1.18 Review and Approval of HRPP Policies and Procedures

1.0 Purpose

The purpose of this policy is to describe the Organization's requirements for the review and approval of HRPP policies.

2.0 Policy

It is the policy of the Organization to continually assess the adequacy of existent policies in consideration of new information and Organizational requirements that may affect the HRPP, including federal, state, and local laws, regulations, and guidance, as well as emerging ethical and scientific issues.

3.0 Review of HRPP Policies

- **3.1.** The IRB Administrators, the Assistant Vice-Chancellor for Regulatory Affairs, the IRB Executive Chair, and IO will review HRPP policies on a rolling basis, with a target of review of policies at least every three years. However, anytime a policy requires revision due to new or revised federal, state or local laws, federal regulations or guidance, changes in Organizational requirements, or identification of deficiencies, the policy will be revised accordingly.
- **3.2.** New and revised (draft) HRPP policies which are regulatory in nature (that is, which are dictated by federal, state, and local laws, regulations, and guidance), or which solely describe ORA procedures, will be provided to the IRBs for their information, but do not require approval by the IRBs.
- **3.3.** New and revised (draft) HRPP policies which are extra-regulatory in nature will be reviewed and approved by the IRBs that have scheduled meetings (IRBs -01, 02-, 04 {Pediatrics}, and -05 {SIRB}), the IO, and in select cases, other Organizational officials.
- **3.4.** All new and revised HRPP policies must be approved by the IO and the Assistant Vice-Chancellor for Regulatory Affairs. The Assistant Vice-Chancellor for Regulatory Affairs, in consultation with the IO, will determine when policies also should be reviewed by other Organizational Officials (for example, Compliance Officer, Privacy Officer, General Counsel, and/or Vice Chancellor for Research).
  - **3.4.1.** New and revised policies that do not require IRB approval (section 3.2) will be approved by the IO prior to notification of the board. New and revised policies that require IRB approval (section 3.3) will be reviewed by the boards prior to approval of the IO.

4.0 Full IRB Review of Draft HRPP Policies

- **4.1.** New and revised (draft) HRPP policies requiring review by the full IRB (per section 3.3 above) will either be (1) discussed at all regularly scheduled IRB meetings as described in section 4.2 below, or (2) subject to an email vote as described in section 4.3 below.
- **4.2.** Review at convened IRB meetings
  - **4.2.1.** IRB members will receive a copy of the policy to be reviewed with the detailed meeting agenda in advance of the scheduled IRB meeting.
  - **4.2.2.** All IRB members may cast their vote (for, against, abstain) either in person at the IRB meeting or via e-mail. IRB members may provide written statements in support of their vote or ask other IRB members to express their opinions at the meeting.
  - **4.2.3.** For the vote to be valid, a majority of the entire IRB membership must cast a vote, either in person or by e-mail. For the policy to be approved, a majority of those voting must be attained.
  - **4.2.4.** If the motion to approve a policy fails to pass, the draft policy may be referred to the IRB Executive Chair or an IRB subcommittee for further discussion and revision before re-consideration.
- **4.3.** Review by email
  - **4.3.1.** At the discretion of the IO, the Assistant Vice-Chancellor for Regulatory Affairs, or the IRB Executive Chair, voting procedure by e-mail alone will be allowed for consideration of a policy. In general this procedure should be limited to new policies that represent existing IRB practices, non-major revision of existing policies, or instances where approval of a policy is necessary before the next regularly scheduled meeting.
  - **4.3.2.** IRB members will receive by email a copy of the policy to be reviewed, as well as a summary of key points in the new policy, or relevant changes to the existing policy. The email will also describe the deadline for response, and the interpretation of non-response

(that is, non-response is considered a vote in favor).
- **4.3.3.** IRB members may provide written statements in support of their vote or request that the policy be brought to a convened meeting for discussion. The IO has the authority to decide on such requests, based on the nature of the members' concerns, and the urgency of the policy review.
- **4.3.4.** For the vote to be valid, a majority of the entire IRB membership must cast a vote. For the policy to be approved, a majority of those voting must be attained.
- **4.3.5.** If the motion to approve a policy fails to pass, the draft policy may be referred to the IRB Executive Chair or an IRB subcommittee for further discussion and revision before re-consideration.

5.0 Organizational Notification of Changes to HRPP Policies

- **5.1.** Changes to HRPP policies will be communicated to the Organization's research community by email, notification on the IRB website, and/or other media as appropriate.
- **5.2.** IRB Administrators and staff will be notified by email or at a staff meeting.

DOCUMENT HISTORY:

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Revised: 6/30/2022 - Revised required frequency of policy review; revised number of IRBs; clarified order of review and approval of policies by boards and IO; removed requirement for "read receipt" for email votes; clarified mechanism for notifying ORA staff. {Approved: 7/2/2022 Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

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