1. PURPOSE OF THE INSTITUTIONAL REVIEW BOARDS

There are two Institutional Review Boards (IRB) at Creighton University: IRB-01 Biomedical and IRB-02 Social and Behavioral. The IRB protects the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of Creighton University. The IRB is granted its authority by Creighton University President or designee. As part of its charge, the IRB holds the responsibility for determining: 1) whether human subjects have volunteered for a research endeavor by means of informed consent; and 2) whether risks to these subjects are outweighed by potential benefits to them and importance of the knowledge to be gained by the research endeavor. The specific evaluation of risk involves estimating the potential for injury to the subject by reason of direct application of an experimental procedure or circumstance, or by reason of the subject's exclusion from ordinary standards of practice of care. Rights of subjects regarding confidentiality and access to professional care and counseling are included in IRB deliberations so that human dignity, rights, and physical, behavioral and social welfare are protected. Both Boards review and approve research in accordance with the Department of Health and Human Services (DHHS) regulation (45 CFR 46). In addition, for studies involving products regulated by the U.S. Food and Drug Administration (FDA), IRB-01 complies with the requirements set forth in 21 CFR 11, 21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 812, and 21 CFR 814.

2. DEFINITIONS

2.1. Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. [45 CFR 46.102(b)]

2.2. Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or [45 CFR 46.102(e)(1)(i)]

Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. [45 CFR 46.102(e)(1)(ii)]

2.3. 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. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research. [45 CFR 46.102(i)]

2.4. Public Health Authority means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate. [45 CFR 46.102(k)]

2.5. 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 that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

2.5.1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected

2.5.2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters)

2.5.3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes

2.5.4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions [45 CFR 46.102(l)(4)]

2.6. Written, or In Writing, for purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic format. [45 CFR 46.102(m)]

3. PRINCIPLES GOVERNING THE IRB

The IRB is guided by the federal regulations and ethical principles regarding all research involving humans as subjects. The federal Department of Health and Human Services (45 CFR 46) and the federal U.S. Food and Drug Administration (FDA 21 CFR 50 and 56; 21 CFR 312 (Investigational New Drugs) and 21 CFR 812 (Investigational Devices) are the primary agencies that regulate the IRB. In addition, the IRB is guided by *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979) and the *World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects* (1964, amended October 2013).

4. IRB-01 BIOMEDICAL

4.1. The Biomedical Institutional Review Board (IRB-01) is one of the administrative bodies established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of Creighton University.

4.2. The IRB-01 shall review all biomedical research involving human subjects for compliance with federally mandated research guidelines.

4.2.1. *Biomedical research* (or *experimental medicine*), in general known as medical research, is basic research, applied research, or translational research conducted to add to the body of knowledge in the field of medicine. A new paradigm to biomedical research is being termed translational research, which focuses on iterative feedback loops between the basic and clinical research domains to accelerate knowledge translation from the

bedside to the bench, and back again

4.3. The IRB-01 shall review the following research categories:

4.3.1. Clinical trials (both drug and device)

4.3.2. Medical registries

4.3.3. Patient medical treatment and outcome studies

4.3.4. Biological samples (including genetics and pathology)

4.3.5. Research involving medical procedures (including labs and radiology)

4.3.6. Medical chart reviews

4.3.7. Epidemiological research using any of the above

4.4. The IRB-01 meets regularly and is composed of faculty/staff from Creighton University and representatives from the community. A full roster and meeting schedule are available on the IRB website.

5. IRB-02 SOCIAL AND BEHAVIORAL

5.1. The Social and Behavioral Institutional Review Board (IRB-02) is one of the administrative bodies established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of Creighton University.

5.2. The IRB-02 shall review all social and behavioral educational research involving human subjects for compliance with federally mandated research guidelines.

