**OKLAHOMA CHRISTIAN UNIVERSITY**

**Procedures for the Review of Human Subjects Research**

**Prepared by:**

 **Institutional Review Board (IRB)**

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I. INTRODUCTION

A. Overview: This procedure addresses the use of human subjects in research (hereinafter "human subjects research" or HSR). Both the state and federal governments control human subjects research conducted at Oklahoma Christian University. For federally funded, aided, or “otherwise regulated” human subjects research, Oklahoma Christian University must assure the federal government that it complies with the federal regulations.1 The University does this on a case basis, using the “Federal-Wide Assurance” method.2 If the federal government does not regulate the research, then Oklahoma law applies.

B. Scope: As a matter of policy, all Oklahoma Christian University faculty, students, staff, and administrators are responsible for protecting the rights and well-being of human subjects of research. The following principles are the basis for Oklahoma Christian University’s human subjects research procedure:

(1) All research involving humans as subjects must protect the subjects' safety, privacy, health, and welfare, recognizing that humans are made in the image of God and should be treated with love and kindness;

(2) The benefit of the research must outweigh the risk to the subjects. For the University, only an authorized University committee may make this determination;

(3) The participation of humans as research subjects shall be voluntary. Voluntary means that the subject has given informed consent. Researchers must document informed consent except where the law explicitly waives such documentation;

(4) A human subject surrenders no rights by participating in research. In no case shall a human subject lose any benefit or entitlement by refusing to participate. In addition, subjects may withdraw from research at any time;

(5) Researchers shall protect private information about human subjects that is obtained in the course of research;

(6) All researchers, whether students, faculty members or staff, shall ensure that research complies with this procedure and all applicable laws, regardless of the location of the research.

C. Updating: In the event of a regulatory or statutory change, then this procedure should be construed to conform to that change. The researcher should bring any change to the attention of the IRB and explain how the research project complies with the new law. All members concerned with HSR shall be familiar with the applicable laws.

II. DEFINITIONS

Caution: Institutions with US Department of Health and Human Services, HHS-approved assurances on file are to abide by provisions of title 45 CFR part 46 subparts A-D. This procedure is provided solely for general guidance and is not an acceptable substitute for the applicable law. Inasmuch as the federal law may define these terms, then that legal definition shall govern unless an applicable state law provides additional protections for human subjects.

A. “**Exempt**” research means that although the research is controlled or governed by an applicable law, the same law specifically exempts research of that type and a committee with jurisdiction over the research found the proposal to satisfy that legal exemption.3

B. “**Human Subject Research (HSR)**” generally means a systematic investigation designed to expand knowledge by obtaining data from a living individual, using:

(1) an intervention or interaction (i.e. interpersonal contact) between a researcher and another person as a subject4; or

(2) the collection of identifiable private information, examples of which include physical procedures such as venipuncture, the observation of behavior while manipulating a person's environment, or a review of personal records.

C. “**Institutional Review Board (IRB)**” means a federally required committee that reviews research, using federal standards, for the protection of human subjects.5

D. “**Institutional Review Board Approval**” means that the OC IRB has reviewed a research proposal under the applicable standard and has authorized the research from a human subjects perspective.6 Although no Human Subjects Research may proceed without such approval, it does not replace administrative approval of research. As in all cases of research compliance, Human Subjects Research review should follow administrative review.

E. “**Jurisdiction**” means the legal scope of a committee's authority. The jurisdiction of the IRB is federally sponsored research and all non-exempt research and non-federally sponsored research exempt from the Federal statute.

F. “**Minimal risk**” means that the probability and magnitude of harm or discomfort in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. This definition may vary for vulnerable classes of human subjects.7

G. “**Non-affiliated member**” means an IRB member who is not affiliated with or employed by the University, nor part of the immediate family of a person who is affiliated or employed by the University.8,9

H. “**Otherwise subject to regulation**," as a federal term, refers to research that is not conducted or supported by the federal government, but still subject to human subject regulations for a different reason.10 If the federal government has a specific responsibility to regulate a research activity regardless of whether it funds that research, and that research activity also includes HSR, then the HSR is "otherwise subject to regulation." This phrase promotes consistency in HSR whenever the federal government is involved. Examples include cases like the Food and Drug Administration’s regulation of new drug investigations, or the Environmental Protection Agency's regulation of new chemicals; incidental regulation such as the Wage and Hour requirements of the Department of Labor does not make research “otherwise subject to regulation.”

