1.30 Use of the Rapid Response IRB

1.0 Purpose

The purpose of this policy is to describe the constitution of, the criteria for use of, and the procedures for review by, the Rapid Response IRB (RR-IRB; IRB-03).

2.0 Policy

It is the policy of the Organization that

- 2.1. The Rapid Response IRB (RR-IRB) will be utilized as appropriate to facilitate the review of human subject research that meets criteria listed below.
- 2.2. The standard procedures for full IRB review (as per HRPP policy 2.2 {Full IRB Review}) may be modified as described below, to facilitate rapid and meaningful IRB review, in accordance with federal regulations at 45 CFR 46 and 21 CFR 56.

3.0 Constitution

- 3.1. The RR-IRB is a fully constituted and registered IRB (IRB00002686) operating under FWA 00002939.
- 3.2. The RR-IRB is composed of at least 8 members (at least one of whom is a non-scientist and one who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution), and a variable number of alternates.
- 3.3. The RR-IRB will include one Chair and at least one Vice-Chair.
- 3.4. Members and alternates will represent a variety of colleges, departments and medical and academic disciplines, including but not limited to, College of Public Health, Infectious Disease, Pharmacy, and ethics.
- 3.5. The RR-IRB shall include a prisoner representative with appropriate background and experience to serve in that capacity, as per 45 CFR 46.304(b).
- 3.6. Membership will satisfy requirements of HRPP policy 1.6 (IRB Composition, Leadership, Qualifications, & Responsibilities).

4.0 Criteria for Use

- 4.1. The RR-IRB may be activated by the Executive Chair or designee for rapid review of new protocols, previously tabled protocols, requests for change in approved research or continuing reviews of approved research.
  - 4.1.1. In order for the RR-IRB to review a previously tabled protocol, one member of the convened RR-IRB must also have been present at the IRB meeting during which the protocol was tabled, or a member of the board that tabled the protocol must be present at the RR-IRB meeting, as a non-voting observer, to answer questions regarding the issues raised by that board.
- 4.2. Activation is at the discretion of the Executive Chair or designee, in consultation, if necessary, with the IO. In general, the RR-IRB will review research which fits ALL of the following criteria:
  - 4.2.1. The research provides the potential for meaningful benefit to potential subjects that cannot be obtained outside the context of the specific research protocol, OR the research provides the potential for significant benefit to the Organization.
  - 4.2.2. Review is urgent; that is, there is insufficient time to wait for a scheduled meeting of IRB-01, IRB-02 IRB-04, or IRB-05.
  - 4.2.3. The research is not eligible for expedited review, per HRPP policy 2.3 (Expedited Review).
- 4.3. In general, the RR-IRB will not review research where the urgency arises from delays on the part of the investigator.

5.0 Process of IRB review and ORA release

- 5.1. Upon activation, one or more IRB Analysts will be responsible for contacting members in order to identify a quorum, and an appropriate meeting day/time. Once a quorum and meeting time are identified, the investigator will be notified.
- 5.2. The investigator will begin the process of completing the IRB application online
- 5.3. The RR-IRB will review as per HRPP policy 2.2 (Full IRB Review), except as noted below.
- 5.4. Depending on the urgency of the review, as determined by the Executive Chair and/or the RR-IRB Chair, in consultation as appropriate with the IO, any or all of the following modifications in the process of IRB review and/or ORA release may be utilized:
  - 5.4.1. The investigator and the IRB Analyst, Executive Chair and/or the RR-IRB Chair may discuss issues related to the protocol, IRB application and CF in an iterative fashion during the completion of the online application, in order to proactively address potential concerns.
  - 5.4.2. The primary and secondary reviewers may begin review of the draft IRB application and CFs as they become available prior to the meeting; they will be supplied with any revisions of these documents as they are available.
    - 5.4.2.1. All RR-IRB members will be supplied with the complete IRB application, full protocol, and CFs at the time of the meeting.
  - 5.4.3. RR-IRB review may occur concurrently with review by other committees (for example, Pharmacy and Therapeutics, IBC).
    - 5.4.3.1. The Executive Chair and/or RR-IRB Chair or designee will be responsible for assuring that changes (if any) required by those other committees do not require further review by the IRB.
  - 5.4.4. The investigator or their designee may be present at the IRB meeting during the presentation of the protocol and discussion by the board, in order to interactively

address concerns or questions raised by the RR-IRB. The RR-IRB will be provided adequate time for further discussion and vote without the investigator or designee present.
    - 5.4.5. The IRB analyst assigned to the protocol may make modifications to the IRB Application and the CF based on discussion with the investigator during the RR-IRB meeting, and the investigator's responses to IRB directed comments following the meeting.
    - 5.4.6. The Executive Chair and/or RR-IRB Chair, in consultation with the IO as appropriate, may waive the requirements that some or all of the ancillary committee reviews be completed prior to ORA release.
- 5.5. Following review of the protocol by the RR-IRB, the IRB Analyst assigned to the protocol (in consultation with the Executive Chair or RR-IRB Chair as needed) will review the investigator's written responses, and revised application and CFs, and grant approval if the conditions placed by the full RR-IRB have been satisfied.

DOCUMENT HISTORY:

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? Revised 10/17/2024 – clarified the size and composition of the RR-IRB (sections 3.2 and 3.4); deleted requirement that RR-IRB include representatives from UNMC, NM and CN (section 3.4); clarified the role of the non-voting observer when the RR-IRB reviews protocols tabled by another board (section 4.1.1); when RR-IRB review occurs concurrently with review by other committees specified who is responsible for assuring that those reviews do not raise conflicts with the IRB review (section 5.4.3.1); added that Executive Chair and/or RR-IRB Chair may waive the requirements that some or all of the ancillary committee reviews be completed prior to ORA release (section 5.4.6); stylistic changes. {Approved Russell McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

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