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 Documentation and Records

MaineHealth prepares and maintains adequate documentation of the IRB's activities. All records are accessible for inspection and copying by authorized representatives of the FDA, OHRP, sponsors, and other authorized entities at reasonable times and in a reasonable manner.

1.1 IRB Records

IRB records include, but are not limited to:

1. Written operating procedures;
2. IRB membership rosters;
3. IRB member files including documentation of appointments, experience, education/training, and expertise;
4. IRB correspondence including reports to regulatory agencies;
5. IRB Protocol Files (See Section 14.2);
6. Convened IRB meeting minutes;
7. Documentation of review by an external IRB, when appropriate;
8. Documentation of IRB reliance and cooperative review agreements;
9. Documentation of independent or external investigator agreements;
10. Federal Wide Assurances;
11. Federal IRB Registrations; and
12. Documentation of complaints and any related findings and/or resolution.

1.2 IRB Protocol Files

The IRB maintains a separate file for each protocol (including expanded access), HUD, emergency use, or report it receives for review in IRBNet under a unique identification number assigned by the system. As applicable, protocol files include, but are not limited to the following:

1. The initial application and all associated documents and materials;
2. Modification requests and all associated documents and materials;
3. Continuing review/progress reports and all associated documents and materials;
4. Closure reports and all associated documents and materials;
5. Reports submitted after study or HUD approval including reports of significant new findings, data and safety monitoring reports, protocol violation reports, complaints, noncompliance, and reports of injuries to subjects including reports of potential unanticipated adverse device events and unanticipated problems involving risks to subjects or others;

6. IRB-approved consent, parental permission, and assent forms;
7. DHHS-approved sample consent form and protocol;
8. DHHS grant application
9. IRB reviewer forms and checklists
10. Documentation of scientific or scholarly review (if available);
11. Documentation of the type of IRB review. For exempt determinations and expedited review, this will include the category under which the review is allowed;
12. For expedited review, documentation of any findings and determinations required by the regulations and study-specific findings supporting those determinations, including, but not limited to, waiver or alteration of consent, waiver of documentation of consent, research involving pregnant women, fetuses, and neonates, research involving prisoners, and research involving children. For research reviewed by the convened board these findings and determinations are recorded in the minutes;
13. For expedited review, documentation of the risk determination and period of approval. For research reviewed by the convened board these determinations are recorded in the minutes;
14. Documentation of all IRB review actions;
15. Notification of expiration of IRB approval to the investigator;
16. Notification of suspension or termination of research;
17. Letters to investigator informing them of IRB review outcomes;
18. IRB correspondence to and from investigators related to the protocol;
19. All other IRB correspondence related to the research;
20. For studies evaluating the safety or effectiveness of medical devices, documentation of the device determination (exempt, non-significant risk, significant risk);
21. Reports of unanticipated problems involving risk to subjects or others; and
22. Any statements of significant new findings provided to subjects.

1.3 The IRB Minutes

Draft minutes of IRB meeting proceedings are written and available for review by the next regularly scheduled IRB meeting. Once reviewed and accepted by the members, the IO will be notified that the minutes are available for review in IRBNet. Changes may not be made to finalized minutes without re-review by the IRB to verify accuracy.

Minutes of IRB meetings must contain sufficient detail to show the following, as applicable:

1. Attendance:
   a. Each member's full name.
   b. Each member's representative capacity (scientist, non-scientist, member who represents the general perspective of research participants, unaffiliated).

c. The names of members who participated in the convened meeting via an alternative mechanism, such as telephone or video conferencing.

d. If a consultant is present at the convened meeting, the name of the consultant, and a brief description of the consultant's expertise, and documentation that the consultant did not vote with the IRB or EC on the study.

e. The names of non-members and guests, such as IRB or EC support staff, researchers, and study coordinators.

f. When an alternate member replaces a primary member, including the name of the alternate member.

g. The names of IRB or EC members who leave the meeting because of a conflict of interest along with the fact that a conflict of interest is the reason for the absence.

Note: The minutes will indicate, by name, those members who enter or leave the meeting. The vote on each action will reflect the numbers of members present for the vote on that item.

