for expedited or full review. The above process must be completed before any changes are made to a study that has been granted an exemption certification. The PI will be made aware of this requirement in the initial IRB Exemption Certification email.

E.1.1.4 Informing IRB members of Exemption Certification

At the end of each month, the IRB Coordinator will make available to the IRB a list of new research applications that have been awarded an exemption certification. This information will be provided to the committee via email and will be sent with the IRB monthly meeting minutes.

E.1.2 Expedited Review

E.1.2.1 New Application

Upon confirmation that a new application is classified as human subjects research, the IRB Coordinator, Assistant Coordinator, or IRB GSA will use chart eight of OHRP's decision chart series (Appendix A) to determine whether the application is eligible to be reviewed under Expedited Procedures. Research activities in which the involvement of human participants constitutes no more than minimal risk and falls within one or more of the expedited review categories described in 45 CFR 46.110, as outlined below, may be eligible for expedited review. Expedited reviews are for projects that do not meet the criteria for exempt status and fall into one of the following categories:

- Collection of data from voice, video, digital, or image recordings made for research purposes.
- 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 participants. [45 CFR 46.101\(b\)\(2\)](#) and (b)(3). This listing refers only to research that is not exempt.)
- 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.
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - from healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or from other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- 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 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.
- 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, including studies of cleared medical devices for new indications, are not generally eligible for expedited review.)
 - 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.
- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch 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 participants. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)

- Continuing review of research previously approved by the convened IRB as follows:
 - where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; or
 - where no participants have been enrolled and no additional risks have been identified; or
 - where the remaining research activities are limited to data analysis.

E.1.2.2 Preliminary Review and Approval Determination

Only the IRB may certify whether the proposed research meets the expedited review criteria requirements outlined above. The IRB Chair, Coordinator, Assistant Coordinator, or GSA will make this determination during its preliminary review process. The IRB Chair or Coordinator may review Expedited proposals not requiring exceptionally special expertise. In addition to the IRB Chair or Coordinator's review, additional IRB committee members, alternates, or consultants may review Expedited research proposals when their expertise areas fit the particular characteristics of the research proposal. The Chair or Coordinator may request such reviews and additional specialized consultation as appropriate. After preliminary review and review by additional committee members, alternates, or consultants, the IRB may take one of the following actions:

- Approve the research application and decide on the length of time the study is approved (one year or less); the PI is then sent a notification of approval via email.
- Require additional information or modifications. The IRB Chair or designee will contact the PI to request the required additional information or modification(s). The reviewers may decide that one or both of them need to review the additional information or modifications. The reviewer may also appoint the IRB Coordinator to verify the required revisions and approve the protocol. If the reviewers and/or Coordinator are satisfied that the protocol meets the IRB review criteria, the research project is approved for one year or less, and a notification of approval is sent to the PI via email.
- Require a full review of the application. If the protocol does not fall within one or more of the expedited review categories, the reviewers have concerns about the rights and welfare of the participants, or the additional information or modifications are extensive, the reviewers will forward the application for a full review. Additionally, the PI may be asked to revise the application prior to distribution of the application to the full IRB committee. If the PI does not return the requested revisions to the committee within 5 business days of the next scheduled IRB meeting, the IRB Application may be held until the following month's IRB meeting. See F.1.3.1 (Full Review-New Application) for requirements pertaining to the initial submission of Full Review applications.

E.1.2.3 Change in Protocol Request

The PI must request approval for any proposed modifications to the research project's protocol, informed consent or assent forms, and any other supporting documents. This information is sent when communicating the IRB approval decision by clearly outlining the regulatory requirements to notify the IRB of changes to the approved protocol and by providing the Change in Protocol

form as an attachment to the approval email (See Appendix B for the Change in Protocol form). The modifications must be approved by the IRB Chair or approved designee prior to implementation, which will be made clear to the PI in the IRB approval correspondence via email. Once the Chair or designee approves the requested Change in Protocol, the PI will be notified via email of this decision. If the Chair determines that (a) proposed revisions modify participant risk significantly and/or (b) change the basic nature of the research project, the Chair will direct the PI to submit an entirely new application for consideration by the Board. This application will then be reviewed as a new application (see section F.1.1.1, F.1.2.1, or F.1.3.1.)

E.1.2.4 Continuation Request

Research projects are approved for a period of one year, unless a shorter interval is specified by the IRB in its approval notice. It is the PI's responsibility to monitor the study's timeline and to submit a continuation request within the approved time period for the study when necessary. All data collection that will continue beyond the maximum approval time frame shall require an Annual Review Form (See Appendix B) by the 11th month of the study, which is communicated in the initial approval correspondence email. The Primary Investigator will also receive a reminder email during the 11th month of approval from the IRB reminding him/her to submit the Annual Review Form, if necessary. Any changes to the approved protocol must be reported on a separate form (See Appendix B: Change in Protocol form) by following the procedures outlined in Section F.1.2.3.

The Annual Review Form should be submitted directly to the IRB via email for review. The IRB Chair, or designee, may approve the continuation. If a continuation request is approved, the IRB Chair (or designee) will notify the PI of the approval via email within two weeks of the submission of the Annual Review Form. If the PI fails to request a continuation or submit requested information, IRB approval will be terminated on the expiration date. All research activities, including data analysis, **must cease** unless the IRB finds it is in the best interest of the individual research participants to continue participating in the research interventions or interactions. The IRB Chair, Coordinator, Assistant, or GSA will send a notification to the PI, and, if appropriate, the funding agency will also be notified via email. If the PI contacts the IRB past the annual review deadline and wishes to continue the study, the IRB may request a new application or accept a study update at its discretion.

E.1.2.5 Informing IRB members of Expedited Reviews

At the end of each month, the IRB Coordinator will make available to the IRB a list of new research applications, modification requests, and continuation requests that have been approved through the expedited review process. This information will be provided to the committee via email and will be sent with the IRB monthly meeting minutes.

E.1.3 Full Review

E.1.3.1 New application

Upon confirmation that a new application is classified as human subjects research, the IRB Chair, Coordinator, Assistant, or GSA will classify the application as a full review when the research does not fall within one or more of the exemption or expedited review categories (See Sections F.1.1. and F.1.2.) Research activities involving human participants in which there is more than minimal risk, or involving fetuses, pregnant women, prisoners, groups who may have

diminished capacity to provide consent, or who may be at high risk must undergo a full IRB review.

E.1.3.2 Preliminary Review and Approval Determination

If the PI identifies his or her project as one that may need a full-committee review, the completed IRB Application and supporting documents must be submitted to the IRB at least 10 working days prior to a scheduled meeting to allow for the preliminary review process prior to the meeting. Meeting dates are posted on the IRB website. Submission of materials by the deadline does not guarantee the full review will be conducted at the next meeting. Reasons for delaying review until the next meeting may include an already full agenda, failure to resubmit the application with revisions after preliminary review has taken place, or the protocol requires extensive revisions prior to review. Therefore, the IRB recommends that the PI submit the materials as early as possible. If a majority of the IRB members deem it appropriate, they may waive this materials submission deadline.

During the full-review process, the convened IRB committee will discuss issues pertinent to the wellbeing of potential research participants, including issues of adequate informed consent, research designs and procedures adequate to provide safety and confidentiality, and risk/benefit ratios. The PI is invited and encouraged to attend the meeting in which the application will be reviewed to facilitate clarifications and to respond to questions and revision suggestions. If the PI is a student, the faculty sponsor and student are both invited to attend.

The committee will use the approval criteria set forth in 45 CFR 46.111 (Also outlined in Section B.6 of this handbook) to determine whether the application may be approved by the IRB. After discussion and deliberation at the meeting, the IRB may take one of the following three actions:

- Approve the research application and decide on the length of time the study is approved (one year or less from the date of the convened meeting at which the IRB reviewed and approved the proposal). The PI is sent a notification of approval via email with the Change in Protocol and Annual Review forms attached. An official approval memo will also be attached as a PDF to the email.
- Conditionally approve the application. This determination is used when the committee asks for additional information or modifications during the IRB meeting. At this point, the committee must also decide whether revisions need to be reviewed by the convened IRB committee or if the IRB Chair and Coordinator can verify and approve the revisions once received from the PI. Following the meeting, the PI will receive an email from the Coordinator summarizing the revisions required for approval. The PI will then return the revised application and supporting documents to the IRB for further review. At the conclusion of this review, the IRB committee or Coordinator and Chair will make one of the following determinations:
 - The additional information or modifications meet the IRB requirements for approval. Official IRB Approval is sent via email to the PI.
 - The additional information or modifications are not sufficient. The IRB Chair or designee may continue to work individually with the PI until the IRB requirements are met.

- The additional information or modifications must be reviewed by a quorum of committee members or at the next IRB meeting. The PI would again need to be present at the meeting.
- Disapprove the research application. The PI is sent a notification describing the reasons the research application was not approved. The PI may revise the research application in accordance with IRB recommendations; discuss the reasons for disapproval with the IRB Chair or a designee; or withdraw the research application.

Projects that require full-committee review and are approved shall provide the IRB with an annual report (at a minimum) about the progress of the project and adherence to the approved project protocol. Information about the need for annual reports is included in the IRB approval notice. The IRB may also request more frequent reports. Additional information may be required by the Board at the time the project is reviewed and approved and shall be specified at that time.

E.1.3.3 Change in Protocol Request

The PI must request approval from the convened IRB for any proposed modifications to the research project's protocol, informed consent or assent forms, and any other supporting documents. The IRB recommends that Change in Protocol requests be submitted to the IRB at least 10 working days prior to the posted meeting date. Information about this process is sent when communicating the IRB approval decision by clearly outlining the regulatory requirements to notify the IRB of changes to the approved protocol, and by providing the Change in Protocol form as an attachment to the approval email (See Appendix B for Change in Protocol form). The modifications must be approved by the convened IRB prior to implementation, which will be made clear to the PI in the IRB approval correspondence via email. Once the convened IRB approves the requested Change in Protocol, the PI will be notified via email of this decision. If the committee determines that (a) proposed revisions modify participant risk significantly and/or (b) change the basic nature of the research project, the committee will direct the PI to submit an entirely new application for consideration by the Board. This application will then be reviewed as a new application (see section F.1.1.1, F.1.2.1, or F.1.3.1.)

E.1.3.4 Continuation Request

Research projects are approved for a period of one year, unless a shorter interval is specified by the IRB in its approval notice. All data collection that continues beyond the maximum approval time frame shall submit an Annual Review Form (See Appendix B) by the 11th month of the study, which is communicated in the initial approval correspondence email. The Primary Investigator will also receive a reminder email during the 11th month of approval from the IRB, via email, reminding him/her to submit the Annual Review Form, if necessary. Any changes to the approved protocol must be reported on a separate form (See Appendix B: Change in Protocol form) by following the procedures outlined in Section F.1.3.3.