5.2.1. Research on social and behavioral processes involves the study of humans at the level of the individual, small group, institution, organization, community, or population. At the individual level, this research may involve the study of behavioral factors such as cognition, memory, language, perception, personality, emotion, motivation, and others. At higher levels of aggregation, it includes the study of social variables such as the structure and dynamics of small groups (e.g., couples, families, work groups, etc.); institutions and organizations (e.g., schools, religious organizations, etc.);

communities (defined by geography or common interest); and larger demographic, political, economic, and cultural systems. Research on social and behavioral processes also includes the study of the interactions within and between these two levels of aggregation, such as the influence of socio-cultural factors on cognitive processes or emotional responses. Finally, this research also includes the study of environmental factors (both natural and human created) such as climate, noise, environmental hazards, and residential and other built environments and their effects on social and behavioral functioning (National Institutes of Health definition)

5.3. The IRB-02 shall review the following research categories:

5.3.1. Experimental non-medical research (cognitive, behavioral, group, etc.)

5.3.2. Archival research (except medical chart reviews)

5.3.3. Survey/questionnaire research

5.3.4. Observational research

5.3.5. Research interviews

5.3.6. Educational research

5.3.7. Epidemiological research using only social-behavioral methodologies

5.4. The IRB-02 meets regularly and is composed of faculty/staff from Creighton University and representatives from the community. A full roster and meeting schedule is available on the IRB website.

6. IRB SCOPE AND AUTHORITY

All human research authorized and conducted under the jurisdiction of Creighton University is subject to review by the IRB for risk, benefit, and informed consent without regard to the source of financial, physical (facilities), or logistical support. The IRB shall conduct this review before a project can be started. The IRB is responsible for research activity that involves human subjects involving any of the following:

6.1. Conducted at Creighton University

6.2. Conducted by Creighton faculty, staff, and students

6.3. Conducted per contractual agreement

The IRB shall have the authority to approve, require modifications to, table, disapprove, suspend, or terminate approval of research involving human subjects and to observe, or have a third party observe, the consent process and the conduct of the research, and, by its recommendations to the President or designee, can affect action that withholds or withdraws financial support from projects involving human subjects that are not in compliance with Creighton University policies, federal regulations, or state or local laws. Creighton University administrators (Departmental Chairs, Deans, Vice Provosts, Provost, President) should remind prospective investigators of IRB requirements whenever a proposed research activity involves human subjects.

7. PROJECT ASSIGNMENT

7.1. The investigator shall submit a new study to the appropriate Board based on the above definitions. However, the IRB Chair or designee of either Board may transfer oversight for a study if there is more appropriate expertise on the other IRB. The Chair or designee may seek collaboration with the other Board for complex studies.

8. ADMINISTRATIVE ROLES AND RESPONSIBILITIES

8.1. **The Institutional Official**

The Institutional Official for the IRB or designee:

8.1.1. The Institutional Official (IO) is appointed by the Creighton University President

8.1.2. Has legal authority to commit on behalf of Creighton University and signs the Institution's Federal-wide Assurance of Protection for Human Subjects (FWA), which is required by the DHHS (45 CFR 46.103)

8.1.3. Appoints IRB members and Chair(s)

8.1.4. Supports IRB decisions

8.1.5. Has authority to approve or disapprove research projects previously approved by the IRB, however, the Institutional Official is prohibited from approving research that has not been approved by the IRB

8.2. **Director for Research Compliance**

8.2.1. Is responsible for the implementation, oversight, and monitoring of the Human Research Protection Program (HRPP) this includes ensuring appropriate resources are secured for the program. On at least a yearly basis the Director reviews the following resources:

8.2.1.1. Space: The HRPP must ensure adequate space to enable the personnel to adequately carry out their jobs and be able to communicate with investigators in private

8.2.1.2. Personnel: The HRPP must ensure adequate staffing is available to provide investigators and committees with quality assistance

8.2.1.3. Legal Counsel: Access to legal counsel must be available to consult regarding HRPP issues. If an issue with access arises, the Director will report directly to the Institutional Official

8.2.1.4. Conflict of Interest: The University must have a committee to review and manage any potential conflicts of interest

8.2.1.5. Quality Improvement Plan: Quality Improvement is assessed on an ongoing basis but is formally reviewed once a year through evaluation of members, administrations and participant feedback

8.2.1.6. IRB committees: The HRPP must have adequate representation and members must be able to commit adequate time to their respective IRB committees

8.2.2. Assists Creighton University human research oversight committees and offices responsible for ensuring compliance with the regulatory requirements related to human subject research activity conducted at and/or approved through Creighton University

8.2.3. Is responsible for following Creighton University's Budget Office Policy, "Planning and Budgeting Cycle," regarding evaluation of resources needed for the Research Compliance department

8.3. **The IRB Chair or designee**

8.3.1. Ensure(s) the IRB carries out its responsibilities in accordance with federal requirements and these policies and procedures

