1. **PURPOSE**

This policy describes the interaction of the IRB with other Creighton University committees to ensure compliance in all areas of human subject research. This applies to both IRB-01 (Biomedical) and IRB-02 (Social-Behavioral).

2. **REVIEW OF HUMAN SUBJECT RESEARCH ACTIVITIES BY OTHER UNIVERSITY COMMITTEES**

2.1. Creighton University (CU) IRBs coordinate reviews with other institutional committees, as described below. None of these committees are a formal part of the CU IRBs, but there is communication between the committees regarding status of review and/or conditions of approval.

2.2. Though other institutional committees share the responsibility for following guidelines in the collective effort to protect human subjects, the final authority for the determination of human subjects research falls on the IRBs. Investigators shall submit their projects to other institutional review committees (Institutional Biosafety Committee, Radiation Safety Committee, and Financial Conflict of Interest Committee) if required. Requirements and directions for review by other committees can be found on their respective web sites, listed for each committee in the sections below.

2.3. Researchers are not required to wait for the approval of the other CU institutional review committees before submitting proposals to the IRBs, but they shall submit the other committee approvals to the IRBs prior to final approval by the IRBs.

2.4. The IRB Chairs or designees shall review the recommendations of each committee and give final approval to any proposed modification to the research protocol or consent, as requested by the committees. If the IRB Chairs or designees deem modifications affect the risk/benefit ratio of a project, the modifications shall be sent to a convened meeting for review.

2.5. Research shall not be initiated until receipt of a final approval letter from the IRB.
3. OTHER UNIVERSITY COMMITTEES

3.1. Radiation Safety Committee (RSC)

Creighton University is guided by state and federal regulations governing safe use, transportation, and disposal of radioactive materials, radiation-generating equipment, and lasers. The RSC reviews and approves the use of radioactive materials for clinical, research, and educational purposes. It represents Creighton in regulatory matters with the Nebraska Department of Health and Human Services, including state regulations and licensure. The Radiation Safety Office ensures appropriate training of personnel, monitors personnel exposure to radiation, and documents use of radioactive materials and radiation-generating equipment according to regulations, and reports this information to the RSC. The Radiation Safety Office also oversees appropriate handling and disposal of radioactive waste.

3.2. Institutional Biosafety Committee (IBC)

It is the policy of Creighton University that any possession of and/or activity involving known or potential biohazardous materials shall be reviewed and approved by the IBC. Biohazardous materials subject to review by the IBC include, but are not limited to, the following:

3.2.1. Infectious Biological Agents: infectious biological agents and biologically derived materials that present a risk or potential risk to the health of humans or animals, either directly through infection or indirectly through damage to the environment. Infectious agents have the ability to replicate and give rise to potentially large populations in nature when small numbers are released from controlled situations.

3.2.2. Recombinant DNA: the National Institutes of Health Guidelines define recombinant DNA molecules as either

3.2.2.1. molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or
3.2.2.2. molecules that result from the replication of those described in 3.3.2.1 above.

3.2.2.3. In addition, synthetic DNA segments that are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart.

3.2.3. **Select Agents:** by law, Creighton University must report all specified biological “select agents” in its possession to the government. These “select agents” are identified on the “Select Agents and Toxins List” provided by the CDC and USDA.

3.3. **Conflict of Interest Review Committee (CIRC)**

3.3.1. The Conflict of Interest Policy and the Financial Conflict of Interest Policy were developed to protect the best interests of Creighton University when entering into any transactions, while ensuring that such transactions will not be adversely affected by any conflict of interest held by University employees responsible for the transaction.

3.3.2. It is the policy of Creighton University that all employees shall carry out their responsibilities to the University in the best interests of the University. All investigators and other study personnel shall disclose to the University any potential conflicting interests, including financial interests.

3.3.3. The CIRC shall review the disclosure and decide whether a conflict of interest exists. The CIRC shall prepare a resolution plan to manage, reduce, or eliminate any identified conflict of interest before the project can proceed. If the project involves human subjects research, the IRB shall approve at a convened meeting a Resolution Plan presented by the CIRC, or the IRB may impose additional requirements. The IRB may request a reconsideration of the CIRC’s initial decision. The CIRC shall review the request and any supporting materials and issue its final determination, which shall not be subject to further appeal.