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 Multi-site and Collaborative Research

When engaged in multi-site research, research involving external collaborators, or research that is otherwise under the jurisdiction of more than one IRB, MaineHealth acknowledges that each organization is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable federal regulations. MaineHealth may choose to review the research in its entirety, only those components of the research MaineHealth is engaged in, rely on the review of another qualified IRB, or make other arrangements for avoiding duplication of effort. When MaineHealth is the prime awardee on a HHS grant, it will ensure that at least one IRB reviews the research in its entirety (**see section 9 regarding the single IRB requirement for multicenter grants awarded from NIH, where all sites are conducting all research procedures**).

When relying upon another IRB or when serving as the reviewing IRB for an outside organization or external investigator, a formal relationship must be established between MaineHealth and the outside organization or investigator through an IRB Authorization Agreement, Investigator Agreement, a Memorandum of Understanding, or other such written agreement. The written agreement must be executed before MaineHealth will accept any human research proposals from the outside organization or investigator or rely on the review of an external IRB.

IRB reliance agreements establish the authorities, roles, and responsibilities of the reviewing IRB and the relying organization. The procedures for reliance, including for communication, information-sharing, and reports, may be outlined in the reliance agreement or in companion SOPs or other materials. ORC staff utilize a checklist to ensure that reliance agreements and any accompanying materials address all requirements and are consistent with MaineHealth's standards. To support compliance, MaineHealth will make every effort to ensure as much consistency as possible across reliance agreements.

MaineHealth has signed the SMART IRB joinder agreement. When the organizations participating in the research are signatories to the joinder agreement, IRB reliance may be requested and documented utilizing the SMART IRB online reliance platform. MaineHealth will determine on a study-by-study basis whether the SMART IRB SOPs or alternative procedures will be utilized to implement the reliance via a reliance arrangement agreed upon between the relying and reviewing sites.

Requests for MaineHealth to either rely upon an external IRB or to serve as the IRB of record for an external organization or investigator should be submitted as early as possible in the grant/contract process by submitting a reliance request following the instructions in Section 8 of these SOPs.

See Section 8 for procedures and considerations involved in IRB reliance arrangements.