The Annual Review Form should be submitted directly to the IRB via email for review at least 5-7 working days prior to the posted meeting date. Only the convened IRB may approve the continuation. If a continuation request is approved, then the IRB Chair (or designee) will notify the PI of the approval via email within two days of the convened IRB meeting. If the PI fails to request a continuation or submit requested information, IRB approval will be terminated on the expiration date. All research activities, including data analysis, **must cease** unless the IRB finds

it is in the best interest of the individual research participants to continue participating in the research interventions or interactions. The IRB Chair, Coordinator, or GSA will send a notification to the PI, and, if appropriate, the funding agency will also be notified via email. If the PI contacts the IRB past the annual review deadline and wishes to continue the study, the IRB may request a new application or accept a study update at its discretion.

E.1.3.5 Informing IRB members of Full Reviews

At the end of each month, the IRB Coordinator will make available to the IRB a list of new research applications, modification requests, and continuation requests that have been approved through the full-review process. This information will be provided to the committee via email and be sent with the IRB monthly meeting minutes.

E.2 Administrative Review

In addition to the IRB's normal review procedures, some projects may involve administrative review and approval at LU in order to take place. This section describes LU's administrative review procedures.

Liberty University supports and cultivates a climate of research. Liberty's dynamic setting presents unique opportunities that have often proven to be of interest to researchers. The University will examine and approve on a case-by-case basis all studies involving human subjects affiliated with LU or researchers affiliated with the institution.

This approval process involves both an Institutional Review Board (IRB) review of ethical aspects of the study (as described in this handbook) and an administrative review when appropriate. Four considerations are involved in determining the specific review process: IRB-regulated ethical aspects of the proposed project, non-IRB-related ethical aspects, public relations aspects, and relationship of the researcher to LU (LU-affiliated or non-LU affiliated). This administrative approval process shall be as follows:

IRB Guideline for All Research Involving LU

For any proposed research involving human subjects affiliated in any way with the University, the IRB examines ethical aspects in accordance with federal and state guidelines. The IRB Chair or Coordinator will inform the researcher of the final LU decision, including when proposals involve administrative review (see below).

Internal Research that Raises Ethical or Public Relations Concerns

In the case of research conducted by an internal (LU-affiliated) researcher, the IRB will address any ethical concerns under its purview. Additionally the IRB will consider concerns that arise over the collection of data for research purposes that might be used by the researcher in a way that could reflect negatively on the University. For any such identified concerns, the IRB Chair will forward the proposed study to the University Associate Research Officer (currently the Associate Dean of the Graduate School) to

determine whether administration is willing to approve the proposed investigation. The Associate Research Officer may consult the research investigator and additional administrative officials in making this determination. When revisions are made administratively, the Associate Research Officer forwards the revised proposal back to the IRB for a second review. Proposals may also be disapproved on administrative grounds. The IRB Chair or Coordinator will inform the researcher of the final LU decision.

Internal Research that Does NOT Raise Ethical or Public Relations Concerns

Studies involving only one department. When research proposals from LU-affiliated investigators contain no identified ethical aspects outside of the IRB's review domain, do not contain issues of concern to administration, and involve only one specific academic department, the IRB may forward the study's information to the appropriate school Dean or program Chair (cc'ing the Associate Research Officer) for administrative approval. The Dean/Chair may request changes or disapprove the study. The Dean/Chair will forward any altered proposal back to the IRB Chair for re-review and decision dissemination.

Studies involving more than one department. If projects involve more than one academic department, the projects are forwarded to the Associate Research Officer who will then determine the administrative approval process. For example, the Vice Provost for the Graduate School and Online Programs, the Provost, and specific school Deans, may all be contacted for an administrative approval determination if necessary. The University's administration reserves the right to request changes to any research study or to disapprove it. Administration will forward any altered proposal back to the IRB Chair for a second review and decision dissemination.

External Research

The Associate Research Officer must approve all research projects proposed by non-LU-related investigators, regardless of whether non-IRB ethical or administrative concerns exist. In the case that human subjects are involved, IRB approval should precede review by the Associate Research Officer. At the Associate Research Officer's discretion, additional administrative officials (for example, the Vice Provost for the Graduate School and Online Programs, the Provost, and specific department deans) may be consulted. As in other studies, the University's administration reserves the right to request changes to any research proposal or to disapprove it. Administration will forward any altered proposal back to the IRB Chair for re-review and decision dissemination.

E.3 Length of IRB Approval

Typically, the IRB approves a research study or continuation request for up to one year. However, approval may be granted for less than one year in some circumstances, which may

include, but are not limited to, high-risk protocols, projects involving unusual types of risk to participants, projects involving vulnerable participants (e.g., prisoners), and projects conducted by a PI who has previously failed to comply with IRB requirements. If the approved IRB application falls under one (or more) of the above categories, the IRB committee may determine a length of approval of less than one year during the convened IRB meeting. The length of IRB approval will be communicated to the PI in the approval email.

E.4 Verification from Sources other than the PI

Some projects may require verification from sources other than from the PI that no material changes have occurred since the previous IRB review. The criteria for determining which studies may need outside verification include, but are not limited to, complex projects involving unusual levels or types of risk to participants and projects conducted by PIs who previously failed to comply with 45 CFR 46 or the requirements of the IRB. Studies needing outside verification may also include projects where concern about possible material changes occurring without IRB approval have been raised based on information provided in continuing review reports or from other sources, such as the faculty advisor, site supervisors, or the participants taking part in the research. The IRB reserves the right to randomly select approved projects and request a report from the PI of the number of participants enrolled in the study, any changes to the approved protocol, or other factors in the study that may impact the welfare and rights of the participants.

E.5 Preparation of Public-Use Data Files

Many funding agencies require or recommend that projects produce public-use data files. If the PI knows that a public-use data file will be created, he or she must indicate this in the initial application form. Once the project is completed, the PI shall submit the proposed public-use data file to the IRB for inspection. The funding agency may provide guidance in the creation of public-use files. The PI should provide this information to the IRB when submitting the protocol to prepare a public-use data file. If the PI does not initially plan to develop a public-use data file, once the determination to develop a public-use data file is made, he or she will need to submit a modification request to the IRB. For the IRB to classify the file as a public-use data file, one of the two following situations must apply:

- The data were anonymous when originally collected or data were collected from unknown persons.
- The data were collected from identified persons, but the file has been stripped of individual identifiers and any other information that may risk disclosure of any subject's identity.

When data have been collected from identified persons, the PI must consider the following elements in determining whether he or she has properly addressed the risk of disclosure of participants' identity:

- All individual identifiers of each human research subject or any person named by any human research subject must be removed, and
- All variables that can be surrogates for individual identifiers (e.g., street address of subject) must be removed.
- To remove the possibility of identification when a human research subject is in a small subgroup within the sample, it may be necessary to collapse or combine categories of a

variable. For example, detailed breakdowns of religious denomination in a survey question or medical procedure codes may need to be collapsed into fewer categories.

- Delete or mask, as described above, any variable that a secondary user may employ to identify any research subject. For example, the PI may need to assign a new subject ID to each individual if the original subject ID contained identifying information, such as letters from the last name or part of the date of birth.
- Use statistical methods to add random variation to variables that cannot otherwise be masked. For example, a data file may contain a combination of public and private information on a relatively small sample (i.e., demographic characteristics and salary of a public official along with attitudinal information). The income variable may need to be altered so that it cannot be combined with the demographic characteristics to enable identification of the individual and thereby risk disclosure of private information. This option should be used only if other techniques do not work because it may compromise the integrity of the data.

F. PROBLEMS INVOLVING NONCOMPLIANCE

F.1 Definitions

- A. **Noncompliance**- any instance in which the primary investigator fails to adhere to the research protocol as approved by the IRB or fails to comply with the investigator agreement as outlined in the IRB application (See Appendix B). Instances in which the primary investigator fails to seek IRB approval prior to data collection also qualify as noncompliance.
- B. **Non-serious or minor noncompliance**- any instance in which the primary investigator submits a change in protocol form to the IRB but implements the change to the approved research protocol prior to receiving approval from the IRB to implement the change.
- C. **Serious noncompliance**- any instance in which the primary investigator does not submit a change in protocol or discuss the change with his/her faculty advisor but implements a change to the approved research protocol that directly impacts the research participants.
- D. **Continuing noncompliance**- any instance in which the primary investigator has been identified as noncompliant more than one time. This includes determinations of non-serious/minor or serious noncompliance.
- E. **Allegation of noncompliance**- any instance in which noncompliance is suspected to have taken place by the primary investigator. These instances may be current or past and may be reported by the faculty advisor, research participant(s), the primary investigator him/herself, or any other party deemed acceptable by the IRB.
- F. **Determination of noncompliance**- any instance in which the allegation of noncompliance against the primary investigator has been found to be true by the IRB. *Only the IRB may make this determination.*

F.2 General Description

In addition to reviewing and approving human subjects research being carried out by faculty, staff, and students at Liberty University or research being carried out at the University, the Institutional Review Board reserves the right to monitor the Primary Investigator's continuing compliance with their research protocol as approved by the IRB. Monitoring compliance with the research protocol provides an additional protection to human subjects volunteering in Liberty University research by ensuring investigators are not implementing unapproved changes to their approved protocols. Problems of noncompliance may be **non-serious or minor, serious, or continuing** in nature and may be reported by the Primary Investigator, Faculty Advisor, Participant, or other persons deemed appropriate by the IRB.

F.3 Procedures

F.3.1 Allegations of Noncompliance

Persons wishing to report noncompliance must contact the IRB at irb@liberty.edu with the Primary Investigator's name and information about the suspected or confirmed noncompliance. The noncompliance may fall under any of the three listed noncompliance categories in section G.2 and may involve instances such as leaving portions of the approved protocol out of the

research procedures, adding unapproved items (surveys, interview questions, informational documents) to the research protocol, or other behavior not in compliance with the Investigator Agreement (See Appendix B, IRB Application: Investigator Agreement & Signature Page) signed by the PI and the Faculty Advisor, if applicable.

F.3.2 Investigations of Noncompliance

Upon receiving a report of suspected or confirmed noncompliance, the IRB Chair or Coordinator will request written documentation from the person(s) reporting noncompliance. This documentation will include a brief report of why the person believes the PI to be engaging in noncompliance and facts about what he/she witnessed. The IRB will then review the approved research protocol and compare the written report to determine any discrepancies between the two. Additional information may be requested from the person(s) reporting noncompliance, and other parties involved in the research (e.g., assistants, participants, faculty advisors, etc.) may be contacted with questions about the alleged noncompliance.