8.3.2. Review(s) all documents submitted for non-exempt (with the exception of exempt initial review HIPAA waiver projects) initial review and re-reviews IRB files for projects submitted for continuing review. The review is completed by the person who is the designated Chair for the meeting at which the project will be reviewed (Full Board Review)

8.3.3. Report(s) directly to the Institutional Official and keep(s) the Institutional Official informed of IRB activities

8.3.4. At a convened meeting, the Chair abstains on each voted action but counts towards meeting the quorum. However, if the vote "for" or "against" an action is tied, the Chair will cast the deciding vote (i.e., to vote "for" or "against" an action). If the Chair is unable to attend a meeting, the Vice Chair will act as the Chair and follow the same voting rules. The Vice Chair acts as a normal voting member when the Chair is present

8.4. **The IRB Administrator(s) or designee**

8.4.1. Reports to the IRB Chair(s) and the Director for Research Compliance

8.4.2. Receives all research protocols and supporting documentation, communicates decisions to investigators and forwards documentation of IRB determinations to appropriate research personnel

8.4.3. Provides regular publication of meeting schedules and transmission of documents to and from investigators

8.4.4. Ensures preparation and distribution of the agenda and review materials for IRB members prior to each meeting

8.4.5. Ensures that minutes of IRB meetings are adequately recorded and maintained

8.4.6. Maintains all records of IRB action for at least three years after the conclusion of the research and shall, upon request, make such records available for review by the President, General Counsel, Provost, Deans, IRB members, Catholic Health Initiative (CHI) Research Center, contracted entity's designee and federal authorities

8.4.7. Shall report to the Director for Research Compliance, any: 1) serious or continuing noncompliance by investigators with requirements and/or determinations of the IRB, or 2) suspension or termination of IRB approval

8.5. **The Institutional Review Board**

8.5.1. Reviews and approves, requires modification to, tables, or disapproves all research as defined in Section 6, "IRB Scope and Authority"

8.5.2. Conducts continuing review of previously approved research at appropriate intervals based on risk, but not less than once a year

8.5.3. Has authority to suspend or terminate previously approved research that is not being conducted in accordance with the IRB's requirements or has been associated with unexpected serious harm to research subjects

8.5.4. Has authority to place any restrictions on an approved project as necessary to ensure protection of human subjects

8.5.5. The IRB does not give retrospective approval of research studies. All determination letters must be received prior to study initiation

8.6. **The Principal Investigator**

8.6.1. Has the primary responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of the Institution's FWA, federal laws and regulations and the Institution's policies and procedures

8.7 **AAHRPP**

8.7.1 The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) is the accrediting body that indicates that Creighton University follows rigorous standards for ethics, quality and protections for human research

8.7.2. Creighton University must report to AAHRPP within 48 hours after the University or any investigator (if the investigator is notified rather than the University) becomes aware of:

8.7.2.1. Any negative action taken by a government oversight office, including, but not limited to, OHRP determination letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA restrictions placed on IRBs or ECs or researchers

8.7.2.2. Any litigation, arbitration, or settlements initiated related to human research protections

8.7.2.3. Any press coverage (including, but not limited to radio, TV, newspaper, online publications) of a negative nature regarding Creighton University's HRPP

9. SELECTION AND COMPOSITION OF THE IRB

9.1. IRB members shall be appointed by the Institutional Official from the faculty and from the community at large to ensure representation of professional competence and concerns of the public. The Chair shall be appointed by the Institutional Official and shall be (an) experienced scientific investigator(s). In addition to the Chair(s), the IRB shall be composed of some combination of people who may have the following areas of expertise and professional competence:

9.1.1. Licensed physician(s)

9.1.2. Licensed dentist(s)

9.1.3. An individual skilled in ethical analysis

9.1.4. Lawyer(s) skilled in human rights provisions of the law

9.1.5. Behavioral/social and/or biomedical scientist(s)

9.1.6. Pharmacist(s), pharmacologist(s) or toxicologist(s) skilled in human applications

9.1.7. Nonscientist/Layperson(s) who are not otherwise associated with Creighton University or its contracted entities, apart from membership on the IRB and are not in the immediate family of anyone so associated