I. “**Regulated research**" or "research subject to a particular law” means simply that the law describes itself as applying to or governing research of that type. The federal regulations apply only to research "conducted, supported, or otherwise subject to regulation by any federal department or agency."11

J. “**Responsible Project Investigator (RPI)**” refers to an OC faculty or staff member who serves as the project supervisor, assumes responsibility for the research proposal and for ensuring compliance with Federal, State, and University guidelines. A student cannot serve as a RPI.

K. “**Investigator**” refers to individuals who are directly responsible for any of the following: the project’s design, implementation, consent process, data collection, and/or data analysis. Investigators include faculty members, students, administrators, and staff.

L. “**Researcher**” refers to any individual affiliated with the research project, including the RPI and investigators. M. “**Support**” means any involvement, including assistance such as the mere provision of data.

III. RESEARCHER PROCEDURES

A. Background: Responsible Project Investigators (RPI) bear the primary responsibility for compliance with all applicable laws and regulations. All of the University’s HSR is governed by federal laws and regulations.

The federal regulations are at 45 CFR §§ 46.101-409. A variety of federal agencies are authorized to issue their own HSR regulations, with perhaps the most prominent being the Food and Drug Administration’s regulation of clinical investigations involving new drugs or food additives, 21 C.F.R. § 50 et seq. (under the Federal Food, Drug, and Cosmetic Act). However, many agencies have sought consistency in HSR regulation by adopting the "common rule" or "federal policy" that is described in the HHS regulations; these agencies are:

Central Intelligence Agency: Executive Order 12333

Consumer Product Safety Commission: 16 CFR § 1028

Department of Agriculture: 7 CFR § 1c

Department of Commerce: 15 CFR § 27

Department of Defense: 32 CFR § 219

Department of Education: 34 CFR §97

Department of Energy: 10 CFR § 745

Department of Housing and Urban Development: 24 CFR § 60

Department of Justice: 28 CFR § 46

Department of Transportation: 49 CFR § 11

Department of Veterans Affairs: 38 CFR § 16

Environmental Protection Agency: 40 CFR § 26

National Aeronautics and Space Administration: 14 CFR § 1230

National Science Foundation: 45 CFR § 690

Social Security Administration: Public Law 103-296

The RPI is strongly advised to be aware of any deviations between sponsoring federal agencies in order to fully comply with all requirements. For student research, the responsible project investigator bears a supervisory responsibility for the conduct of the HSR and compliance with this procedure.

B. Scope: This procedure applies to all Human Subject Research projects. Failure to comply may result in administrative review of the project and a suspension of IRB approval. In addition, failure to comply with federal regulations may jeopardize present and future funding.

C. Project Design Considerations: Researchers should consider human subjects issues during the design of research projects. Effort invested at this stage of the research will reap rewards during the review and execution stage. On the other hand, a research project designed without consideration of human subjects issues may be unnecessarily risky and face difficulties and delay in the review process. Even a project with minimal risk must have benefits that outweigh the low level risks identified and every precaution taken to ensure that participants will not feel pressured to participate.

For example, minimizing risk to human subjects is a basic objective; not only will this benefit the human subjects, but it can also simplify the research protocols and possibly the review process. Certain types of research that pose little risk to human subjects are deemed exempt by 45CFR46. Researchers will find that the review process is easiest if they are able to design their project so that it is likely to be found exempt by the IRB. At the same time, the risk to human subjects will be minimized. Even if an exemption is not available, attention to human subject issues in the design of research can expedite the IRB process. If the identity of subjects in a non-exempt project is not important, then anonymous data collection and coding of the data may protect the subjects from the risk of disclosure and avoid more complicated steps to ensure confidentiality.12 Note, however, that only the IRB is institutionally authorized to assess the risks and benefits of a particular non-exempt project.