Within 7-10 working days of the initial report, the IRB will contact the primary investigator in writing, detailing the allegation, findings, and possible outcomes of the pending case of noncompliance. The primary investigator will have the chance to reply to the IRB in writing within five (5) working days to either confirm or deny the allegation of noncompliance.

F.3.3 Determination of Noncompliance

Upon receipt of a response from the primary investigator or five (5) working days from the date contact with the primary investigator was initiated, the IRB Chair and Coordinator will determine whether the allegation of noncompliance will be upheld or dismissed. If the allegation is upheld, the IRB Chair and Coordinator (or the committee) may make the following determinations:

1. The PI must cease all research activity immediately and may not engage in further research activity until notified by the IRB.
2. The PI must cease all research activity immediately and must complete additional research ethics training within a period of time established by the IRB before continuing with his/her research.
3. In rare occasions, the PI may continue limited research activities due to the significantly harmful impact ceasing such activities immediately would have on the participants involved. Once such harmful risks are resolved, all of the PI's research activities must cease. Additional research ethics training and other requirements may be established by the IRB before the PI may resume research activities.

F.4 Corrective Actions

The institution may not reverse any decision made by the IRB, but the institution may decide to take additional corrective action upon notice of an instance of noncompliance. Once the IRB arrives at a determination (see Section G.3.3), the primary investigator, faculty advisor, department chair, associate research officer, and research officer will be notified, in writing, of the IRB's determination of noncompliance. Corrective action, in addition to that determined by the IRB, may be taken by any or all of the notified parties. If the act of noncompliance was one that also violated the Liberty Way or the Code of Honor (as discussed in the Investigator Agreement), the primary investigator will also be referred to the appropriate authorities.

G. PROBLEMS INVOLVING RISK, AND ADVERSE EFFECTS

G.1 Definitions

It is essential to have a good understanding of several terms in order to properly interpret this policy.

- A. Unanticipated problem** - any unforeseen or unexpected incident or experience (including an unanticipated adverse event) which is not described in the general investigational plan, elsewhere in the current IRB application, with the current investigator brochure, or in the consent document.

- B. Adverse event** – an undesirable effect detected in participants in a study. The effect may be the result of:
 - 1. the interventions and interactions used in the research;
 - 2. an underlying disease, disorder, or condition of the subject; and/or
 - 3. other circumstances unrelated to the research or any underlying disease, disorder, or condition of the subject.

- C. Unanticipated problem involving risk to participants or others** - any unforeseen or unexpected event or experience that adversely affects the rights, safety, or welfare of subjects or others, which is not described in the general investigational plan, elsewhere in the current application, with the current investigator brochure, or in the consent document. The event or experience could involve psychological harm/risk, physical harm/risk (i.e., adverse event), social harm/risk (e.g., inappropriate breach in confidentiality, harm to a subject's reputation, or invasion of privacy), or legal harm/risk. The experience could also involve events not previously identified in severity or degree of incidence. An adverse event could be considered an “unanticipated problem involving risk to subjects or others.”

- D. Anticipated problem/adverse event** – any foreseen or expected incident/experience, which was described in the general investigational plan, elsewhere in the current application, with the current investigator brochure, or in the consent document.

- E. Serious problem/adverse event** - any incident that results in significant harm to or increased risk for the subject or others. Examples of events which are serious would include but are not limited to inpatient psychiatric or medical hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse event when, based upon appropriate medical judgment, they may jeopardize the subject's health or welfare and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse. A disability is a substantial disruption of a person's ability to conduct normal life functions.

- F. Life-threatening event** - any experience that places the subject, in the view of the investigator, at *immediate* risk of death from the reaction as it occurred, i.e., it does not include a reaction that, had it occurred in a more severe form, might have caused death.
- G. Related** - There is a reasonable possibility, in the opinion of the Principal Investigator, that the experience was likely to have been caused by the research procedures.
- H. Internal event/problem** – occurrence involves research subjects enrolled in a project approved by the LU IRB and directed by a principal investigator employed by LU or one whose project is under the purview of the LU IRB (e.g., student dissertations and theses). [Internal events/problems are reported to the IRB on the LU ADVERSE EVENT REPORTING FORM.]
- I. External event/problem** - occurrence involves research subjects enrolled in multi-center research projects that do not fall under the purview of the LU IRB. [External events/problems are reported to the IRB on the “LU EXTERNAL PROMPT REPORTING FORM For Unanticipated Problems, Serious or Life-Threatening Events, and Related Anticipated and Unanticipated Deaths.”]

G.2 Reporting Table

The table below describes examples of whether a prompt report to the IRB is needed.

| Prompt report to IRB? | Incident | Examples |
|-----------------------|---|--|
| REQUIRED | Unanticipated problem involving risk to participants or others and related to the research procedures | Sensitive participant data stored on a computer is misplaced, lost, or stolen. |
| | Unanticipated serious or life threatening event related to research procedures | A participant needs psychiatric hospitalization after receiving a new psychological intervention involved in the study. |
| | Anticipated or unanticipated death related to research procedures | Any death related to the procedures involved in the study occurs. |
| NOT REQUIRED | Unanticipated problem with no harm involved to subjects | A participant talks in general terms to the press about the study. |
| | Adverse event that is anticipated | A participant in a survey on child abuse issues needs a counseling referral. This potential issue was anticipated by the researcher appropriate referral |

| | | |
|--|---|--|
| | | mechanisms were described in the already-approved IRB application information. |
| | Unanticipated adverse event that is NOT related to the study procedures | A participant in a psychotherapy study is hospitalized after receiving news that her 3 children were killed in an automobile accident. |

G.3 General Description

In response to the regulatory obligation, the Liberty University (LU) IRB utilizes a three-category reporting system. This system facilitates review of reports and permits determination of whether the problem/event raises new concerns. The reporting categories are as follows:

- A. Prompt** (within 2 work days) Reporting of an unanticipated problem involving risk to subjects or others (including unanticipated serious or life-threatening adverse events) and anticipated or unanticipated related deaths to the IRB.
- B. Non-Prompt** (after 2 work days) Reporting to the IRB of anticipated problems/anticipated serious adverse events or unrelated deaths;
- C. Continuation Review** Reporting if any problems/adverse events occurred within 12 months prior to the continuation review (CR) request for a written summary of all problems/adverse events involving participants since the study was initiated, whether anticipated or unanticipated, serious or non-serious, life-threatening or not life threatening, or related or not related.

The policy details the IRB requirements for reporting, including adverse events and unanticipated problems involving risks to research subjects and others. The policy applies to all research projects/clinical investigations falling under the purview of the LU IRB. In addition to the three categories noted above, there are two broad types of reports, internal and external. An *internal adverse event* is one that occurs with research participants enrolled in a project approved by the LU IRB and directed (or supervised) by an investigator employed by the University. An example of investigator supervision would be an LU faculty member's oversight of a student's dissertation or master's thesis.

An *external adverse event* is one that occurs with research subjects enrolled in multi-center research projects that do not fall under the purview of the LU IRB.

G.4 Procedures

- A. Prompt Reporting of Problems/Adverse Events: Basic Reporting Requirements (See Policy on Prompt Reporting for Definitions)**

PI = Primary Investigator below

1. The PI reports all problems/adverse events that meet these 3 conditions (a-c):
 - a) The event is serious or life-threatening, AND
 - b) unanticipated, AND
 - c) related to the study procedures

The PI will phone or email the IRB within 2 working days to report general information about the incident and will use the applicable LU Adverse Event Reporting Form in making the detailed written report. The written report should be submitted by the timeline shown below.

2. If there is insufficient information to determine whether the adverse event is related to study procedures, the PI will report the event according to the timeline in item 3 below.
3. Timeline for reporting serious and unanticipated or life-threatening events/problems using the LU Adverse Event Reporting Form:
 - a) As noted above, the PI phones or emails the IRB within 2 working days to report general information about the incident.
 - b) The PI reports unanticipated life-threatening experiences within 7 calendar days of his/her receipt of the information using the LU Adverse Event Reporting Form.
 - c) All other serious and unanticipated events/problems are reported within 10 calendar days of his/her receipt of the information using the above form.
 - d) Institutional policy requires the investigator to provide follow-up reports on serious or life-threatening and unanticipated and related events within 10 calendar days of his/her receipt of the information.
4. Timeline for reporting deaths:
 - a) The PI reports all deaths related to study procedures occurring during a study through a phone call or email to the IRB within 2 working days.
 - b) If the death is related to the study procedures, the investigators report such deaths in written form (after contacting the IRB as noted in (a)) within 3 calendar days by utilizing the appropriate LU Adverse Event Reporting Form
 - c) If the deaths are not related to the study procedures (i.e., due to underlying medical disease progression), these are reported in the summary of problems/adverse events submitted at the time of IRB continuation review.
5. The IRB may request more stringent requirements for reporting events for individual research studies if the respective committee determines it to be necessary.
6. If an event does not fall under the IRB's prompt reporting requirements, but in the PI's judgment, prompt reporting of the event(s) is in the best interest of the participant(s) (e.g., it may affect the welfare of participants, it changes the risk level of the study, or the frequency of the same event significantly increases), the PI should

submit the LU Adverse Event Reporting Form according to the applicable timeline for prompt reporting.

7. Any problems/adverse events that were initially determined to not be related to the study procedures and are subsequently determined to be related must be reported according to the requirements listed in items 1-3 above.

B. Prompt Report: Submissions/Screening and Review of Internal Problems/Events

1. The PI makes the preliminary determination if the event meets the criteria for an IRB reportable event in accordance with the LU Adverse Events Policy.
2. The PI completes the LU Adverse Event Reporting Form and submits the form to the IRB in the time period outlined above in the LU Adverse Events Policy.
3. If the PI recognizes the problem/event involves risk to subjects or others and the information is not already in the informed consent/assent document, he/she submits a revised consent/assent form with changes underlined, if applicable. If the revised informed consent/assent form impacts the protocol/research description, the PI also submits a revised research description containing the underlined changes as well as a clean copy of both the consent/assent form and the research description.
4. IRB staff screen the report to determine whether it is complete, enter the report into the IRB database, and place the report on the IRB agenda.
5. Staff then forward the report(s) and related material(s) to the IRB Chair (or designee if the project relates to the Chair or the Chair is indisposed) who serves as the primary reviewer. The IRB Chair informs the LU Associate Research Officer of the adverse event. The Associate Research Officer determines whether other LU administrative officials should be notified.
6. The IRB Chair (or primary reviewer designee) receives, at a minimum, the completed Adverse Event Form. Related material(s) that may be received include, but are not limited to, documents revised as a result of the problem/event or documents which provide additional assessments or summary information.
7. After review of the materials received, the IRB Chair (or primary reviewer) makes comments and returns the report to the Associate Research Officer and the IRB.
8. IRB staff sends copies of the adverse event materials with the IRB Chair comments in the agenda packet to each IRB member.
9. The IRB reviews internal events and problems at an online or on-campus convened IRB meeting using full-review procedures.