9.1.8. Representative(s) from contractually affiliated entity(ies)

9.2. Members shall be diversified regarding race, gender, cultural background and sensitivity to community attitudes. Members shall be from separate professions and/or disciplines. At least one member of each gender shall serve on the IRB. The IRB shall consist of a minimum of five members, at least one of whom shall be primarily concerned with nonscientific areas and one of whom shall be

primarily concerned with scientific matters. In addition, the membership shall include at least one member who is not otherwise affiliated with the University and who is not part of the immediate family of a person who is affiliated with the University. Each IRB shall have at least one member who represents the perspective of research subjects. IRB members and the Chairs shall serve under the direction of the Institutional Official. The IRB shall notify the Office of Human Research Protection (OHRP) each time there is a change in membership. The IRB may invite consultants to assist in any review, but consultants shall not be members of the IRB and shall not vote.

9.3. Members may choose to share an IRB position. If two members share a position, they shall have similar backgrounds and experience. The first member shall attend the first meeting of the month while the second member shall attend the second meeting of the month (IRB-01). If both members are present at a meeting, the only member who can vote is the regularly scheduled member for that meeting. If a shared member cannot attend his/her regularly scheduled meeting, if available, the alternate member may attend and vote. Shared positions are listed on the membership roster, and the members who share the position are listed as alternates for each other.

9.4. The Creighton University Provost, the designated Institutional Official (IO), all Colleges' and Schools' Deans of Research and the Director of Sponsored Programs shall not serve as IRB members or be involved in the day-to-day operations of the IRB.

9.5. Creighton University provides liability coverage for IRB members for any legal action arising from their actions and decisions while serving as members of the IRB.

9.6. Evaluation of IRB members and Chairs:

9.6.1. IRB members shall receive an evaluation and feedback on this evaluation on an annual basis

9.6.2. The Director for Research Compliance, IRB administrative staff and the IRB Chairs shall evaluate IRB members. The Director for Research Compliance and the IRB administrative staff shall evaluate the IRB Chairs, with IRB member input

9.6.3. The annual performance evaluations shall be based upon IRB Document, "IRB Member Evaluation," and a written evaluation of each member

9.6.3.1. IRB members and Chairs shall complete a self-evaluation form, which is reviewed by the IRB administrative staff and Director for Research Compliance

9.6.3.2. Performance shall be assessed according to the IRB member's meeting attendance records, level of participation during and outside of meetings, thoroughness of reviews, maintenance of confidentiality and understanding of the regulations. In addition, Chairs shall also be assessed according to leadership ability, meeting management, engagement in the expedited review process and effectiveness as representatives of the IRBs

9.6.4. IRB Chairs and members shall receive the results of their annual performance evaluations in writing

10. IRB MEETINGS

The Biomedical IRB meetings shall be held on the first and the third Tuesday of each month beginning at 4:00 p.m. The Social and Behavioral IRB meetings shall be held on the second Tuesday of each month beginning at 11:00 a.m. If an IRB meeting falls on a scheduled Creighton University holiday, the meeting shall be rescheduled at a time more convenient for Board members and IRB administrative staff. The schedules for regular IRB meetings and submission deadlines are available on the IRB website. Prior to each meeting (both IRB-01 and IRB-02), e-mail communication shall be sent to participating investigators and IRB members (and consultants), notifying them of the date, time, and place of the meeting. In addition to the regularly scheduled meetings, additional Board meetings may be scheduled if necessary, including emergency meetings to address issues of noncompliance or serious and/or unexpected injury to research subject(s).

10.1. Meeting Materials

The IRB administrative staff shall share, in the electronic system(s), the items for review with each member of the Board approximately 14 days prior to the regularly scheduled meeting:

10.1.1. The agenda

10.1.2. A copy of the minutes from the previous meeting, which shall include information on official IRB activities conducted through the IRB office since the previous minutes, such as protocols reviewed to determine exempt status, protocols reviewed by expedited review, approved advertisements, approved subject information material, reportable new information, projects that have been terminated, approval of modification

to protocols and attendant material that does not pose an increase risk to subjects

10.1.3. Reports and plans of action for unanticipated problems involving risks to subjects or others that have been determined by the Chair or designee to alter the risk/benefit ratio for the project

10.1.4. A copy of the IRB application, protocol, and informed consent, permission, and/or assent documents and other supporting documents for each new project subject to Full Board Review

