Human Research Protection Program / Institutional Review Board

Standard Operating Procedure

2018 Common Rule

For Studies Initially Approved on or After January 21, 2019

Table of Contents

1 Quality Assurance

MaineHealth performs Quality Assurance and Improvement activities for the purposes of monitoring the safety of ongoing studies and measuring and improving human research protection effectiveness, quality, and compliance with organizational policies and procedures and applicable federal, state, and local laws.

1.1 External Monitoring, Audit, and Inspection Reports

The ORC should be notified in advance, whenever possible, of upcoming external audits or inspections/monitoring of research whether the study is reviewed by the MaineHealth IRB or an external IRB on MaineHealth's behalf. HRPP representatives may participate in entrance and exit interviews and otherwise observe or support the audit or inspection. Likewise, MaineHealth representatives may assist in the development of any responses to audits or inspections.

All reports from external monitors, auditors, or inspectors must be submitted to the SEQuR Office for review. The RECO will review such reports to monitor for issues that could impact the rights or welfare of human subjects and for issues indicative of possible serious or continuing noncompliance. If such issues are identified, the ORC will initiate the process for noncompliance as identified in Section 19. The SEQuR Office will conduct further investigation or training as necessary.

When MaineHealth is engaged in research reviewed by an external IRB, all reports from audits or inspections must be submitted to ORC for review. Corrective and preventative actions (CAPA), a follow up review, or other actions may be required to ensure the protection of human subjects and to support compliance.

Reports indicative of any negative actions by a government oversight office regarding research conducted at or by MaineHealth, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated (classification as "OAI" is typically made after the FDA has the opportunity to review any responses to a 483), FDA Restrictions Placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections must be immediately reported to the HRPP/IRB office by phone or email regardless of whether the research is reviewed by an internal or external IRB. See Section 22 for more information.

1.2 Investigator Compliance Reviews

The Support of Education and Quality Improvement for Researchers (SEQuR) Office is a division of the ORC. The SEQuR Office or, on occasion, other internal or external staff, conduct post-approval directed (for cause) and routine (not for cause) compliance reviews of human subjects research conducted under the auspices of MaineHealth. Additionally, the IRB may appoint a subcommittee for the purpose of conducting a for-cause or not for-cause compliance review of one or more research plans under its jurisdiction. The subcommittee may be composed of IRB members and staff from within, or individuals from and outside of the organization.

Compliance reviews are conducted to assess investigator compliance with federal, state, and local law, and MaineHealth policies, to identify areas for improvement, and to provide recommendations based on existing policies and procedures. As appropriate, the results of compliance reviews will be reported to the ORC Director, IRB Manager, the MaineHealth IRB (when the MaineHealth IRB is the IRB of record), the investigator, and other MaineHealth leadership, as appropriate.

If it is identified during the course of a review that subjects in a research project may have been exposed to unexpected serious harm or risk of harm, the reviewer will promptly report such findings to the ORC Director and the IRB Manager. The study team will be responsible for reporting such findings to the IRB of Record.

If issues are identified that indicate possible misconduct in research, the procedures in the Responding to Allegations of Scientific or Other Scholarly Misconduct Policy will be initiated.

Compliance reviews may include:

- Requesting progress reports from investigators
- Examining investigator-held research records and records held by pharmacy or other ancillary services
- Reviewing source documentation
- Reviewing the recruitment process and materials
- Reviewing consent materials and the documentation of consent
- Observing the consent process and other research activities
- Verifying HIPAA authorization
- Interviewing investigators and research staff
- Interviewing research subjects
- Reviewing projects to verify from sources other than the investigator that no unapproved changes have occurred since previous review
- Conducting other monitoring or auditing activities as deemed appropriate by the HRPP or IRB.

1.3 IRB Compliance Reviews

The SEQuR Office of the ORC, or, on occasion, other internal or external staff, will periodically review the activities of the IRB to assess compliance with regulatory requirements and to identify areas for improvement; this will include a review of IRB records.

Review activities may include:

- Review of the IRB minutes to evaluate whether adequate documentation of the meeting discussion and any required determinations has occurred, and that quorum was met and maintained
- Reviewing IRB files to evaluate whether adequate documentation of exemptions, expedited review, and other outside of committee reviews has occurred
- Reviewing consent forms to evaluate whether all required elements are included
- Reviewing IRBNet Reports to evaluate whether all required fields are completed accurately
- Verifying IRB approvals for external sites or investigators
- Reviewing metrics (for example, time from submission to first review) to evaluate the quality, efficiency, and effectiveness of the IRB review process

- Reviewing the workload of the IRB and IRB staff
- Other review activities as appropriate

The ORC Director, IRB Manager, and IRB Chair will review the results of IRB compliance reviews with the IRB at a minimum of once annually. If substantive deficiencies are identified in the review, a corrective action plan will be developed by the IRB Chairs and the ORC Director and approved by the IO. The ORC Director will have responsibility for implementing and reporting progress on the corrective action plan, the results of which will be evaluated by the IO.

1.4 HRPP Quality Assessment and Improvement

Not less than annually, a meeting is held by the ORC Director and IRB Manager in consultation with others as needed to establish a quality assessment/ improvement (QA/QI) plan to assess the compliance, and the quality, efficiency, and effectiveness, of the HRPP. The plan will include, at a minimum, the following:

- The goals of the plan with respect to achieving and maintaining compliance
    - At least one objective to achieve or maintain compliance
    - At least one measure of compliance
    - The methods to assess compliance and make improvements
- The goals of the plan with respect to achieving targeted levels of quality, efficiency, and effectiveness
    - At least one objective of quality, efficiency, or effectiveness
    - At least one measure of quality, efficiency, or effectiveness
    - The methods to assess quality, efficiency, or effectiveness and make improvements.

The ORC Director will meet regularly throughout the year with the staff responsible for performing the assessments called for in the plan to review progress and to identify opportunities for improvement. As required, the ORC Director, IRB Manager, IO, and Senior Director of Research Administration will evaluate whether the respective goals were achieved and determine if any additional actions or monitoring are necessary. If at any time substantive or concerning issues or trends are identified, the ORC Director will report those issues or trends to the appropriate parties (e.g., the IO, the IRB Chair, SEQuR) and, if appropriate, propose a CAPA plan.

The SEQUR Office is responsible for tracking internal data and metrics that are informative when considering HRPP and IRB efficiency, effectiveness, workload, and resources. Metrics reports will be provided to the ORC Director, IRB Manager, and IRB Chair at least annually.