D. Research Practica: This involves classroom research activities designed to provide instruction or training in research methods. Faculty members often assign Research Practica as student projects in order to demonstrate research methods, techniques, and strategies. Research Practica can include student class projects conducted under faculty supervision or other “hands-on” classroom activities. Because of the participation of others and the collection of data, such activities are best treated as HSR. Even though the data gained may be used solely to demonstrate the ability to perform a particular research method, all researchers must still adhere to University procedure.

The “lead” faculty member is the responsible project investigator. Thus, the faculty member must act as the lead researcher and ensure that all student researchers comply with applicable laws and this procedure. Where possible and appropriate, student projects should be designed to meet an exemption under the applicable law (e.g., surveys of anonymous human subjects with no linking identifier from data to the human subject, or limiting survey data to non- sensitive topics with no other risk [see IV.B.(2)(i)§(ii)]). If an instructor agrees to award extra credit for student participation as human subjects of research, an alternate means of earning equivalent extra credit for an equivalent commitment of effort should be made available to students. Any faculty member who uses human subjects in a research practicum or student project must apply for review and approval by the IRB.

If a degree seeking student at OC is employed through another agency such as OU or OSU and no faculty member is involved from OC, then the degree seeking student that is an employee at OU or OSU or any other agency that has an IRB should seek approval through that agency's IRB and not OC's IRB.

If a degree seeking student at OC works for OU or OSU and a faculty member is involved from OC for purposes of theses or dissertations then the student has the option to seek approval through either IRB, not limiting where he/she can get approval as long as it has been approved. However, the OC IRB will need to provide the expedited approval, if the study has already been approved outside OC's IRB.

E. Applications: In order to ensure full compliance, the RPI shall direct the completion of the Human Subject Research Review Application Form (appendix 2) and submit this application, an informed consent document (appendix 5), and all protocols to the IRB by the designated due date. The RPI must document completion of required HHS Training for members of the research team. The free online tutorial course, [Human Research Protection Foundational Training](https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/human-research-protection-foundational-training/index.html) (<https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/human-research-protection-foundational-training/index.html>) fulfills the OC IRB requirement for education on the protection of human research participants. A copy of the RPI’s HHS certificates of completion for each of the five lessons in this course must be included with the IRB application. RPIs must complete the HHS training within 36 months of each application submission. Incomplete applications may delay review.

In addition, RPI’s who propose studies with patient populations are required to document HIPAA (Health Insurance Portability, and Accountability Act) training. RPIs must access the NIH booklet entitled “Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule” at <http://privacyruleandresearch.nih.gov/pr_02.asp>, and must submit an attachment to the review application stating that the material has been read and will be adhered to in the proposed research. The attachment must include the date the material was read, which must be within the 12 months prior to the application.

(1) Researchers who believe their study is not federally regulated and exempt from state law (see section IV below) shall complete an application for exempt research using the Application Form for Exempt Research (appendix 1).

(2) All others must complete the Human Subject Research Review Application Form (appendix 2).

(a) The responsible project investigator, or a member of the research team familiar with the project, should attend IRB meetings, when requested by the IRB Chair.

(b) The responsible project investigator, or member of the research team, shall submit the original and an electronic copy of the entire proposal and the proposed informed consent document to the IRB Chair.

F. Informed Consent: Researchers shall give human subjects enough information in plain, easily understandable wording, to enable the subject to give informed consent. The standards of informed consent may vary depending on the applicable law. See 45 CFR 46.116. Studies involving special or vulnerable populations (e.g., children, pregnant women, fetuses, prisoners, disabled persons, etc.) must conform to the appropriate informed consent standards for that population.13 Some of the basic elements of informed consent are:

(1) A plain language, jargon-free description of the research project including:

(a) a brief statement that the subject will be involved in research;

(b) the purposes of the research;

(c) the expected duration of the subject's participation;

(d) the procedures to be followed and whether any of the procedures are experimental;

(e) any generally accepted alternatives to experimental procedures;

(2) A clear explanation that the subject’s participation is voluntary and that there will be no retaliation for refusal or withdrawal;

(3) A description of any direct benefits to the subject but may include the general benefits of research if so noted. The potential advancement of knowledge should not be considered a direct benefit to the subject. If applicable, include any alternatives to the research by which the subject might gain the same benefit;

(4) A description of how the researcher will handle the data and, if applicable, what actual steps the researcher may take to keep records confidential; and

(5) For research involving more than minimal risk, a description of any compensation and whether the researcher is able to pay for medical care in the event of injury. In addition, the researcher should describe how to get more information about the HSR project and their rights as human subjects.14

Caution: This is a condensed explanation; researchers must be familiar with the applicable regulations. Researchers should refer to the sample informed consent documents and the specific statutory requirements.