10.1.5. A copy of completed continuing review forms to be reviewed

10.1.6. A copy of materials requiring modification, to include modified protocol and modified consent, permission, and/or assent documents

10.1.7. New or updated policies, new or updated supporting documents, educational information pertinent to IRB review

10.1.8. Internal auditing and monitoring reports

10.1.9. Reports on potential serious and/or continuing noncompliance

10.1.10. Any other information necessary for the meeting

10.2. **Quorum**

A simple majority of members must be present to establish a quorum and allow business of a convened IRB to be conducted. At least one member whose primary concerns are in scientific areas, at least one member whose primary concerns are in nonscientific areas and one unaffiliated member shall be present to constitute a quorum. Proxy votes shall not be accepted. The final approval or disapproval of any research project application shall require a majority vote of IRB members present and voting.

10.3. **Loss of Quorum**

If a quorum is lost (either loss of required number of members or loss of nonscientist or unaffiliated member) at any time during the meeting, the meeting shall be adjourned and no further action taken until a quorum is attained.

10.4. Review of Projects Involving Administration of Investigational New Drugs or Devices

For review of projects involving investigational new drugs or devices, the IRB shall include not less than two members licensed to administer drugs (or trained in pharmacology) and one who is not so licensed.

10.5. Review of Projects Involving Vulnerable Research Populations

For review of projects involving vulnerable research populations, the IRB shall include a member who has expertise in working with the particular vulnerable population.

10.6. Attendance

10.6.1. Members are expected to attend a majority of IRB meetings. The IRB office shall maintain records of attendance and members who attend fewer than 50 percent of meetings per year shall be contacted and encouraged to increase their attendance. Anticipated absence from an IRB meeting should be communicated to the IRB administrative staff at least 24 hours before the meeting. Unaffiliated members and members who represent the general perspective of subjects are required to attend at least 80% of convened meetings each year

10.6.2. Principal Investigators or investigators shall attend IRB meetings at the date and time scheduled for full IRB review of their initial submission. In addition, the Principal Investigator and/or investigator may be asked to attend to present changes to a previously approved research project. For projects involving administration of investigational new drugs or devices, an investigator who is licensed to administer drugs or trained in pharmacology shall attend. An investigator's presence may not be required for continuing review. Once a project has been scheduled by the IRB office for presentation at a particular meeting date and time, the Principal Investigator should contact the IRB administrative staff to request a scheduling change, if such a change is necessary

10.7. Minutes

Minutes shall not be altered by anyone, including a higher authority, once approved by the IRB members at a subsequent IRB meeting. Minutes of meetings shall include the following information:

10.7.1. Attendance of members and guests

10.7.2. IRB deliberations and actions taken on each research project reviewed, including the level of risk as determined by the IRB, the approval period, and any required modifications for IRB approval

10.7.3. Votes on actions, including the number of members voting for or against the action, the number and names of members abstaining from voting and notation of members who were not present during deliberations and voting on projects with which they have a conflict of interest

10.7.4. The basis for requiring modifications to, tabling, or disapproving research

10.7.5. A written summary of the discussion and resolution of controversial issues

10.7.6. The names of IRB members who leave the meeting because of a conflict of interest, along with the fact that a conflict of interest is the reason for the absence

10.7.7. Required determinations and protocol-specific findings justifying those determinations for:

10.7.7.1. Waiver or alteration of the consent process

10.7.7.2. Research involving pregnant women, fetuses, and neonates

10.7.7.3. Research involving children

10.7.7.4. Research involving prisoners

10.7.7.5. Research involving IND/Exemption

10.7.7.6. Research involving IDE/Exemption

11. CONFLICT OF INTEREST OF IRB MEMBERS/CONSULTANTS

11.1. Conflict of Interest Defined

11.1.1. An IRB Member shall notify the IRB Chair if s/he or an immediate family member (spouse and/or dependent children) has any of the following

potential conflicts of interest related to one or more projects subject to review by the IRB:

11.1.1.1. Serves as a Principal Investigator or investigator, or has served or will serve as a scientific/medical advisor on the project

11.1.1.2. Any financial conflict of interest, as defined in Creighton University Policy, "Financial Conflict of Interest in Research"

11.1.1.3. Holds a position as director, officer, partner, trustee, or any other significant position (e.g., scientific advisory board/consultant) in the entity sponsoring the research

