2.1 Submission for Items for Review by the IRB

1.0 Purpose

The purpose of this policy is to describe Organization's requirements for submission and pre-review of all applications and research related forms and reports.

2.0 Policy

It is the policy of the Organization that all submissions will be processed efficiently by the Office of Regulatory Affairs (ORA) for review in accordance with applicable HRPP policies.

3.0 Submission Requirements

- **3.1.** All applications and research related forms and reports will be submitted using the online Research Support System RSS, except as below:
- **3.2.** CRs and certain other forms related to research protocols approved prior to January 16, 2012 may continue to be submitted on paper. All necessary forms are available on the UNMC IRB website and the IRB will maintain paper files for the duration of these studies.
  - **3.2.1.** Research protocols remaining in paper format will continue to be transitioned to RSS as appropriate.

4.0 Deadlines for Submission

- **4.1.** The deadline for submission of any materials requiring review by IRB-01, -02, and -04 is 10 working days prior to each meeting. The deadline for submission of any materials requiring review by the IRB-05 is 6 working days prior to each meeting. The deadlines are published on the IRB website.
  - **4.1.1.** All new applications and re-submissions of tabled protocols will undergo pre-review to the greatest extent possible in consideration of the submission date, and ORA workload.
  - **4.1.2.** Exceptions to the above deadline may be made on a case-by-case basis by the IRB Executive Chair or his/her designee.
  - **4.1.3.** Items that qualify for expedited review in accordance with HRPP policy 2.3 (Expedited Review) have no deadlines for submission.
  - **4.1.4.** Items that qualify as exempt in accordance with HRPP policy 2.6 (Exempt Research) have no deadlines for submission.

5.0 IRB Review Limits

- **5.1.** The IRB will normally review no more than 10 protocols (new submissions and previously tabled protocols) at each full meeting. Assignment to the IRB meeting are made on a first-come, first-served basis. Protocols in excess of 10 will be assigned to the following IRB meeting.
- **5.2.** The IRB will review reports of internal Adverse Events, Requests for Change, Incident Reports and Special Review Items at the earliest possible full IRB meeting without review limits.

6.0 Determination of Required IRB Review

- **6.1.** Protocols and other action items submitted through RSS will be triaged to the appropriate IRB administrator and processed in accordance with ORA SOPs.
- **6.2.** The IRB Administrator, in consultation as necessary with the IRB Executive Chair, will determine whether or not a protocol or other action item requires review by the full IRB or qualifies for expedited review in accordance with HRPP policies 2.2 (Full IRB Review) and 2.3 (Expedited Review.)

DOCUMENT HISTORY:

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Revised: 7/19/2022 - Deleted list of types of forms for review; clarified which items allowable for submission in paper format; corrected deadlines for submission; clarified maximum number of protocols to be reviewed {Approved Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

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