G. Informed Consent Exemptions: In certain cases, a researcher may ask the IRB for an exemption from the requirement of a signed informed consent document. This may be appropriate for research involving minimal risk and when the following conditions exist:

(1) The research comprises an anonymous (no means of identifying subjects) mailed questionnaire or randomly dialed telephone interviews; and

(2) The only record linking the subject and the research would be the signed consent document and the principal risk would be potential harm resulting from a breach of confidentiality.15

H. Request for Waiver of Informed Consent: Researchers requesting a waiver of informed consent or a waiver of the consent procedure requirement to include all or alter some or all of the elements of informed consent must complete the Request for Waiver of Informed Consent form (appendix 7). The IRB may consider a waiver or alteration of the informed consent requirement only if all four of the following are true:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

I. Drugs, Devices, and Agents: Research involving the use of drugs, chemicals, nonhuman biological agents, or devices, is subject to Food and Drug Administration (FDA) regulations. Researchers planning to use these agents or devices in human subjects research must complete the Drugs, Agents, and Devices Form (appendix 8) and include it with the original IRB application, as applicable.

J. Biological Materials: Researchers planning to collect, analyze, or bank human cells, tissues, fluids, DNA or other human biological samples (existing or to be collected) as part of the research must complete the Biological Materials Form (appendix 9) and include it with the IRB Application.

K. Disapproved Projects: If a research project has been disapproved by the IRB, and the RPI feels that the project complies with the applicable law, then the RPI may reapply to the IRB, including a detailed, written explanation of how the research project does, in fact, comply. The IRB’s application of the governing law, however, is in no way limited by this process.

L. Continuing Review: Approvals expire after one year. Following initial approval, the RPI must seek review for projects that last longer than a year. Additionally, the RPI must ensure that progress reports are submitted more frequently if mandated by the IRB.16

(1) For projects that last longer than a year, the researcher shall forward the original and an electronic copy of a “Human Subjects Research Progress Report” (appendix 3) to the IRB Chair. This report should be submitted no later than two months prior to the anniversary of the initial approval. This allows the IRB to review the project well before it expires, thus avoiding an interruption in research. Failure to seek annual review may jeopardize present and future projects. If the study is active/open to subject enrollment, researchers should submit one copy of the currently approved Informed Consent Document with each report (two copies with the original). If any changes to the protocol or the consent form are being requested at the time of this continuing review, submit a cover letter indicating the requested changes, and submit the new informed consent document in place of the previously approved version.

(2) If a research proposal was authorized by expedited review, the researcher shall submit a Human Subjects Research Progress Report and an approval (to continue the study) letter from the primary reviewing board no later than one month prior to the anniversary date of project approval.

(3) The researcher shall complete a Human Subjects Research Progress Report at more frequent intervals if mandated by the IRB.

M. Project Close Out: Upon completion of a project, the RPI shall provide the IRB with a Close out Report (appendix 4). A Close Out report should be submitted when data collection and data analysis are complete. The report is due to the IRB Chair no later than one month (30 days) after the project is complete.

N. Reporting of Adverse Events:

(1) Adverse events experienced by research subjects must be reported to the IRB in a timely manner. The procedures vary based on the nature of the event, whether serious, unexpected, both or neither.

An adverse event is any injury, trauma, or illness experienced by a subject that required medical or psychological treatment. If such events are brought to the attention of the researcher, even if they appear to be unrelated to the protocol, then the researcher will report them as outlined below.

A serious adverse event is an event that results in any of the following outcomes: death, a life-threatening situation, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect.

An unexpected adverse event is any adverse event, the specificity or severity of which is not listed in the current informed consent.