2. The presence of a quorum throughout the meeting, including the presence of one member whose primary concern is in a non-scientific area;
3. Business Items discussed, and any education provided;
4. Actions taken, including separate deliberations, actions, and votes for each submission undergoing review by the convened IRB;
5. Vote counts on these actions (Total Number Voting; Number voting for; Number voting against; Number abstaining; Number of those recused). When a member is recused due to conflict of interest, the name of the member and reason for the recusal will be noted;
6. Basis or justification for actions disapproving or requiring changes in research;
7. Summary of controverted issues and their resolution;
8. Approval period for initial and continuing reviews, including identification of research that warrants review more often than annually and the basis for that determination;
9. Risk determination for initial and continuing reviews, and modifications when the modification alters the prior risk determination;
10. Justification for deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document;
11. Study-specific findings supporting that the research meets each of the required criteria when approving a consent procedure that does not include or that alters some or all of the required elements of informed consent, or when waiving the requirement to obtain informed consent altogether;
12. Study-specific findings supporting that that the research meets each of the required criteria when the requirements for documentation of consent are waived;

13. Study-specific findings supporting that the research meets each of the criteria for approval for vulnerable populations under any applicable Subparts;
14. Exempt/significant risk/non-significant risk device determinations and the basis for those determinations;
15. Determinations related to conflicts of interest and acceptance or modification of conflict management plans;
16. Identification of any research for which there is need for verification from sources other than the investigator that no material changes are made in the research;
17. Review and determinations related to interim reports (e.g., unanticipated problems or safety reports, serious or continuing noncompliance, suspensions or terminations, etc.);
18. A list of research approved under expedited review procedures since the time of the last such report;
19. An indication that, when an IRB member or alternate has a conflicting interest (see Section 25.2) with the research under review, the IRB member or alternate was not present during the final deliberations or voting; and
20. Key information provided by consultants will be documented in the minutes or in a report provided by the consultant.

1.4 IRB Membership Roster

A membership list of IRB members will be maintained; it will identify members sufficiently to describe each member's chief anticipated contributions to IRB deliberations. The list will contain the following information about members:

1. Name;
2. Earned degrees;
3. Employment or other relationship between each member and the organization (i.e., affiliated or non-affiliated). To be categorized as non-affiliated, neither the member nor an immediate family member of the member may be affiliated with MaineHealth.
4. Status as scientist or non-scientist. Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline are considered a scientist for the purposes of the roster. Members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline are considered a nonscientist. Physicians, nurses, and pharmacists are considered scientists;
5. Indications of experience, such as board certifications, licenses, and areas of practice sufficient to describe each member's chief anticipated contributions to IRB deliberations;
6. Representative capacities of each IRB member; including which IRB member(s) is a prisoner representative, and which IRB members are knowledgeable about or experienced in working with

children, pregnant women, adults with impaired decision-making capacity, and other vulnerable populations commonly involved in MaineHealth research;

7. Role on the IRB (Chair, Vice-Chair, etc.);
8. Voting status; and
9. For alternate members, the primary member or class of members for whom the member could substitute.

The IRB office must keep the IRB membership list current. Changes in IRB membership are reported to OHRP and FDA on the federal IRB registration within 90 days of the change.

1.5 Documentation of Exemptions

Documentation of verified exemptions consists of the reviewer's citation of a specific exempt category and written concurrence that the activity described in the investigator's request satisfies the conditions of the cited exempt category as detailed in Section 5.

1.6 Documentation of Expedited Reviews

IRB records for initial and continuing review by the expedited procedure must include the reviewer's verification that the study qualifies for expedited review including the specific permissible category(ies), documentation that the activity satisfies the criteria for approval, the period of approval, and any determinations required by the regulations, or by MaineHealth policy, including study-specific findings justifying the following determinations:

1. Approving a procedure which waives or alters the informed consent process;
2. Approving a procedure which waives the requirement for documentation of consent;
3. Approving research involving pregnant women, human fetuses, or neonates;
4. Approving research involving prisoners;
5. Approving research involving children;
6. Approving research involving subjects with impaired decision capability

1.7 Access to IRB Records

IRB protocol files are secured in IRBNet, and are stored on MaineHealth serves behind the firewall, with administrative access controlled by the IRB office. Likewise, investigators control access to investigator records in the electronic system. All other IRB records (e.g., membership rosters) are kept secure in a limited access file on MaineHealth's servers, locked filing cabinets or locked storage rooms.

Ordinarily, access to IRB records is limited to the IO, ORC Director, IRB Manager, ORC staff, IRB members, authorized organizational officials, and officials of federal and state regulatory agencies (e.g., OHRP and FDA). Research investigators are provided reasonable access to files related to their research. Appropriate accreditation bodies are provided access.

Records are accessible for inspection and copying by authorized representatives of federal regulatory agencies during regular business hours.

IRB member rosters are available online at www.mmcri.org, and are only provided upon request to regulatory agencies, accreditation bodies, and persons or offices within MaineHealth with a legitimate need (e.g., Legal Counsel etc.).

All other access to IRB records is limited to those who have legitimate need for them, as determined by the IO, ORC Director, or IRB Manager.

1.8 Record Retention

In order to comply with the requirements of OHRP, FDA, and HIPAA, IRB records are maintained for at least six (6) years after completion of the research.

IRB records for research cancelled without participant enrollment will be retained for at least three (3) years after closure.

IRB minutes are retained until all of the studies that were reviewed at that meeting have been completed for at least three (3) years.

After the noted times, IRB records may be shredded or otherwise securely destroyed.