10. If the study is federally funded (e.g., by the Department of Health and Human Services), or regulated by the Food and Drug Administration, additional IRB reporting requirements may be in effect.
11. IRB staff separate new internal reports submitted at Continuation Review (CR) from the regular CR materials and process them according to the provisions of this policy.

C. IRB Review Outcome(s)

1. For all unanticipated problems/events submitted under the IRB's prompt reporting policy, the IRB determines whether the problem/event involves risk to participants or others. If the problem/event involves risk to subjects or others, the IRB will follow established federal reporting policies as appropriate. The IRB actions may include:
 - a) Acknowledgement/acceptance without further recommendation;
 - b) A request for further clarification from the investigator;
 - c) Changes in the protocol (e.g., additional test or visits to detect similar events in a timely fashion);
 - d) Changes in the consent/assent form(s);
 - e) A requirement to inform subjects already enrolled about additional risks;
 - f) A change in frequency of continuation review;
 - g) Further inquiry into other protocols utilizing the particular drug, device, or procedure in question;
 - h) Suspension or termination of the study; or
 - i) Request for quality improvement review or other actions deemed appropriate by the IRB.
2. If the IRB acknowledges/accepts without recommendation the internal problem/event, IRB staff generate and send an email and letter to the PI indicating the review outcome.
3. If the committee requests clarification(s) or additional information or revisions, IRB staff notify the PI via email and letter of the need for additional information and/or changes.
4. The PI responds to IRB requests for information or revisions in writing and sends the response to the IRB. IRB staff forward investigator responses to the IRB Chair for further review; the Chair may forward the responses to the entire IRB for additional review, request additional information, or acknowledge/accept the response without recommendation.
5. If the PI has concerns regarding the IRB decision/ recommendations for changes in the study, he/she may submit concerns to the IRB in writing including a justification for changing the IRB decision. The IRB reviews the request and makes a final determination. IRB staff sends correspondence to the PI on the IRB's final determination.

D. Submissions/Screening and Review of External Problems/Events: Prompt Report

An *external event/problem* is one that occurs with research participants enrolled in multi-center research projects that do not fall under the purview of the LU IRB.

1. The PI makes a preliminary determination if the event meets the criteria for an IRB reportable external event or unanticipated problem in accord with the Policy on Prompt Reporting.
2. The PI completes the External Prompt Reporting Form and submits it to the IRB in the time period outlined in this policy.
3. An IRB staff member screens the External Prompt Reporting Form for completeness.
4. IRB staff forward the External Prompt Reporting Form(s), any attached external reports of problems/events, and related material(s) to the IRB Chair or designee. The IRB Chair or designee serves as an expedited reviewer using expedited review procedures. Related material(s) the expedited reviewer may receive include, but are not limited to, documents revised as a result of the problem/event or documents which provide additional assessments or summary information.
5. If the expedited reviewer determines that the unanticipated event is an unanticipated problem involving risks to subjects or others, he/she makes comments on the External Prompt Reporting Form and returns the materials to the IRB. IRB staff schedule review of the unanticipated event(s) by the online or on-campus convened IRB. IRB staff sends copies of each External Prompt Reporting Form with the expedited reviewer's comments in the agenda packet to each IRB member.
6. If the expedited reviewer determines it is not an unanticipated problem involving risk to subjects or others, he/she documents his/her review by signing the original report and lists any concerns/recommendations. IRB staff place the original report in the protocol file.
7. IRB staff list the external problem/event on the IRB agenda for a convened online or on-campus meeting. Any IRB member may request to review the entire IRB file and the expedited reviewer's recommendations.
8. IRB staff separate new external problem/event reports submitted at Continuation Review (CR) from the regular CR materials and process them as outlined in this policy.

E. Review Outcomes

1. The IRB actions may include:
 - a) Acknowledgement/acceptance without further recommendation;
 - b) A request for further clarification from the investigator;

- c) Changes in the protocol (e.g., additional tests or visits to detect similar events in a timely fashion);
 - d) Changes in the consent form;
 - e) A requirement to inform subjects already enrolled about additional risks;
 - f) A change in frequency of continuation review;
 - g) Further inquiry into other protocols utilizing the particular drug, device, or procedure in question;
 - h) Recommendation for full review;
 - i) Request for quality improvement program review or other actions deemed appropriate by the IRB; or
 - j) Suspension of the study or termination of IRB approval.
2. If the IRB acknowledges/accepts without recommendation the external unanticipated problem/event, IRB staff generate and send a letter to the PI indicating the review outcome.
 3. If the reviewer requests clarification(s) or additional information or revisions, IRB staff notifies the PI in writing of the need for additional information and/or changes.
 4. The PI responds to those requests for information or revisions in writing and sends the response to the IRB. IRB staff forward those responses to the IRB Chair or designee for further review. The IRB Chair or designee may request additional information, recommend full review, or acknowledge/accept the response without recommendation.
 5. The IRB Chair or designee reviews any replies from the investigators on behalf of the committee unless the IRB Chair or designee determines the reply needs further review by the full committee. The IRB Chair or designee documents acknowledgement/acceptance of the report, and IRB staff notify the PI in writing in a timely manner.
 6. If the PI has concerns regarding the IRB decision/recommendations for changes in the study, he/she may submit the concerns to the IRB in writing including a justification for changing the IRB decision. The IRB reviews the request and makes a final determination. IRB staff sends correspondence to the PI notifying him/her of the final IRB determination.

F. Reporting of Problems/Events that do not Meet Prompt Reporting Requirements (Non-Prompt Reporting) to the IRB (Required by Sponsors; Not Required by LU IRB)

1. If a PI recognizes that a problem/event does not meet the prompt reporting requirements, but the sponsor has requested reporting to the IRB, the PI should comply with this recommendation utilizing the LU Adverse Event Reporting Form. The PI includes comments in the report stating why the event does not meet prompt reporting guidelines.

2. Upon receipt of the above form and related materials, IRB staff enter the applicable code in the IRB database to indicate receipt of a Non-Prompt Report. IRB staff then forward the Non-Prompt Report and its attachments to the IRB Chair or designee.
3. If the IRB Chair or designee determines the problem(s)/event(s) should be reported per the prompt reporting requirements, he/she documents this on the PI's materials and returns the materials to IRB. IRB staff notifies the PI that the incident falls under the prompt reporting guidelines.
4. If the IRB Chair or designee affirms the problem(s)/event(s) do not meet the prompt reporting requirements, he/she makes a notation on the PI's report to acknowledge receipt and returns the notated report and materials to the IRB.
5. IRB staff enters the applicable code in the IRB database to indicate IRB acknowledgement of the Non-Prompt nature of the report materials. IRB staff generates a letter from the IRB indicating the acknowledgment of the materials received although the problem(s)/event(s) do not meet the LU IRB's prompt reporting requirements.
6. The IRB retains a copy of the materials and IRB acknowledgement letter in the IRB protocol file.

G. Continuation Review Reporting of Problems and/or Adverse Events

1. If any problems or adverse events occurred within 12 months prior to the continuation review request, the PI provides a written summary of **all** problems/adverse events involving subjects since the study was initiated whether anticipated or unanticipated, serious or not serious, life-threatening or not life-threatening, or related or not related. The summary includes the PI's assessment of whether the problems/events warrant changes in the protocol, consent process, or risk/benefit ratio. The summary includes both a qualitative and quantitative assessment.
2. For policies and procedures for conducting continuation review, see the LU Continuation Review Policy.

H. CONFLICT OF INTEREST POLICY

Several types of conflicting interests may arise when conducting both funded and unfunded research. While [45 CFR 46](#) does not directly address conflicts of interest, the IRB is required to determine that information provided to potential and actual participants regarding the research is objective and complete regarding the risks and benefits. It is also required to determine whether risks of the research have been properly addressed by the protocol. If conflicting interests exist, such objectivity and handling of risks can be compromised.

Research staff or consultants must report all real or potential conflicts of interest to the Principal Investigator (PI). The PI is responsible for making certain that no research staff or consultants perform research tasks if there is likely to be a conflicting interest unless the conflict has been previously reported to the IRB and proper methodological safeguards have been approved.

H.1 Definitions

H.1.A. *Conflict of Interest*: a set of conditions in which an investigator's judgment concerning a primary interest (e.g., subjects' welfare, integrity of research) may be biased by a secondary interest (e.g., personal gain).

H.1.B. *Investigator, Research Staff, or Consultant Conflict of Interest*: any situation in which a financial interest or other opportunity for tangible personal benefit may compromise or appear to compromise his or her professional judgment in proposing, conducting, or reporting research.

H.1.C. *IRB Member or IRB Staff Conflict of Interest*: any situation in which the ability of the reviewer or staff to make fair and impartial judgments about an application is impaired. Examples include a financial interest, opportunity for tangible personal benefit, a scholarly or social commitment, or a pre-existing relationship with the investigator(s). Review of initial applications, renewals, revisions, unanticipated problems involving risk to subjects or others, non-compliance investigations, or suspension/termination decisions are situations that may be impacted by the conflicts listed above.

H.2 Types of Conflicting Interests

Potential conflicting interests include but are not necessarily limited to those discussed below.

H.2.A. *Financial Conflict of Interest*: conflicting interests involving anything of monetary value including but not limited to salary or other payment for services, equity interests, and intellectual property rights (e.g., patents, trademarks, licensing agreements, copyrights, and royalties from such rights). Federal policy covers financial conflicts of interest in research that is funded by DHHS, FDA, and NSH, among others. Disclosure of any such conflicts must be made in writing.

H.2.B. *Conflicts of Commitment*: conflicting interests in which an investigator's time or other commitments to a project cannot be honored because of other existing commitments to the University.

H.2.C. *Personal Conflict of Interest*: conflicting interests including any existing relationship with persons or entities involved in the research, instrument authors, participants, and research sites. Existing relationships may include but are not limited to spouses, relatives, or friends.

H.2.D. *Dual Relationship Conflict of Interest*: exists whenever one role of the investigator calls into question his or her ability to be objective about the fulfillment of another role. While such dual relationships may involve financial conflicts of interest, many do not. Types of dual relationships may include but are not limited to faculty/student relationships and former, current, or future employment relationships.

