Human Research Protection Program / Institutional Review Board

Standard Operating Procedure

Pre-2018 Common Rule

For Studies Initially Approved on or Before January 20, 2019

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1 Education & Training

1.1 Training / Ongoing Education of IRB Chair, Members, and Staff

MaineHealth recognizes that a vital component of a comprehensive human research protection program is an education program. MaineHealth is committed to providing training and on-going education for IRB members and the staff of the HRPP and IRB, related to ethical concerns and regulatory and organizational requirements for the protection of human subjects.

Orientation

New IRB members, including alternate members, will meet with the IRB Manager and others as applicable for an orientation session. At the session, IRB processes, regulations, and resources will be reviewed. The new member will receive copies of, or links to, the following and other relevant information:

- Belmont Report
- These standard operating procedures
- Federal regulations relevant to the IRB
- Tools used by IRB reviewers (checklists etc.)
- IRB Meeting Schedule
- Contact Information for the ORC, IRB Manager, and the ORC Director

Initial Education

IRB members and ORC and IRB staff must complete the required modules in the biomedical CITI Course in the Protection of Human Research Subjects or other training determined to be equivalent by the IRB Manager, in consultation with the ORC Director. IRB members must complete the CITI Good Clinical Practice (GCP) course as well.

New members are required to complete orientation and the Initial Education requirement before they may serve as Primary Reviewer.

Continuing Education

To ensure that oversight of human research is ethically grounded, and the decisions made by the IRB are consistent with current regulatory and policy requirements, training is continuous for IRB members throughout their service on the IRB.

In addition to CITI training, MaineHealth may also use the following activities as a means for offering continuing education to IRB members and ORC and IRB staff:

- In-service training at IRB meetings
- Training workshops
- Webinars

- Email distribution of articles, announcements, presentations, and other materials relevant to human subject protections

IRB members and HRPP and IRB staff are also required to complete CITI basic or refresher training every 3 years or other training determined to be equivalent by the ORC Director.

The activities for continuing education vary on a yearly basis depending on areas of need, as determined by the IRB Manager and ORC Director. Whenever possible, the HRPP provides support for staff and IRB members to attend PRIM&R, OHRP, and other relevant conferences.

The ORC determines minimum attendance requirements for continuing education and tracks participation. Fulfillment of training requirements is included as part of the evaluation of the performance of IRB members, alternates, and staff. Continuing failure to complete training may result in a member's service being discontinued or not renewed.

1.2 Training / Ongoing Education of Investigators and Research Team

As stated previously, a vital component of a comprehensive human research protection program is an education program for all individuals with human subject responsibilities. MaineHealth is committed to providing training and on-going education for investigators and research staff members on human subject protections and other relevant topics.

1.2.1 Initial Education

Investigators and research staff who interact or intervene with subjects, or who use subjects' identifiable information for the purposes of research, must complete MaineHealth's CITI Courses relevant to the type of research being conducted and the investigator or staff member's responsibilities. Additional information detailing MaineHealth's CITI training requirements is available www.mmcri.org.

Evidence of current training (date of completion within 3 years of application date) for each member of the research team is confirmed by ORC staff. Applications and additions of study personnel will not be approved unless all study team members are current in training.

Waiver of Initial Education

Individuals who can provide documentation verifying that they have successfully completed human subject research training equivalent to that required by the MaineHealth may request a waiver of MaineHealth's specific training requirements. ORC Staff will review the documentation and determine if it satisfies organizational standards.

1.2.2 Continuing Education

Initial training is considered current for a period of three years by which time investigators and research staff must complete basic or refresher CITI training or provide evidence of equivalent training as described above. There is no exception to this requirement.

Training will be verified at the time of continuing review and with applications to add study personnel. If training has not been completed or has lapsed and is not completed in a timely manner, the investigator or staff member may be removed from the study or otherwise restricted from participating in the research.

In addition to the basic requirements described above, MaineHealth will periodically provide training on topics relevant to human subject protections, regulations, policies and standards, and IRB submission processes and requirements. Training may be provided via in-service, workshops, webinars, e-Learning, or through the distribution of articles, presentations, and other materials. Investigators and staff may request training or offer training suggestions by contacting the ORC.