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:**
   a. Use the **Exempt Application** for:
      i. Categories 1, 2, 3, 5, 6 and FDA category (d)
      ii. Category 4 if it involves identifiable private information (but **not** from medical records)
   b. Use the **Human Biological Materials (HBM) Application** for:
      i. Category 4 involving **identifiable biospecimens,** with or without medical records
   c. Use the **Medical Records Application** for:
      i. Category 4 if the research involves **identifiable private information from medical records**
2) **Review Process:**

   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

Criteria for Approval of Exempt Research:

To be approved as **exempt research**, the research must meet **all** of the following:

- Research must fit into 1 or more of the exemption categories listed above
- The research must involve **no more than minimal risk** to participants
- Selection of subjects must be fair and unbiased *(e.g. not targeting or excluding certain groups without justification)*
- If recording identifiable private information (IPI), the research must have adequate safeguards to protect confidentiality *(e.g. encryption, limited access)*
- The study must respect and protect participants' privacy interests, including how data is collected, stored, and shared
- Overall, the research must safeguard the rights and welfare of subjects, even if it qualifies for exemption
- If investigators interact with subjects, the informed consent process must disclose at least the following:
    - State the project involves research
    - State that participation is voluntary
    - Describe the procedures
    - Describe the risks, if any
    - Provide the name and contact information for the researcher
    - **NOTE**: the ORA may require signed documentation of the consent form from the subject or legally authorized representative

Exempt Review Actions:

- **APPROVAL:**
    - All criteria for approval are satisfied and no changes are required
    - The study may start (when institutional requirements are satisfied)
- **CONDITIONAL:**
    - Minor changes are required
    - Final approval contingent upon ORA review and acceptance of changes and/or submission of additional documents
- **REFER FOR EXPEDITED REVIEW**
- **REFER FOR FULL BOARD REVIEW**

Review by Other Committees:

Before the ORA grants final approval, other institutional committees might need to review the study (e.g. SRC, COI, SPA etc.). Final approval only happens after these groups have provided their approval to the ORA.