H.2.E. *Political/Professional Conflicts of Interest*: exists when there are business relationships with instrument authors, participants, the research site, etc.

H.3 Handling Conflicting Interests

Primary investigators are required to report all real and potential conflicting interests that may compromise the integrity of the research in the appropriate section of the IRB application. While the conflicting interests described above may not be able to be completely eliminated, the primary investigator must identify the issues and discuss the safeguards in place to reduce the possibility of compromising the integrity of the research.

Additionally, the primary investigator is responsible to understand the conflict of interest policies from other organizations in their chosen research field. Examples include the [American Psychological Association](#) and [National Institutes of Health](#).

H.3.1. Handling Conflicting Interests Post Approval

If the primary investigator identifies real or potential conflicting interests once the protocol has been approved, the primary investigator must contact the Liberty University IRB office for guidance on establishing safeguards to minimize risks to participants and to optimize researcher objectivity.

For questions or guidance on determining real or potential conflicting interests, please email irb@liberty.edu.

REFERENCES

- 21 CFR 56.108(b)
- 38 CFR 16.103(b)(5)
- 45 CFR 46.103(b)(5)

APPENDIX A: HUMAN SUBJECT
REGULATIONS DECISION CHARTS (OHRP)

Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

September 24, 2004

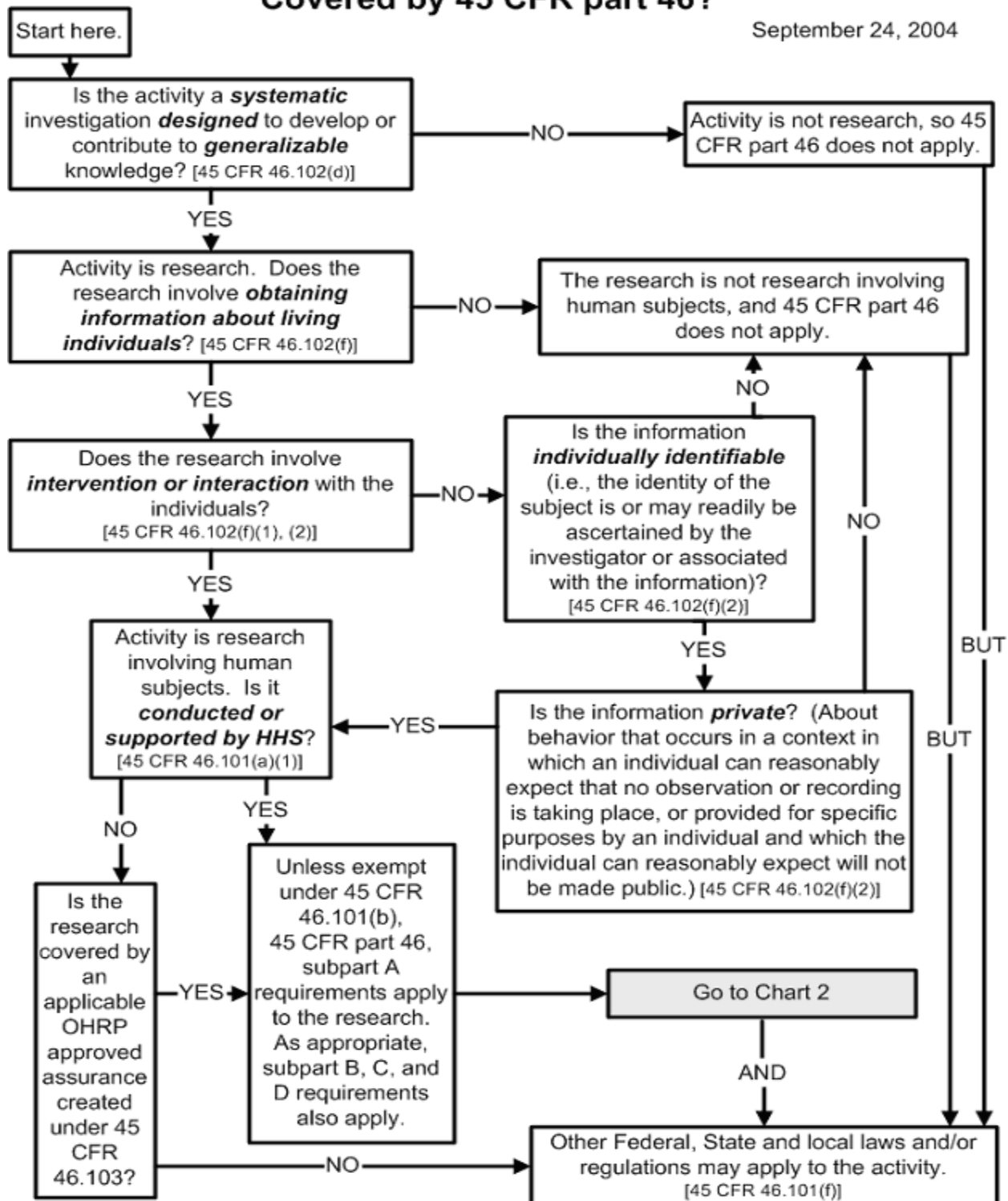


Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

From Chart 1

September 24, 2004

Has HHS **prohibited** exemption of the human subjects research?
(All research involving prisoners, some research involving children.)
[Footnote 1 to 45 CFR 46.101(i), 45 CFR 46.401(b)]

NO

Will the **only**** involvement of human subjects be in one or more of the following categories?

** **"Only"** means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is **not** exempt.

Research conducted in **established or commonly accepted** educational settings, involving **normal education practices**?

YES

Exemption 45 CFR 46.101(b)(1) may apply.

Go to Chart 3

AND/OR

Research involving the use of **educational tests, survey procedures, interview procedures, or observation of public behavior**?

YES

Exemption 45 CFR 46.101(b)(2) or (b)(3) may apply.

Go to Chart 4

AND/OR

Research involving collection or study of **existing** data, documents, records, or pathological or diagnostic specimens?

YES

Exemption 45 CFR 46.101(b)(4) may apply.

Go to Chart 5

AND/OR

Research studying, evaluating, or examining **public benefit or service programs**?

YES

Exemption 45 CFR 46.101(b)(5) may apply.

Go to Chart 6

AND/OR

Research involving **taste and food quality evaluation** or **consumer acceptance studies**?

YES

Exemption 45 CFR 46.101(b)(6) may apply.

Go to Chart 7

NO

YES

No exemptions to 45 CFR part 46 apply. Provisions of 45 CFR subpart A apply, and subparts B, C and D also apply if subjects are from covered vulnerable populations.