(2) An adverse event that is serious must be reported to the IRB within 5 business days of the researcher becoming aware of it. Using the Adverse Event Reporting Form (appendix 10), the researcher describes the nature of the event, the medical treatment that the subject received, the likelihood that the event was related to the research protocol, and any changes in the protocol or informed consent that the researcher feels may be needed to protect other subjects. A consulting physician (the attending physician, or a physician provided through OC) must also comment on the severity of the event and the likelihood that it was related to the protocol.

(3) Unexpected adverse events must also be reported to the IRB within 5 business days of the researcher becoming aware of them, using the Adverse Event Reporting Form. However, if the event is not serious, a consulting physician is not required.

(4) Adverse events that are neither serious nor unexpected in the view of the researcher must be reported to the IRB using the Adverse Event Reporting Form within one month of the researcher becoming aware of them. A consulting physician is not required.

(5) All adverse events, whether serious, unexpected or neither, must be reported at the time of continuing review, using the Human Subjects Research Progress Report Form (appendix 3).

IV. INSTITUTIONAL REVIEW BOARD PROCEDURES FOR EXEMPT RESEARCH THAT IS NOT FEDERALLY SUPPORTED

A. Introduction: One role of the IRB is to determine whether research is “exempt” under the Federal law. In general, exempt HSR poses little risk.

B. Jurisdiction: Exempt research fits into one of the following exempt categories under the Federal law:

(1) Research 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.

(2) Research involving 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 subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving 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 subjects 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.

(4) Research, involving 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 subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of [federal] 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.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Special Note: These exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization, subparts B and C. The exemption at 45CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Caution: IRB members shall rely on current versions of the Federal statute. The above exemptions were current at the time of issuance of this procedure.

C. Composition: At the discretion of the Chair of the IRB, a request for review of exempt research that is not federally supported will be assigned to at least three (3) members of the IRB for review. Members shall be familiar with, and have copies of, the relevant federal regulations.

D. Responsibilities: The responsibilities of the IRB to review exempt research that is not federally supported include:

(1) Each assigned IRB member is charged with the responsibility to be reasonably knowledgeable about the applicable laws and to be reasonably diligent in investigating and reviewing exempt HS Research.

(2) The IRB at least once an academic year, shall consider, among other things, its execution of these responsibilities to review exempt research over the past year.

(3) The IRB shall maintain a standard application form: Application For Exempt Research (appendix 1) by which the Researcher provides a written statement about the research. This form shall identify the exempt categories and provide space for the researcher to describe the study.

(4) The assigned IRB members shall evaluate the entire research proposal, including surveys, questionnaires, and any other related documents and notify the Chair of the IRB of their findings and decision.

(5) The assigned IRB members shall explicitly identify the appropriate exemption. It shall pay close attention to guarantees of anonymity, security of potentially damaging information, and other risks.

(6) The Chair of the IRB shall promptly notify the Researcher of its decision or requirements for modifications.

 (a) Negative decisions should explain why the proposal was considered not exempt.

(b) The Chair of the IRB shall forward a final written notification to the Researcher.

(c) The Chair of the IRB shall refer researchers with non-exempt projects to the full IRB.

(7) The IRB shall reevaluate any proposal in which one of the following conditions occur: (a) Substantial changes in the protocol;

(b) Emergence of problems or unexpected deviations in the HS Research that would alter the exempt status; or

(c) Development of hazardous conditions for the subjects.

(8) The Chair of the IRB shall keep the following records in a secure location, accessible by the

Chief Academic Officer, for at least three (3) years:

(a) The names and occupations of committee members; (b) The names of the reviewing members;

(c) One copy of each proposal reviewed.

(d) A description of the proposal, the decision of the IRB and an explanation of why the research was found unregulated or exempt.

(9) A summary of proposals reviewed shall be submitted to the Senior Chief Academic Officer for forwarding to the Academic Affairs Committee annually. The summary shall include at least such information as the name of the RPI, the research title, whether the research was found exempt (and under which category), and the research end date.

(10) The IRB shall grant an exemption only upon a unanimous vote of its assigned members (no fewer than three members reviewing). The assigned IRB members shall resolve any uncertainty about a proposal in favor of denying the exemption and submitting the proposal to the IRB Chair for full IRB review.

