1.2 Authority Granted to the IRB by the Organization

Last Revised: 5/28/2021

1.0 Purpose

The purpose of this policy and procedure is to describe the authority granted by the Organization for the IRBs operating within the HRPP.

2.0 Policy

It is the policy of the Organization that:

- **2.1** All research involving human subjects conducted at the Organization or conducted by faculty, students, staff or other representatives of the Organization at external sites must receive approval by a designated IRB before the research may commence.
  - **2.1.1** The IRB is authorized to independently review and approve all non-exempt human subject research conducted by the faculty, students, staff, or other representatives of the Organization, or by any non-affiliated investigators, when the research is conducted on the premises of any of the components of the Organization. The IRB may accept review and approval from external IRBs for any research conducted within the Organization on a case-by-case basis in accordance with HRPP policy 1.4 (UNMC Ceding Review to an External Central IRB).
  - **2.1.2** The IRB is authorized to independently review and approve all non-exempt human subject research conducted by the faculty, students, staff, or other representatives of Organization, or by any non-affiliated investigators, when the research is conducted at an external institution. However, the Organization may accept external IRB approval in accordance with HRPP policy 1.4 (UNMC Ceding Review to an External Central IRB).
- **2.2** The IRB shall review and approve all non-exempt human subject research before such research is initiated, as per Section 2.1.
  - **2.2.1** Full IRB Review: The full IRB has the authority to approve, require modifications in (to secure approval), or disapprove any research activities conducted under the jurisdiction of the IRB in accordance with HRPP policy 2.2 (Full IRB Review).

    - **2.2.2** Expedited Review: When expedited review is used, in accordance with 45 CFR 46.110; 21 CFR 56.110, the expedited reviewer designated by the IRB Executive Chair or IRB Chair has the authority to approve or require modifications in (to secure approval) of research activities conducted under the jurisdiction of the IRB. The expedited reviewer is not authorized to suspend or disapprove research in accordance with HRPP policy 2.3 (Expedited Review).
- **2.3** When IRB approval of non-exempt human subject research expires, or is terminated by the IRB or the Organization, or when the research is classified as completed by the investigator or the IRB, no further research activities may occur. This includes collection of existing or additional identifiable private information, or analysis existing identifiable private information.
- **2.4** All exempt research, which is conducted by faculty, students, staff, or other representatives of the Organization must be reviewed and approved by the UNMC Office of Regulatory Affairs (ORA) before it is initiated in accordance with HRPP policy 2.6 (Exempt Research). The ORA will accept approval of exempt research by an external institution on a case-by-case basis.
- **2.5** The IRB has the authority to approve a waiver or an alteration of the Authorization requirement of the HIPAA Privacy rule per 45 CFR 165.512.
- **2.6** The IRB has the authority to observe or have a third party observe the informed consent process for ongoing research protocols.
- **2.7** The IRB has the authority to observe or have a third party observe the conduct of the research for ongoing protocols.
- **2.8** The IRB has the authority to review or have a third party review files related to the research under the jurisdiction of the IRB and when an external IRB serves as the IRB of record.
- **2.9** The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or HRPP policy, or that has been associated with unexpected serious risk or harm to subjects or others.
- **2.10** The IRB Executive Chair/designee, in consultation with the IO and others as necessary, has the authority to suspend research that is not being conducted in accordance with the IRB's requirements or HRPP policy, or that has been associated with unexpected serious risk or harm to subjects or others.
- **2.11** Research approved by the IRB may be subject to further review by an authorized official of the involved component of the Organization. Approval by the IRB can be overturned by those authorized individuals. However, no official of the Organization may approve research that has not been approved by or has been disapproved by the IRB.
    - **2.11.1** The reason(s) for administrative disapproval of research by the authorized official shall be provided in writing to the PI and the IRB.
    - **2.11.2** The PI may appeal the administrative decision to overturn IRB approval by submitting a written justification. The authorized official, in consultation with the IO as appropriate, will make the final determination.
- **2.12.** The IRB or the ORA may be periodically charged by the IO with review of other research activities. Charge by the IO constitutes authority to perform that review and requirement by faculty, students, staff, or other representatives of the Organization to abide by the findings of the IRB or ORA.
- **2.13** Any attempt to unduly influence the IRB from either within (including Organizational conflicts of interest) or outside the Organization is strictly prohibited and must be reported to the IO. The IO will take appropriate action including but not limited to notifying the supervisor of the individual who attempted to influence the IRB, the Chief Compliance

Officer and other appropriate officials of the Organization. A thorough investigation will be undertaken and corrective action including counseling or other disciplinary action will be taken as necessary.

DOCUMENT HISTORY:

? Written: 4/4/2016 (Approved: 4/4/2016)

? Revised: 3/9/2018 - revision not documented

? Revised: 5/28/2021 - Clarified who may act as an expedited reviewer (section 2.2.2); added that the IRB or ORA may be charged with review of other research activities, and granted authority to do so; deleted reference to other specific committees and activities. Notification: not documented

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