Go to Chart 8

Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

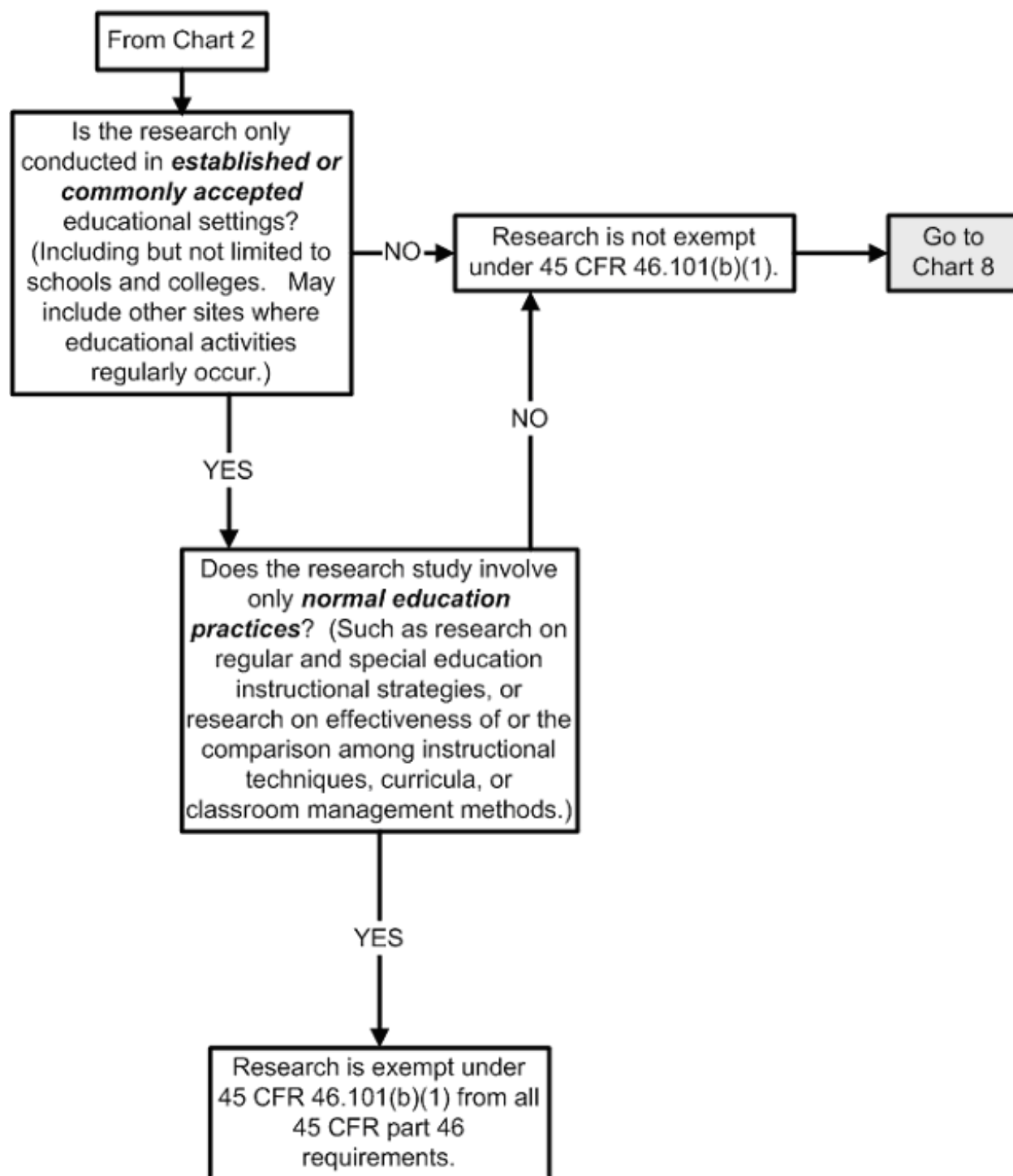
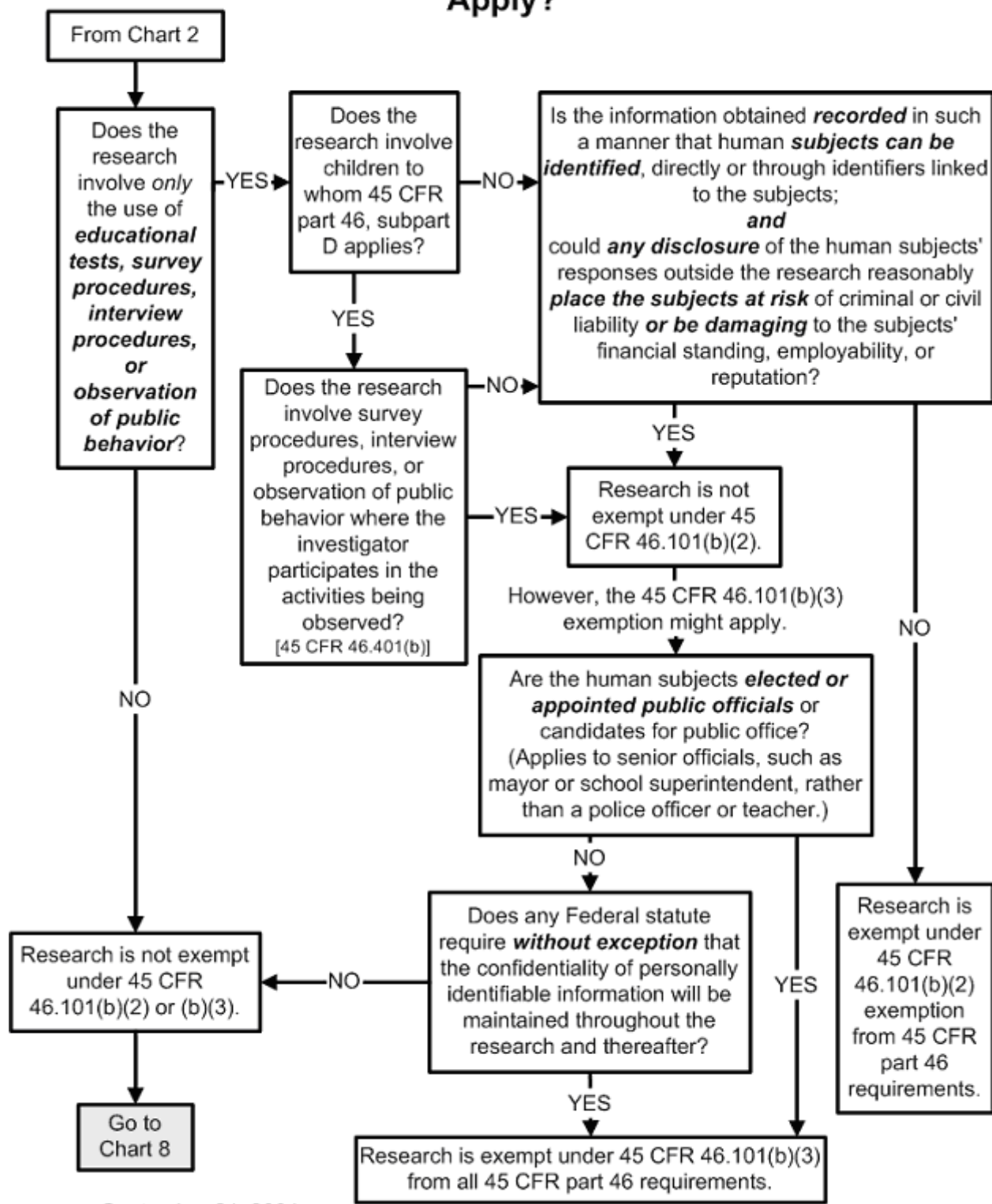
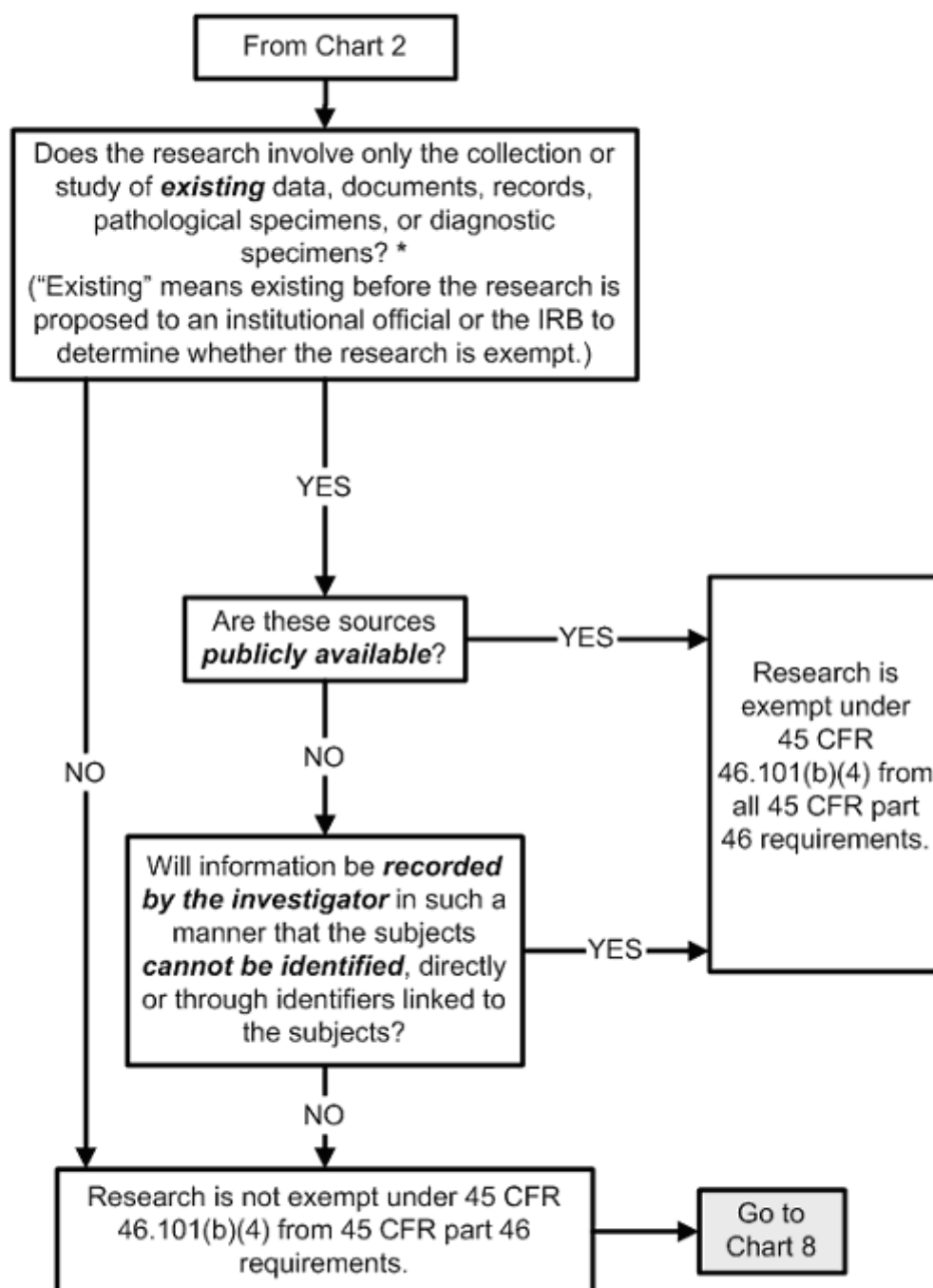


Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?



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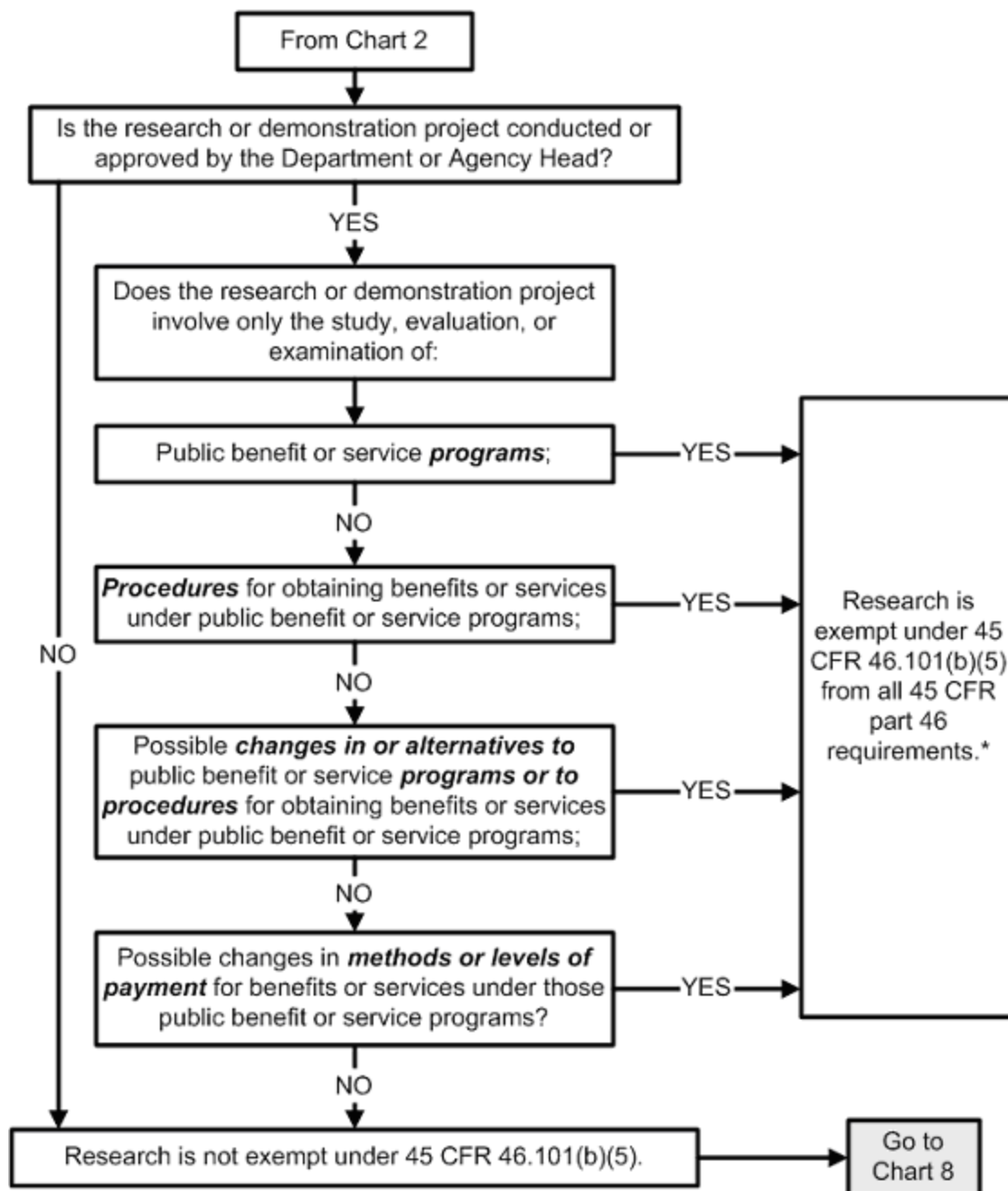
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?