V. INSTITUTIONAL REVIEW BOARD PROCEDURES FOR NON-EXEMPT RESEARCH AND EXEMPT RESEARCH THAT IS FEDERALLY SUPPORTED

A. Introduction: One role of the Institutional Review Board (IRB) is to review all non-exempt research and

exempt research that is federally supported.

B. Jurisdiction:

(1) Federal regulations apply “to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency.”17

(2) Except for those categories specifically exempted or waived under 45 CFR §§ 46.101(b)(1-6) or 101(i) all federally supported, funded, or otherwise regulated research shall be reviewed and approved by the IRB. HSR shall not be permitted until the IRB has reviewed and approved the research protocol and Informed Consent Document has been obtained from the subject or the subject's legal representative.18 Exempt research must be appropriately documented as such.

(3) The IRB review shall comply with applicable federal regulations and the provisions of this procedure for each project. C. Composition:

The IRB nominees shall be identified in accordance with the following Federal statute:

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. Every nondiscriminatory effort shall be made to ensure that no IRB consists entirely of men or entirely of women. No IRB may consist entirely of members of one profession....25

(b) The IRB shall be composed of representatives from varying backgrounds to ensure the competent, complete, and professional review of human research activities conducted or proposed to be conducted or authorized by the institution or agency. Thus, nominees shall come from varying backgrounds and have experience and expertise sufficient to understand the ethical standards, legal requirements, institutional constraints, and any other factors, which may contribute to a determination of the risks and benefits to subjects.

(1) The IRB shall have at least four (4) faculty members appointed by the Chief Academic Officer (CAO), after nomination by the IRB and one (1) community representative identified by the IRB. Membership shall include at least one (1) member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. The community representatives shall not have any direct link with the University, such as employment, or have an immediate family member that is employed by the University. The community representatives shall be nominated by the IRB and appointed by the CAO. No member directly involved in a particular HSR project or the administrative approval of an HSR project can participate in the review of that project. Each member of the IRB shall serve a three-year term but can voluntarily serve additional terms with approval of the Chair of the IRB and the CAO.

(2) The IRB shall meet not less than quarterly and may meet more frequently as required. Official meetings shall not begin until at least a majority of members, including at least one member whose primary concerns are in nonscientific areas and at least one whose primary concerns are in scientific areas are present.19 The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. In some cases, the sponsoring federal agency may permit the IRB to review HSR involving vulnerable subjects such as the handicapped, pregnant, prisoners, children, or mentally disabled persons only when the IRB membership is supplemented by at least "one person primarily concerned" with the welfare of such persons.20

D. Scope of Review: The IRB shall review the HS Research proposal and give proper consideration to: (1) The potential for satisfaction of a regulatory exemption;

(2) The risks to the subjects;

(3) The anticipated benefits to the subjects and others;

(4) The importance of the knowledge that may reasonably be expected; and

(5) The informed consent process.

E. Responsibilities: The responsibilities of the IRB include:

(1) Each member of the IRB is charged with the responsibility to be reasonably knowledgeable about the applicable laws and to be reasonably diligent in investigating and reviewing HS Research under the IRB’s jurisdiction. Each member shall document completion of HHS training, by completing the online tutorial course, [Human Research Protection Foundational Training](https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/human-research-protection-foundational-training/index.html) (<https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/human-research-protection-foundational-training/index.html>) and printing out a copy of the lesson completion certificates for each of the five (5) lesson to be placed on file by the Chair of the IRB. Members must complete the HHS training at least once every 36 months. IRB members are encouraged to read the “The Belmont Report” (<https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html> ) and the Department of Health and Human Services Code of Federal regulations title 45 Part 46 (<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html>).

(2) The IRB shall review, and have the authority to approve, require modification in, or disapprove all research activities under its jurisdiction, including proposed changes in previously approved human subject research. For approved research, the IRB shall determine which activities require continuing review more frequently than every twelve months or need verification that no changes have occurred if there was a previous IRB review and approval.

(3) The IRB shall provide written notice of its decisions and requirements for modifications to the researcher. Written notification of decisions to disapprove shall be accompanied by reasons for the decision. Certification of IRB review and approval for all federally sponsored research involving human subjects will be forwarded to the appropriate federal department or agency by IRB coordination with the OC Office of Development grant manager, as appropriate. Compliance shall occur within the time and in the manner prescribed for forwarding certification of IRB review to HHS or other applicable federal agency.

