1.22 Assessment of the Effectiveness and Efficiency of the HRPP

1.0 Purpose

The purpose of this policy is to describe the Organization's requirements for assessment of the quality, effectiveness, efficiency and support of the Organization's HRPP in carrying out its mission to ensure protection of human subjects and compliance with all applicable federal, state and organizational requirements.

2.0 Policy

It is the policy of the Organization that there will be an ongoing assessment of the HRPP, as well as a comprehensive annual HRPP assessment. These assessments are designed to ensure 1) that the HRPP is fully capable of protecting the rights and welfare of research subjects; and 2) the HRPP will continue to evolve and improve in its effectiveness and efficiency.

3.0 Procedures

- 3.1. On-going Assessment of the HRPP
  - 3.1.1. HRPP Policies will be assessed on an ongoing basis by the IO, IRB Executive Chair and IRB/ORA staff.
  - 3.1.2. Organizational officials may provide input regarding IRB/ORA processes to the attention of the IO and IRB Executive Chair.
  - 3.1.3. The IO, IRB Executive Chair, and IRB/ORA staff will continually monitor the efficiency and effectiveness of the IRB/ORA, utilizing appropriate metrics and data from relevant QA/QI projects and input from stakeholders, in order to maintain and improve IRB/ORA processes.
  - 3.1.4. One set of IRB minutes for each board will be randomly selected for audit quarterly (as available). The IRB will utilize HRPP policy 2.2 (Full IRB Review) and OHRP Draft Guidance "Minutes of Institutional Review Board (IRB) Meetings: Guidance for Institutions and IRBs" (dated November 2015).
  - 3.1.5. PIs and other study personnel are provided an on-going opportunity to assess the effectiveness of the HRPP, including policies, quality and efficiency of IRB review, IRB staff support and other components of the HRPP through communication with the IRB Executive Chair, IO, IRB staff, and senior administration.

    - 3.1.5.1. As appropriate, the IRB Executive Chair and IRB Analysts may schedule focus group discussions with Investigators from components of the Organization to discuss the effectiveness of the HRPP.
    - 3.1.5.2. PIs and other study personnel may utilize the Investigator Feedback link on the IRB website to communicate their concerns, questions or suggestions to the IRB and/or ORA.
    - 3.1.5.3. PIs and other study personnel may utilize the “Report a Research Problem or Complaint” tab on the UNMC IRB website, which provides access to the University of Nebraska EthicsPoint, and to the UNMC Human Subjects Research Comment Portal.
- 3.2. Evaluation of the IRB Executive Chair
  - 3.2.1. The IO will evaluate the performance of the IRB Executive Chair on an annual basis utilizing a discussion format. The focus of the discussion will be on IRB leadership, accomplishments during the past year and goals for the future.
  - 3.2.2. The IO will obtain feedback submitted from the IRB Members and IRB Analysts at least annually, via on-line questionnaires and surveys, and/or via focus group discussion (facilitated by the Research Subject Advocate or designee) as appropriate.
  - 3.2.3. If the IRB Executive Chair’s performance is judged to be deficient, the IO will discuss his/her concerns with the Executive Chair and seek a satisfactory resolution. If the IRB Executive Chair’s performance continues to be deficient, the IO may remove the individual as the Executive Chair, in consultation with the Vice Chancellor for Research.
- 3.3. Evaluation of the Chairs and Vice-Chairs
  - 3.3.1. The IRB Executive Chair will review the performance of the IRB Chairs and Vice-Chairs on an annual basis considering, but not limited to, the following criteria:
    - 3.3.1.1. Meeting leadership
    - 3.3.1.2. General regulatory knowledge
    - 3.3.1.3. Active participation in IRB Executive Committee and involvement in activities of the ORA.
    - 3.3.1.4. Attendance at meetings
    - 3.3.1.5. Timeliness and completeness of IRB reviews
    - 3.3.1.6. Participation in IRB discussions
    - 3.3.1.7. Service on IRB subcommittees
    - 3.3.1.8. Feedback submitted by IRB Members at least annually, via on-line questionnaires and surveys, and/or via focus group discussion (facilitated by the Research Subject Advocate or designee) as appropriate. In addition, the IRB Executive Chair will convene meetings with IRB Analysts to elicit feedback about Chair and Vice-Chair performance.
  - 3.3.2. If an IRB Chair or Vice-Chair’s performance is judged to be deficient, the IRB Executive Chair will discuss his/her concerns with the Chair or Vice-Chair and seek a satisfactory resolution. Upon recommendation of the IRB Executive Chair, the IO at his/her discretion may remove the individual as an IRB Chair or Vice-Chair.
- 3.4. Evaluation of IRB Members and Alternates
  - 3.4.1. The IRB Executive Chair will convene meetings with the IRB Analysts and Chairs at least annually, to evaluate the IRB Members considering, but not limited to, the following:
    - 3.4.1.1. Attendance at meetings for which they have been assigned review items
    - 3.4.1.2. Timeliness and completeness of IRB reviews