* Note: See **OHRP** guidance on research use of stored data or tissues and on stem cells at <http://www.hhs.gov/ohrp/policy/index.html#tissues> and [#stem](http://www.hhs.gov/ohrp/policy/index.html#stem), and on coded data or specimens at [#coded](http://www.hhs.gov/ohrp/policy/index.html#coded) for further information on those topics.

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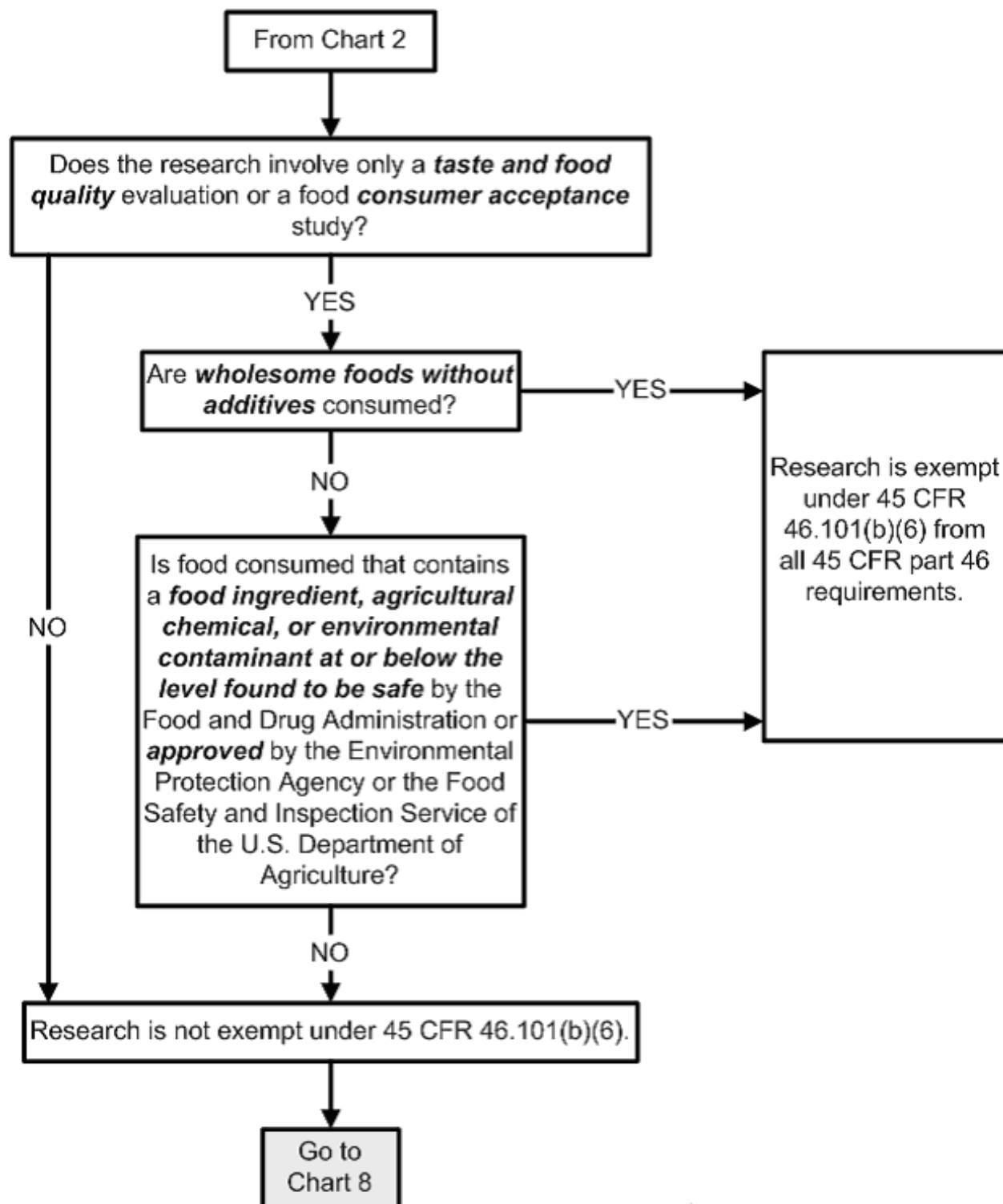
Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?



* Note: See OHRP guidance on exemptions at <http://www.hhs.gov/ohrp/policy/index.html#exempt> for further description of requirements for this exemption.

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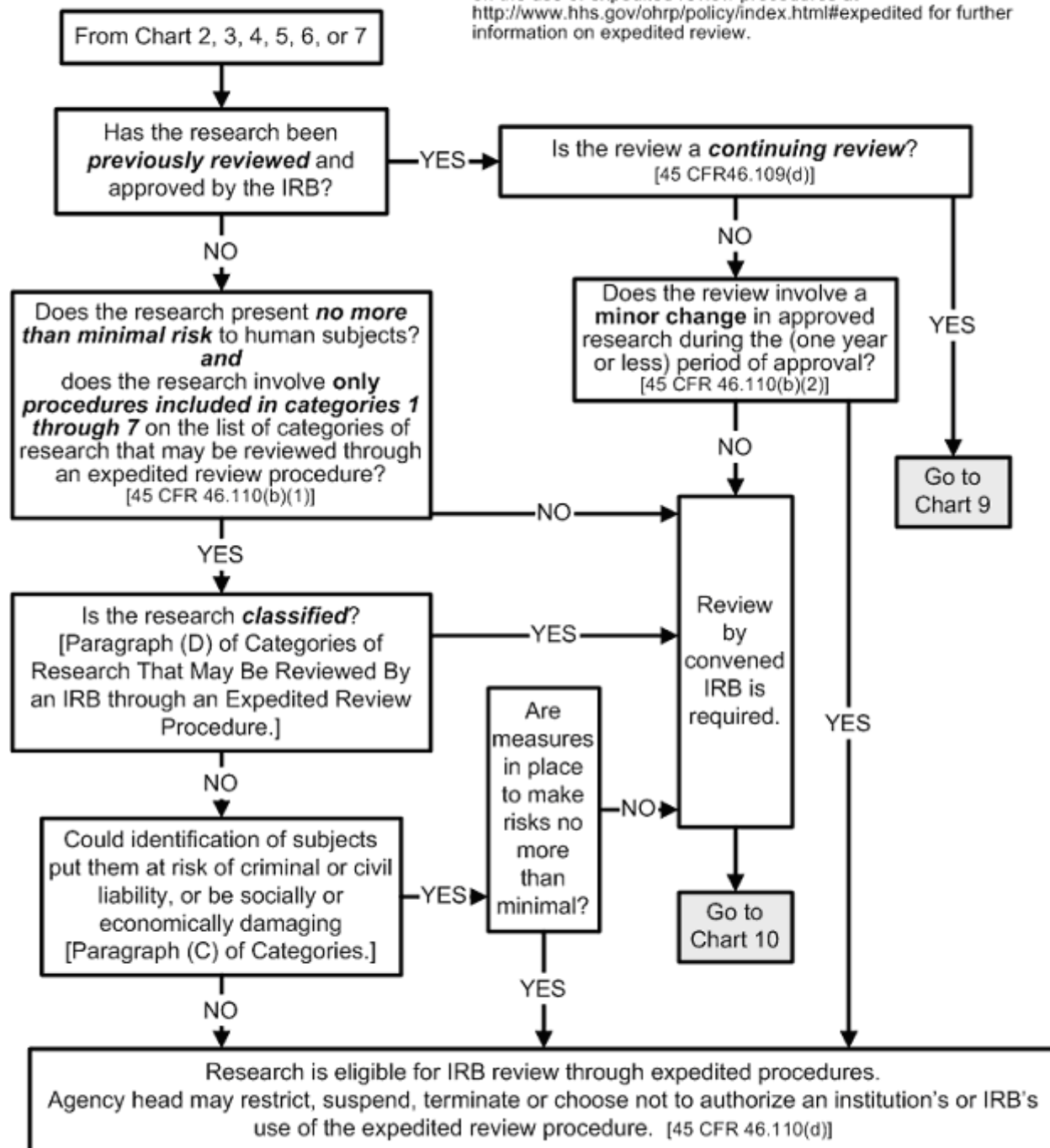
Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?



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Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*

* Note: See expedited review categories and OHRP guidance on the use of expedited review procedures at <http://www.hhs.gov/ohrp/policy/index.html#expedited> for further information on expedited review.



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Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?

