1.30 Use of the Rapid Response IRB

1.0 Purpose

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

2.0 Policy

- **2.1.** It is the policy of the Organization that 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.** It is the policy of the Organization that 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 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 will include representatives from UNMC, Nebraska Medicine and CHMC, representing a variety of colleges, departments and medical 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 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.
- **4.2.** Activation is at the discretion of the Executive Chair, in consultation, if necessary, with the IO. In general, the RR-IRB will review research which fits the following criteria:
- **4.3.** 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.
  - **4.3.1.** Review is urgent; that is, there is insufficient time to wait for a scheduled meeting of IRB-01, IRB-02 or IRB-04.
  - **4.3.2.** The research is not eligible for expedited review, per HRPP policy 2.3 (Expedited Review).
- **4.4.** In general, the RR-IRB will not review research where the urgency arises from delays on the part of the investigator.

5.0 Procedures

- **5.1.** Upon activation, one or more IRB Administrators will be responsible for contacting members by phone, email and/or text message, 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, any or all of the following modifications may be utilized as deemed appropriate by the Executive Chair and/or the RR-IRB Chair
  - **5.4.1.** The investigator and the IRB Administrator, 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. All RR-IRB members will be supplied with the agenda, complete IRB application, full protocol, and CFs at the time of the meeting.
- **5.4.3.** RR-IRB review will occur concurrent with review by other committees (for example, Pharmacy and Therapeutics, IBC)
- **5.4.4.** The investigator or his/her designee may be present in the room 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 investigator will then leave the room allowing the RR-IRB adequate time for more discussion, and then the vote.
- **5.4.5.** The IRB administrator assigned to the RR-IRB will 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 RR-IRB Administrator, in consultation with the Executive Chair and/or the RR-IRB Chair as appropriate, will review the investigator's written responses, and revised application and CFs, and are authorized to grant final approval if the conditions placed by the full RR-IRB have been satisfied

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