(4) IRB review of non-exempt projects shall include the following:

(a) The IRB shall ensure that legally effective informed consent will be obtained and documented in a manner that satisfies federal regulations. The IRB may observe or have a third party observe the consent process.22

(b) The IRB shall evaluate whether the protections for human research subjects are adequate, in accordance with the criteria found at 45 CFR 46.111.

(c) Where appropriate, the IRB shall determine that adequate additional protections are ensured for fetuses, pregnant women, prisoners, and children, as required by Subparts B, C, and D of 45 CFR 46.

F. Expedited Review: The Chair (or one or more experienced reviewers designated by the Chairperson) may engage in expedited review procedures for certain kinds of research involving no more than minimal risk and for minor changes in approved research in accordance with 45 CFR 46.110.

G. Continuing Review: The IRB shall require periodic reports from approved projects to ensure that the project is in compliance. At a minimum, continuing review shall comprise an evaluation of a Close out Report (CR) (appendix 4) or any Human Subjects Research Progress Reports (RPR) (appendix 3) required during the initial review, including any available study-wide findings.23

IRB approval authority extends for only one year. The frequency of continuing review shall be no less than annual. The Chair of the IRB will send the Responsible Project Investigator (RPI) a written notice of a required continuing review at least two months prior to the date of expiration. However, notwithstanding the notice attempt, timely Continuing Reviews and IRB approvals are the responsibility of the RPI.

(1) Continuing Reviews shall be commensurate with the overall risk to the subjects. For example, a brief HSR project involving more than minimal risk, but few subjects might merit less burdensome continuing review than a long HSR project involving more than minimal risk and many subjects. Thus, the factors of consideration in determining the overall risk to

the subjects may include project duration, size and nature of the subject population, intrusiveness, deviation from minimal risk, experience of the researcher, location, and general level of acceptance of the research practices. Any member of the IRB may call for the emergent review of a project upon learning of any HSR non-compliance or injury to a human subject under the IRB’s jurisdiction.

(2) The IRB shall terminate a project if neither an RPR nor a CR is received by the anniversary of approval.

(3) If an RPR is late, the IRB shall notify the researcher that failure to comply with the reporting requirement prompted a withdrawal of IRB approval for the project and a termination of the research project. The IRB may require the RPI to submit either a CR and/or all missing RPR(s). In addition, the IRB may suspend any other HSR or pending applications associated with that researcher.

H. Review of Adverse Event Reports:

(1) Adverse events that are serious or unexpected will be reported to the Chair of the IRB by the researcher within 5 business days of the researcher becoming aware of them. If the Chair judges that such serious adverse events may be related, or are likely related, to the research protocol, then the Chair will report the event to the full board at its next meeting or, if there is reason to suspect increased risk to other subjects prior to the next regularly scheduled meeting, call an emergency meeting of the IRB. The IRB will review the risks and benefits of the research protocol and consider changes in the protocol, changes in the informed consent and possible suspension or termination of the research. The findings of the IRB will be forwarded by the Chair of the IRB to the Chief Academic Officer (CAO), the federal Office of Human Research Protections and, if applicable, the sponsor.

(2) If the Chair of the IRB judges that a serious or unexpected adverse event is unlikely related to the protocol, then the event will be reported to the full IRB at its next meeting and the researcher's report along with the Chair's finding will be filed in the IRB records.

(3) Adverse events that are neither serious nor unexpected will be reported to the IRB Chair by the researcher within one month of the researcher becoming aware of them. Such reports will be filed in the IRB records.

(4) In addition to the prompt submittal of the required Adverse Event Reporting Form (appendix 10), adverse events must also be reported by the researcher as part of the continuing review, using the Progress Report Form (appendix 3). The Human Subjects Research Progress Report form will summarize all adverse events of any nature that had occurred in the reporting period. This report will be reviewed by the full IRB at the time of continuing review so that the board may review the risks and benefits of the research protocol and consider changes in the protocol, changes in the informed consent and possible suspension or termination of the research.