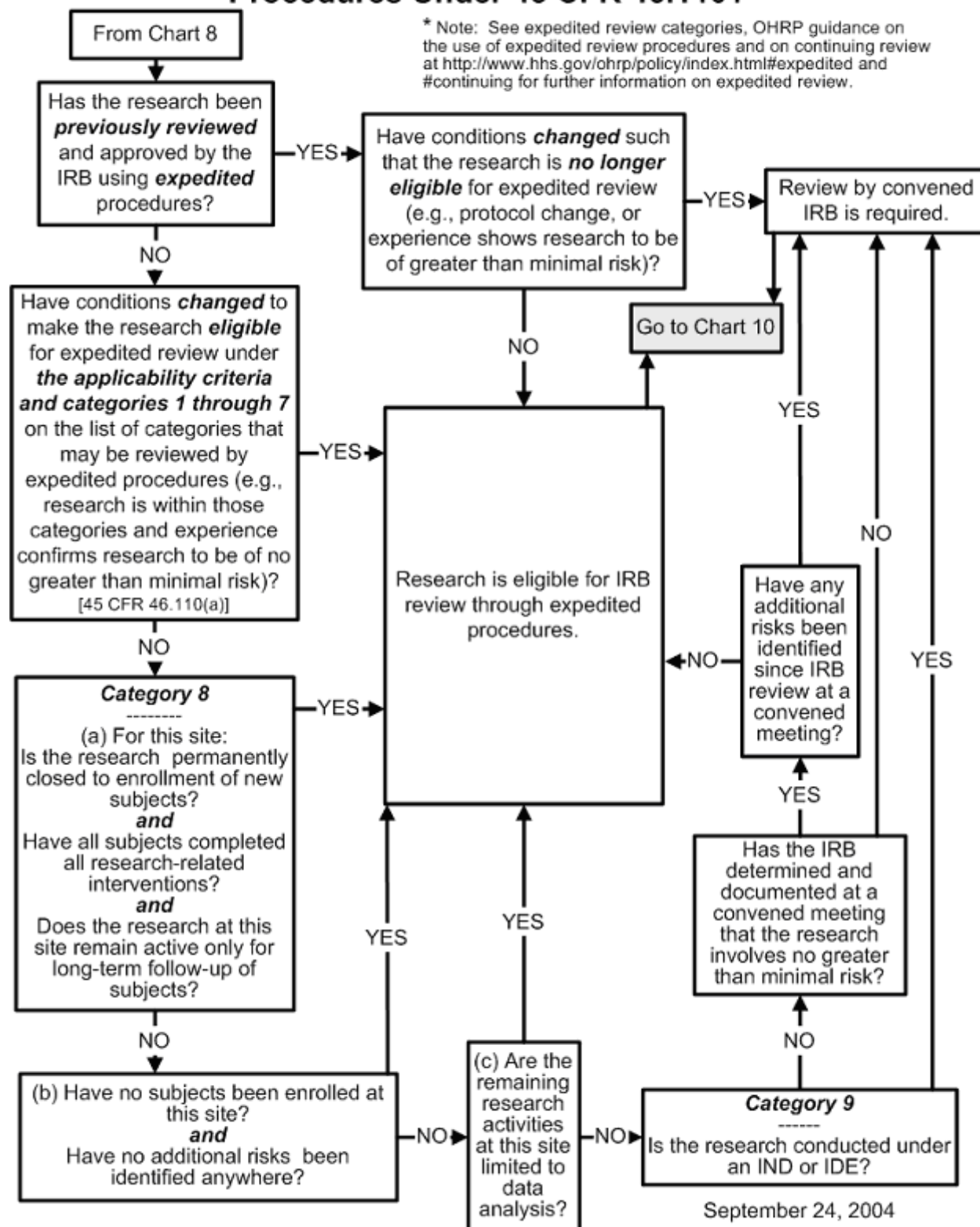
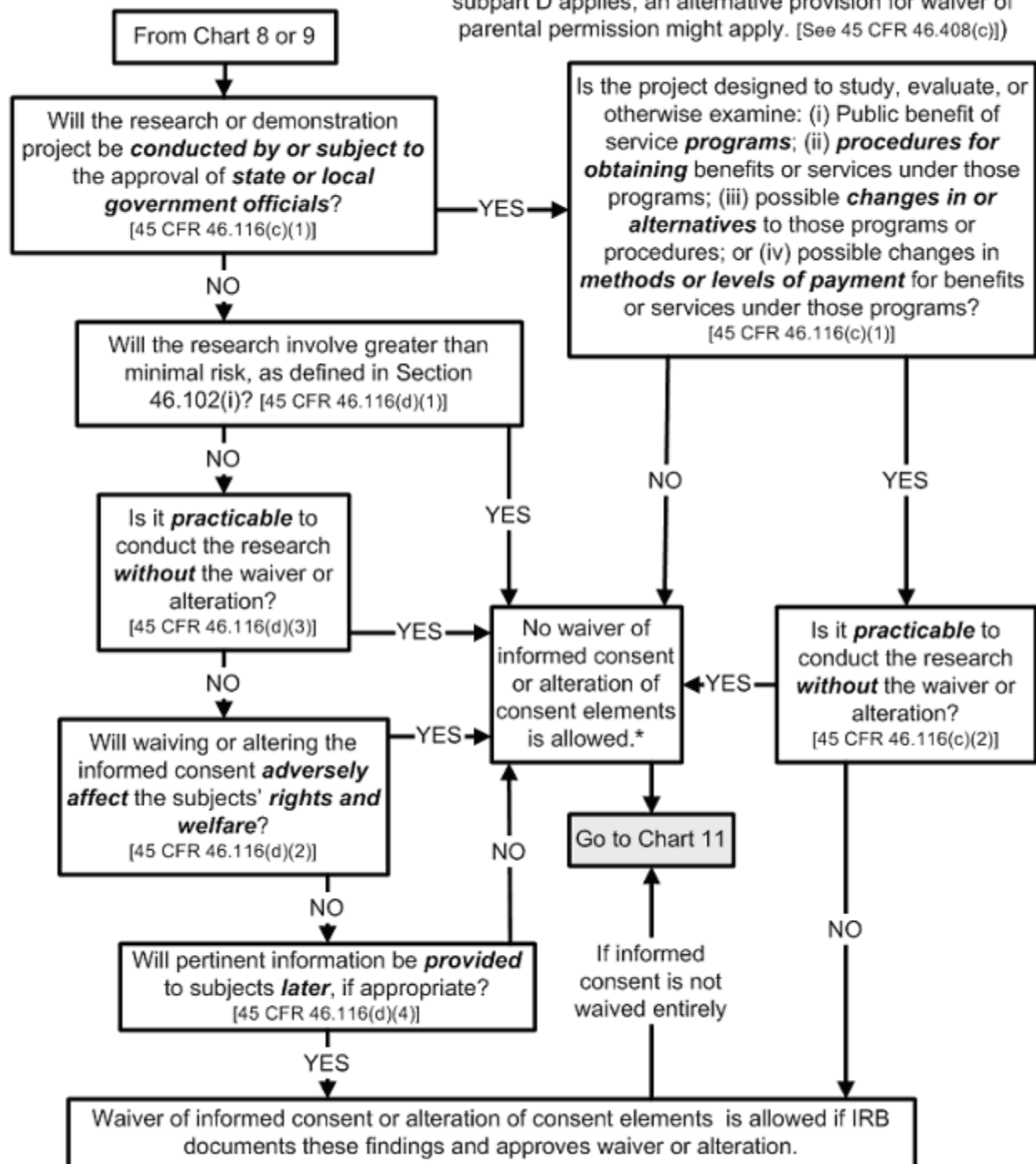


Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?**

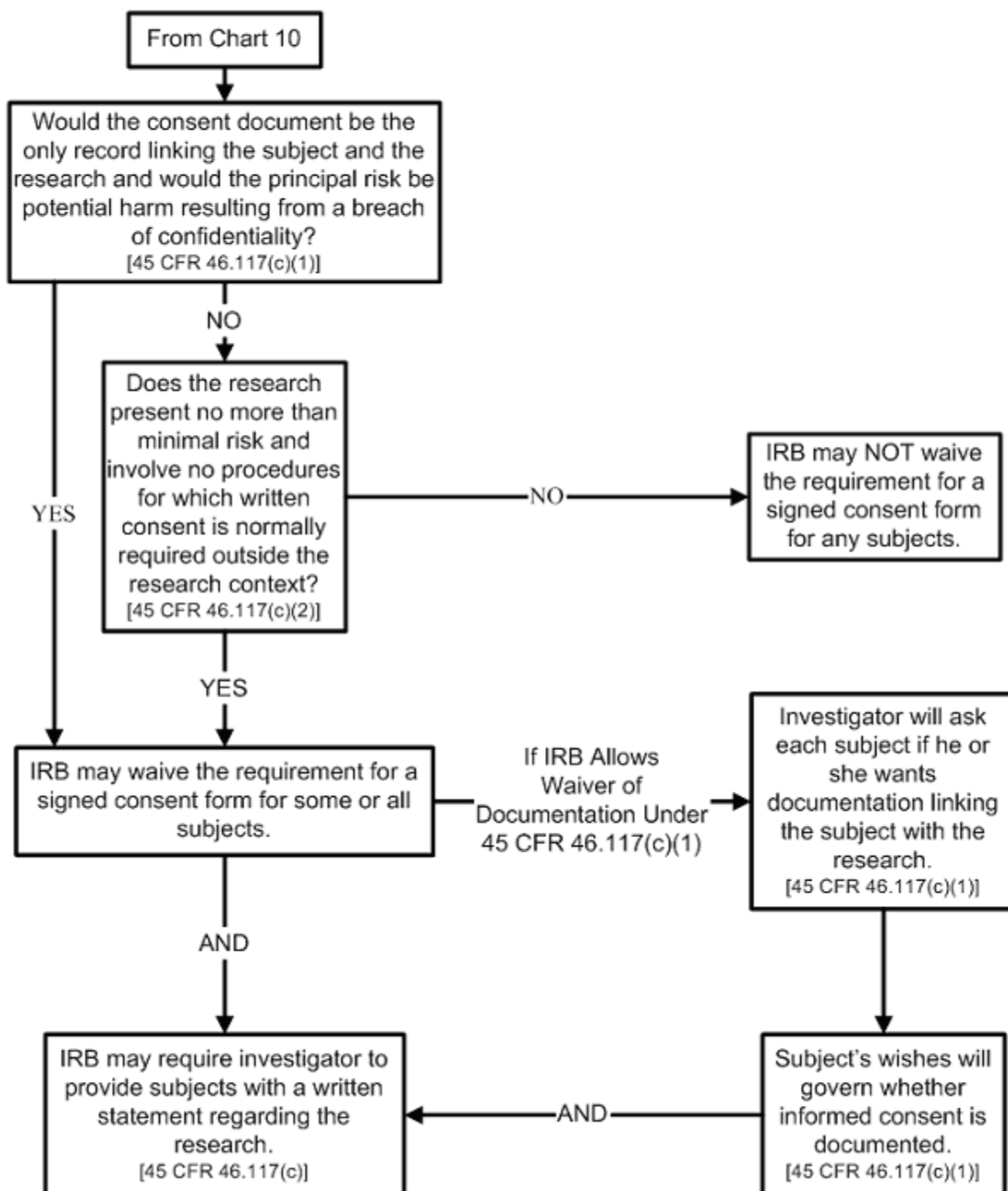
** (Note: If subjects include children to whom 45 CFR part 46, subpart D applies, an alternative provision for waiver of parental permission might apply. [See 45 CFR 46.408(c)])



* Note: See OHRP guidance on informed consent requirements in emergency research at <http://www.hhs.gov/ohrp/policy/index.html#emergency> for further information on emergency research informed consent waiver.

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Chart 11: Can Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?



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APPENDIX B: IRB FORMS AND TEMPLATES

[IRB Application](#)

[Seminary Application](#)

[IRB Annual Review Form](#)

[IRB Change in Protocol Form](#)

[Informed Consent Template](#)

[Child Assent Template](#)