



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 Other Reportable Information

When research is under the oversight of the MaineHealth IRB, in addition to UAPs, noncompliance, and complaints, any change to the research implemented without IRB approval and any information that may impact the rights, safety, or welfare of subjects or inform the IRB's oversight of the research must be reported to the IRB within **7 working days** of discovery using the MaineHealth – Progress Report/Study Completion/Reportable New Information wizard in IRBNet. Investigators conducting research under the oversight of an external IRB must comply with the reporting requirements of the external IRB and the internal reporting requirements outlined in Section 8.3.

Other reportable information includes, but is not limited to, the following:

1. Changes made to the research without prior IRB approval to eliminate apparent immediate hazards to the subject(s);
2. Protocol Deviations - any variation from the IRB approved research plan that happens without prior review and approval of the IRB and isn't necessary to eliminate apparent immediate hazards to the subject(s);
3. Monitoring, audit, and inspection reports in accordance with Section 2.1 of this manual;
4. Notice of:
 - a. 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 (classification as "OAI" is typically made after FDA has had the opportunity to review the responses to a 483), FDA Restrictions Placed on IRBs or Investigators, and any corresponding compliance actions taken under non-US authorities related to human research protections.
 - b. Any litigation, arbitration, or settlements initiated related to human research protections.
 - c. Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding human subjects research conducted at or by [INSERT ORGANIZATION] or [INSERT ORGANIZATION]'s program for the protection of human research participants.

NOTE: The above events (4.a, b, and/or c) must be reported to the HRPP/IRB office by phone or email **as soon as anyone becomes aware**, with the formal submission within the 7-day timeline as noted above. See Section 22 for more information.

5. Sponsor or coordinating center reports;
6. Data Safety Monitoring reports, including reports from DSMBs, DMCs, and others;
7. Enrollment or inclusion of vulnerable populations not previously approved by the IRB for the study (e.g., prisoner, pregnant woman, neonate, child, adult with impaired decision-making capacity);
8. When an existing subject becomes a member of a vulnerable population not previously approved by the IRB for inclusion in the study (e.g., incarceration, pregnancy, or change in decision-making capacity of an already enrolled subject);

9. Holds, suspensions, or terminations of a study, in part or in full, by an investigator, sponsor, or others;
10. Changes that impact the ability of the PI to conduct or supervise the study, temporarily or permanently;
11. Changes that impact the qualifications of investigators or research staff members such as actions taken by regulatory authorities, licensing boards, or credentialing committees;
12. New information that may impact the rights, welfare, or willingness of subjects to continue in the research.

1.1 Review Procedures

1. Upon receipt of the report, the IRB staff pre-reviews the submission and, if needed, contacts the investigator for corrections or additional information. If the information provided suggests that subjects may be at risk of harm without immediate intervention, the ORC Director, IRB Chair, and, when appropriate, the IO, will be notified so that they can take any necessary steps to ensure the safety of subjects, investigate the matter, and where applicable, forward the matter to appropriate institutional officials in accordance with MaineHealth policy (e.g., research misconduct, etc.).
2. The IRB Chair or designated reviewer receives and reviews the report and if the report may represent an UAP or noncompliance, reviews the report as described in Section 18 or 19. When circumstances warrant, the ORC Director or IRB Manager may bypass this step and assign the report for convened board review.
3. If the reviewer determines that the event or issue is not noncompliance or an UAP, they will review the event or issue, any proposed corrective and preventative action plans, and determine if any additional actions are needed to ensure the protection of human subjects. As warranted, the reviewer may refer the matter to the convened IRB for review. The results of the review will be recorded in IRBNet and communicated to the investigator.