(5) IRB approval shall become effective when the appropriate federal department or agency receives assurance of the

IRB review.24

Caution: IRB members shall rely on current versions of the federal regulations. The above requirements were current at the time of issuance of this procedure.

VI. CHAIR OF IRB RESPONSIBILITIES

CHAIR OF IRB

A. Introduction: The Oklahoma Christian University Chair of the IRB is responsible for the day-to-day business of the IRB and for oversight of the humans subjects review process. The Chair of the IRB will have a comprehensive knowledge of all aspects of the University’s systematic protections for human subjects. The Chair of the IRB shall maintain records regarding research compliance issues. The Chair of the IRB serves as the Signatory Official for the IRB with legal authority to represent the University. The Chair of the IRB is the institutional official responsible for ensuring compliance with all Human Subject Research regulations and statutes. The Chair of the IRB reports to the CAO and the Academic Affairs Committee.

B. Responsibilities:

(1) The Chair of the IRB with guidance from the CAO shall supervise the overall execution of this procedure.

(2) The Chair of the IRB is responsible for ensuring constructive communication among administrators, researchers, human subjects, and regulators as a means of safeguarding the rights and welfare of human subjects. The Chair of the IRB through the CAO sets the tone for the University’s culture of respect for human subjects and facilitates participation in human subject education activities.

(3) The Chair of the IRB shall periodically review federal and state regulations and update this procedure accordingly.

(4) The Chair of the IRB shall ensure adequate IRB membership by working through the IRB and CAO. The CAO shall appoint the members of the IRB nominated by the IRB, in compliance with federal requirements.26

(5) For all federally regulated research, the Chair of the IRB shall report promptly to the IRB, the CAO, the National Institutes for Health, Office for Human Research Protections (OHRP), or other sponsoring federal entity:

(a) any injuries to human subjects or other unanticipated problems involving risks to subjects or others, (b) any serious or continuing noncompliance with the regulations or requirements of the IRB, and

(c) any suspension or termination of IRB approval for research.

(6) At a minimum, the Chair of the IRB shall maintain federal research records for at least three years after completion of the research activity.

(7) The Chair of the IRB shall make reports annually to the CAO and Academic Affairs Committee summarizing the actions and decisions of the IRB.

VIII. FOOTNOTES

1. 45 C.F.R § 46.101(a).

2. 45 C.F.R. § 46.103(a).

3. 45 C.F.R. § 46.101(b).

4. 45 C.F.R. § 46.102 (d),(f).

5. 45 C.F.R. § 46.102 (g).

6. 45 C.F.R. § 46.102 (h).

7. 45 C.F.R. § 46.102(i).

8. 45 C.F.R. § 46.103.

9. 45 C.F.R. § 46.107(d).

10. 45 C.F.R. § 46.102(e).

11. 45 C.F.R. § 46.102(e). When an institution has elected to abide by 45 CFR 46, regardless of the source of support, all subparts of 45 CFR 46 are applicable to research even if it is not federally sponsored or sponsored by federal departments or agencies other than DHHS.

12. Note that satisfying an HSR exemption does not remove all regulatory requirements. For example, the U.S. Department of Education mandates prior consent and access to instructional material for certain experimental teaching methods. 37 C.F.R. § 98.1-98.10.

13. 45 C.F.R. § 46.207 (pregnant women); 45 C.F.R. § 46.208- 210 (fetuses); 45 C.F.R. § 46.304-306 (prisoners); 45

C.F.R § 403-409 (children).

14. 45 C.F.R. § 46.116.

15. 45 CFR § 46.116 (c).

16. 45 C.F.R. § 46.109(e).

17. 45 C.F.R. § 46.101.

18. 45 C.F.R. §§46.111, 46.116, and 46.117.

19. 45 C.F.R. § 46.108(b).

20. 45 C.F.R. § 46.107. IRB Membership.

21. Protecting Human Research Subjects, Dep't Of Health And Human Services, Office For Protection From Research

Risks (1993).

22. 45 C.F.R. § §46.116 -117.

23. 45 C.F.R. § 46.109(e).

24. 45 C.F.R. § 46.119.

25. 45 C.F.R. § 46.107(a-f).

26. See supra, note 25.