        - 3.4.1.3. Participation in IRB discussions
        - 3.4.1.4. Service on IRB subcommittees
        - 3.4.1.5. General regulatory knowledge
    - 3.4.2. The IRB Executive Chair, IRB Analysts and Chairs will also evaluate IRB Alternates, using criteria similar to those described in 3.4.1 above, in consideration of the episodic nature of their participation.
    - 3.4.3. IRB members and alternates will be provided feedback, by letter or in person, regarding their performance.
        - 3.4.3.1. If service of an IRB member or alternate is judged to be satisfactory or exceptional, the IRB Executive Chair will so inform the member.
        - 3.4.3.2. If service of an IRB member or alternate is judged to be significantly deficient, the IRB Executive Chair will discuss the concerns with the member and seek a satisfactory resolution.
    - 3.4.4. Any IRB member or alternate whose contribution to the IRB is judged to be continually deficient despite feedback, may have their appointment terminated by the IO upon recommendation of the IRB Executive Chair.
    - 3.4.5. Upon request of individual IRB members or alternates, the IRB Executive Chair and/or the IO will write letters of recommendation which attest to the quality and value of the member's service on the IRB.
- 3.5. Evaluation of IRB Analysts and Staff
    - 3.5.1. The Assistant Vice-Chancellor for Regulatory Affairs will evaluate the performance of the IRB Analysts utilizing the UNMC Employee Evaluation Form and Feedback submitted from the IRB Members at least annually via on-line questionnaires and surveys, and/or via focus group discussion (facilitated by the Research Subject Advocate or designee) as appropriate.
        - 3.5.1.1. The Assistant Vice-Chancellor for Regulatory Affairs will provide feedback verbally to each IRB Analyst during the annual review process, as well as written comments on the UNMC Performance Evaluation Form.
        - 3.5.1.2. The Assistant Vice-Chancellor for Regulatory Affairs will also provide ongoing feedback about the performance of the IRB Analysts throughout the year.
    - 3.5.2. A designated supervising IRB Analyst will evaluate the performance of the IRB staff utilizing the UNMC Employee Evaluation.
        - 3.5.2.1. The supervising IRB Analyst will provide feedback verbally to each IRB staff during the annual review process, as well as written comments on the UNMC Employee Evaluation Form.
        - 3.5.2.2. The supervising IRB Analyst will also provide on-going feedback about the performance of the IRB staff throughout the year.
- 3.6. Annual Evaluation of the HRPP
    - 3.6.1. The evaluation of the HRPP will be conducted utilizing the HRPP Assessment Survey. Each component of the HRPP, IRB members, Office of Regulatory Affairs (ORA), investigators, and other research personnel will be invited to participate and provide feedback. The survey will assess the interactions between the IRBs, the ORA, investigators and other components of the HRPP, as well as the overall effectiveness of the HRPP. The IO in conjunction with the Assistant Vice-Chancellor for Regulatory Affairs and any other personnel deemed appropriate will review the Annual HRPP Assessment Form
        - 3.6.1.1. A corrective action plan will be developed for items determined to be deficient. The plan will include set goals and a time frame for remediation based upon the seriousness of the deficiency.

- 3.6.1.2. At least one other item will be targeted for further improvement before the next evaluation, and to set specific goals dependent upon available staff and resources.
- 3.6.1.3. Accomplishment of the goals arising out of the HRPP Evaluation will be evaluated by the IO in conjunction with the appropriate personnel in accordance with the corrective action and specified time frame.

DOCUMENT HISTORY:

? Written: 4/14/2016 - original author not recorded

? Revised: 2/2/2018 - revision not documented

? Revised: 8/30/2022 - Changed title of policy; clarified frequency of assessments of minutes for various boards; revised and clarified methods of feedback to the ORA/IRB by stakeholders; clarified process and basis for evaluation of Chairs and Vice-Chairs, and IRB members; clarified process of evaluation of IRB administrators and staff; clarified process and goals of Annual HRPP Assessment. {Approved Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Board Notified: 11/30/2022

? Revised 9/25/2024 – Revised to allow flexibility in assessments of HRPP quality, effectiveness, and efficiency, and in evaluation of members, chairs, and analysts. {Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

Revision #10
Created 21 October 2019 21:51:21 by Autumn M Eberly
Updated 23 October 2024 18:27:08 by Robert A Lewis