Exempt Research (HRPP 2.6)

Description:

This policy describes UNMC's requirements for determining if a research proposal is eligible for exemption under 45 CFR 46.104(d) and 21 CFR 56.104.

Categories of Exempt Research:

- **Category 1**: normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or assessment of educators who provide instruction.
- **Category 2**: only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior if **at least one of the following** is met:
    - The information recorded does not easily identify the subject.
    - Disclosure of subjects' responses outside of research does not place them at risk for civil or criminal liability.
- **Category 3**: benign behavioral interventions in conjunction with the collection of information from an adult subject if the subject prospectively agrees and **at least one of the following** is met:
    - Information obtained does not easily identify the subject.
    - Disclosure of subjects' responses outside of research does not place them at risk.
- **Category 4**: secondary research for which consent is not required: secondary research uses of identifiable private information or biospecimens, if **at least one of the following** is met:
    - Identifiable private information of biospecimens is publicly available.
    - information recorded by the investigator such that the identity of the subject is not easily identifiable, the investigator does not contact the subjects, and the investigator will not re-identify subjects.

- involves only information collection and analysis involving investigator's use of identifiable health information when use is regulated under HIPAA Privacy Rule.
- The research involves only information collection and analysis, that either involves research conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology subject to and incompliance with the E-Government Act of 2002 or Privacy Act of 1974.

- **Category 5**: research and demonstration projects conducted by or subject to approval of the department or agency heads which are designed to study/evaluate/examine public benefit or service programs.
- **Category 6**: taste and food quality evaluation and consumer acceptance studies:
  - Wholesome foods without additives OR
  - At or below the level found to be safe by the FDA or approved by the Environmental Protection Agency or Food Safety and Inspection Service of US Department of Agriculture.

Procedures:

1) **Submit an application to the ORA:**
   a. Use an **HBM application** for research involving identifiable biospecimens (with or without medical records).
   b. Use a **Medical Records application** for research involving only identifiable private information from medical records.
   c. Use an **Exempt application** for the rest.
2) The **study is reviewed by a designated IRB analyst** where they will:
   a. Decide if the research meets the exempt category.
   b. Determine whether approval criteria is met.
   c. Communicate the determination with the PI.
3) The **study receives a determination**:
   a. **Approved**- initiation of the research is authorized.
   b. **Conditional Approval**- full release and approval is contingent on modifications specified by the analyst. The PI is notified that the modifications must be made before starting the research.

c. **Referred for Expedited OR Full Board Review**- this may require the PI to submit a different application type.

4) **Final approval/release is granted after approval of necessary** (if any) **committees** (i.e. Buffett Cancer Center Scientific Review Committee, Conflict of Interest Committee, and SPA/executed contracts office).