



Human Research Protection Program / Institutional Review Board  
Standard Operating Procedure  
2018 Common Rule

**For Studies Initially Approved on  
or After January 21, 2019**

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## **1 Reporting to Federal Agencies, Departments, and Organizational Officials**

Federal regulations require prompt reporting to appropriate institutional officials and, as applicable, the federal department or agency (e.g., OHRP, FDA), of (i) any unanticipated problems involving risks to subjects or others; (ii) any serious or continuing noncompliance with the applicable federal regulations or the requirements or determinations of the IRB; and (iii) any suspension or termination of IRB approval. MaineHealth IRB complies with this requirement as follows. When research is under the oversight of an external IRB, the terms of the agreement with that IRB will guide reporting.

### **1.1 Procedures**

ORC staff will initiate these procedures as soon as the IRB takes any of the following actions:

1. Determines that an event may be considered an unanticipated problem involving risks to participants or others
2. Determines that noncompliance was serious or continuing
3. Suspends or terminates approval of research

The ORC Director or designee is responsible for preparing reports or letters which includes the following information (as applicable):

1. Reason for the report (Unanticipated problem involving risks to subjects or others, serious or continuing noncompliance, suspension or termination of IRB approval)
2. Name of the involved institution(s)
3. Title of the research project and/or grant proposal in which the problem occurred
4. Name of the investigator on the project
5. Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement)
6. A detailed description of the problem including the findings of the organization and the reasons for the IRB's decision
7. Actions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring, etc.)
8. Plans, if any, to send a follow-up or final report by the earlier of
  - a. A specific date
  - b. When an investigation has been completed or a corrective action plan has been implemented
9. The IRB Chair and the IO review the letter and recommend modifications as needed
10. The IO is the signatory

11. The ORC Director or designee sends a copy of the report to:

- The IRB Chair
- The IO
- Federal agencies, as follows:
  - a. OHRP, if the study is subject to DHHS regulations or subject to a DHHS FWA.
  - b. If the study is conducted or supported by a Common Rule agency other than DHHS, the report is sent to OHRP or the head of the federal agency, as required by the agency.
  - c. If the study is conducted or supported by a federal agency that has not adopted the Common Rule, and reporting is required, the report is sent to the party identified by the agency.
  - d. FDA, if the study is subject to FDA regulations.

Note:

For studies approved under the 2018 Common Rule, reports are not submitted to federal departments or agencies such as OHRP or FDA unless the research is subject to federal regulations or another mandate that necessitates such reporting.

Reporting to a regulatory agency is not required if the event occurred at a site that was not subject to the direct oversight of the organization, and the agency has been notified of the event by another party (e.g., sponsor).

- Sponsor, if the study is sponsored
- Investigator, if not previously notified of the reporting requirement.
- Others (either internal or external) as deemed appropriate by the ORC Director and IO

The ORC Director ensures that all steps of this policy are completed within 30 working days of the determination. For more serious actions, the Director will expedite reporting. If additional time is needed to gather facts, or determine corrective actions, a preliminary report will be submitted within 30 days, to be followed by a final report as described above.

## 1.2 Reporting to AAHRPP

MaineHealth's HRPP is accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). In addition to the information that MaineHealth routinely provides to AAHRPP in annual reports and the re-accreditation application, AAHRPP requires that any of the following are reported to AAHRPP asap but generally within 48 hours after the organization or any researcher (if the researcher is notified rather than the organization) becomes aware:

- Any negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions Placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections;
- Any litigation, arbitration, or settlements initiated related to human research protections; and/or

- Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding MaineHealth's HRPP.

The HRPP Director (or designee) is responsible for ensuring that such reports are made to AAHRPP and for informing appropriate organizational officials. Investigators, research staff, HRPP/IRB staff, IRB members, and other organizational officials or offices (e.g., the IO, Compliance, Legal, etc.) are responsible for informing the HRPP/IRB office as soon as they become aware of any of the above so that these reporting obligations may be fulfilled.