11.1.1.4. Has an interest, as defined in Creighton University Policy, "Financial Conflict of Interest in Research", in a company that has a marketed project, or is in the process of developing a new product that is, or will be, in direct market competition with the product in the protocol under IRB review

11.1.1.5. Has a personal relationship or a conflict with any investigator(s) listed on the IRB application that would potentially cause the IRB member to be perceived as less than objective in his/her review

11.1.1.6. Has any interest that could be affected by the outcome of the research

11.1.2. All IRB Members/IRB administrative staff shall submit, annually, a disclosure of financial relationships with outside entities/organizations to determine whether any conflicts of interest may arise (See Creighton University Policy, "Financial Conflict of Interest in Research")

11.2. **Management of Member/Consultant Conflicts of Interest**

11.2.1. **Full IRB Review [includes all agenda items (i.e., continuing reviews, initial reviews, modifications, reportable new information, compliance reports)]:** Members should contact the IRB office prior to the meeting at which a conflict of interest may arise. The IRB office shall note all conflicts of interest that are disclosed prior to the meeting. Prior to the beginning of each meeting, IRB members shall be asked to declare, but are not required to describe, any conflicts of interest related to the protocols

under review at that meeting. All previously reported conflicts of interest shall be confirmed prior to the meeting. All disclosed conflicts of interest shall be noted in the minutes. Members who have a conflict of interest with a research project shall not participate in the Board's deliberations and voting concerning that project and shall not be counted toward quorum. Members with a conflict of interest shall leave the meeting room for discussion and voting, and the minutes shall note that a conflict was the reason for the absence. Those who have a conflict of interest may provide information requested by the IRB

11.2.2. **Expedited Review:** Members/consultants shall notify the IRB administrative office of a conflict of interest upon contact for assignment as expedited reviewer. The IRB administrative staff shall reassign an expedited protocol to another member/consultant when notified of a conflict of interest

11.2.3. **Consultants**

11.2.3.1. Consultants to the IRB shall be asked if they have a conflict of interest prior to providing information to the IRB. Creighton University consultants must disclose any conflict of interest. If the consultant does have a conflict as defined in section 11.1 of this policy, the Chair will evaluate and make the decision as to whether to allow the use of the consultant. Those who have a conflict of interest may provide information requested by the IRB. Members will be notified if there is a conflict at the beginning of the presentation

11.2.3.2. All disclosed conflicts of interest shall be noted in the minutes

11.2.3.3. Consultants with or without a conflict shall leave the meeting room for discussion and voting

11.2.3.4. Consultants shall not be counted toward quorum

12. IRB RECORDS

12.1. The IRB shall retain the following records for at least three years after completion of the research :

12.1.1. Copies of all research proposals reviewed, including any scientific evaluations, approved sample informed consent/assent documents, investigator progress reports, and adverse event reports

12.1.2. IRB meeting minutes (retained indefinitely)

12.1.3. Records of continuing review of previously approved research projects

12.1.4. Copies of all correspondence in the electronic system between the IRB and the investigators

12.1.5. List of IRB members, identified by name, earned degrees, representative capacity, indications of experience sufficient to describe each member's chief anticipated contributions, and employment relationship (if any) with the Institution

12.1.6. Written IRB policies and procedures

12.1.7. Statements of significant new findings provided to subjects as required by either the FDA (21 CFR 50.25(b)(5)) or the DHHS [(45 CFR 46.116(c)(5)]

12.2. IRB records, as outlined above, shall be available for inspection and copying by the Institutional Official or his/her designees, affiliated entities, and designated federal agencies.

13. TRAINING OF IRB MEMBERS

See IRB Policy, "Human Subjects Research Education Program."

14. POLICY REVIEW

14.1. The Creighton University IRBs shall review policies and procedures regularly, or as dictated by changes in federal and state regulations and guidelines. Review shall be done by IRB administrative staff. Significant changes to policies shall be taken to the full IRBs for review and approval.

14.2. Changes and updates to policies and procedures are based on federal, state and local laws. If there is a conflict between these laws, the IRB will adopt the most restrictive guideline or law.

14.3. When changes to policies are approved by the IRB, the revised policies shall be posted on the website and an alert shall be sent via email to all investigators listed on active protocols

14.4. Investigators shall share all updated and new policies and procedures with research personnel, including students and sponsors (upon request)