UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-034
AAHRPP:	Element I.5.D., Element II.2.G., Element II.2.H.
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Updated By;	
Reviewed By:	IRB Chair; IRB; ORIO
Procedure Title:	Mandated Reporting to External Agencies

1.0 Objective

1.1. To describe policies and procedures for ensuring prompt Institutional Review Board (IRB)/Office of Research Integrity and Outreach (ORIO) reporting of events to the Institutional Official (IO), sponsor(s), coordinating center(s), and the appropriate federal regulatory agency as required in federal regulations.

2.0 General Description

2.1. University of Southern Maine (USM) policy requires compliance with all applicable accreditation, local, state, and federal reporting requirements in the conduct of research involving human subjects.

2.2. The IRB/ORIO notifies appropriate officials when research falls under the purview of a federal regulatory agency and one or more of the following occurs:

2.2.1. Unanticipated problems involving risks to subjects or others;

2.2.2. Serious or continuing noncompliance with the regulations or requirements of the IRB;

2.2.3. Suspension or termination of IRB approval for research;

2.2.4. U.S. Department of Health and Human Services (HHS) submitted or funded studies which include pregnant women, fetuses, or neonates and are not otherwise approvable under applicable subparts;

2.2.5. HHS submitted or funded studies that include prisoners;

2.2.6. HHS submitted or funded studies that include children and are not otherwise approvable under applicable subparts;

2.2.7. Exception to informed consent in emergency medical research.

3.0 Responsibility

3.1. It is the responsibility of the Office of Research Integrity and Outreach (ORIO) staff, Research Compliance Administrator (RCA), Institutional Review Board (IRB), and investigators to execute this SOP.

4.0 Procedure

4.1. Unanticipated Problems Involving Risks to Subjects

4.1.1. When the convened IRB determines that an unanticipated problem involving risks to the subject or others occurred on a research protocol, the RCA or designee prepares a report within fifteen (15) days from the date the IRB conducts the final review of the unanticipated problem.

4.1.2. The report includes:

4.1.2.1. The title of the research;
4.1.2.2. Name of the PI (Principle Investigator) on the protocol;
4.1.2.3. The IRB number assigned to the research protocol;
4.1.2.4. The number (project identifier) of any applicable federal award(s) (grant, contract, or cooperative agreement);
4.1.2.5. The nature of the event;
4.1.2.6. The findings of the IRB;
4.1.2.7. And actions taken by the PI and IRB to address the issue.

4.1.3. The RCA, in consultation with the IRB Chair, finalizes the report, which the RCA sends to the IO and any applicable federal agencies within fifteen (15) days of the report being finalized.

4.1.3.1. Only when the research is covered by HHS regulations is the report sent to Office of Human Research Protections (OHRP).
4.1.3.2. Only when the research is covered by Food and Drug Administration (FDA) regulations is the report sent to the FDA.

4.1.4. The PI is responsible for reporting to the sponsor, who must report to the FDA with a copy provided to the IRB.

4.1.5. The RCA provides a copy of the report to ORIO staff, who are responsible for including the report(s) in the IRB study record.

4.2. Serious or Continuing Noncompliance

4.2.1. When the convened IRB determines that serious or continuing noncompliance occurred on a research protocol, the RCA or designee prepares a report within

fifteen (15) days from the date the IRB conducts the final review of the serious and/or continuing noncompliance.

4.2.2. The report includes:

4.2.2.1. The title of the research;
4.2.2.2. Name of the PI on the protocol;
4.2.2.3. IRB number assigned to the research protocol;
4.2.2.4. The number (project identifier) of any applicable federal award(s) (grant, contract, or cooperative agreement);
4.2.2.5. The nature of the event;
4.2.2.6. The findings of the IRB;
4.2.2.7. And actions taken by the PI and IRB to address the issue.

4.2.3. The RCA, in consultation with the IRB Chair, finalizes the report, which the RCA sends to the IO and any applicable federal agencies within fifteen (15) days of the report being finalized

4.2.3.1. Only when the research is covered by HHS regulations is the report sent to OHRP.
4.2.3.2. Only when the research is covered by FDA regulations is the report sent to the FDA.

4.2.4. The PI is responsible for reporting to the sponsor, who must report to the FDA with a copy provided to the IRB.

4.2.5. The RCA provides a copy of the report to ORIO staff, who are responsible for including the report(s) in the IRB study record.

4.3. Suspension or Termination of Research

4.3.1. When the IRB suspends or terminates approval of a research protocol, the RCA or designee prepares a report within fifteen (15) days from the date the IRB conducts the final review of the suspension or termination.

4.3.2. The report includes:

4.3.2.1. The title of the research;
4.3.2.2. Name of the PI on the protocol;
4.3.2.3. IRB number assigned to the research protocol;
4.3.2.4. The number (project identifier) of any applicable federal award(s) (grant, contract, or cooperative agreement);
4.3.2.5. The nature of the event;
4.3.2.6. The findings of the IRB;
4.3.2.7. And actions taken by the PI and IRB to address the issue.

4.3.3. The RCA, in consultation with the IRB Chair, finalizes the report, which the RCA sends to the IO and any applicable federal agencies within fifteen (15) days of the report being finalized.

4.3.3.1. Only when the research is covered by HHS regulations is the report sent to OHRP.
4.3.3.2. Only when the research is covered by FDA regulations is the report sent to the FDA.

4.3.4. The PI is responsible for reporting to the sponsor, who must report to the FDA with a copy provided to the IRB.

4.3.5. The RCA provides a copy of the report to ORIO staff, who are responsible for including the report(s) in the IRB study record.

4.4. Pregnant Women, Fetuses and Neonates

4.4.1. Upon receipt of an IRB application or request, the RCA screens protocols for any inclusion of pregnant women, fetuses or neonates in research submitted to or funded by HHS.

4.4.2. If the IRB finds that the research is not otherwise approvable but presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates:

4.4.2.1. The RCA, in consultation with the PI and IRB Chair, finalizes a report based on the current guidance from OHRP.
4.4.2.2. The RCA sends the report to the IO and OHRP within fifteen (15) days of the report being finalized.

4.4.3. If the OHRP disagrees with the IRB findings of the research involving pregnant women, fetuses, nonviable neonates, or neonates of uncertain viability, ORIO staff share the information from OHRP with the IRB and the PI.

4.4.4. The RCA provides a copy of the report and OHRP correspondence to ORIO staff, who are responsible for including the report(s) in the IRB study record.

4.5. Prisoners

4.5.1. Upon receipt of an IRB application or request, the RCA screens protocols for any inclusion of prisoners in research submitted to or funded by HHS.

4.5.2. The RCA, in consultation with the PI and IRB Chair, finalizes a report based on the current guidance from OHRP.

4.5.3. The RCA sends the report to the IO and OHRP within fifteen (15) days of the report being finalized.

4.5.4. If the OHRP disagrees with the IRB findings of the research involving prisoners, ORIO staff share the information from OHRP with the IRB and the PI.

4.5.5. The RCA provides a copy of the report and OHRP correspondence to ORIO staff, who are responsible for including the report(s) in the IRB study record.

4.6. Children

4.6.1. Upon receipt of an IRB application or request, the RCA screens protocols for any inclusion of children in research submitted to or funded by HHS.

4.6.2. If the IRB finds that the research is not otherwise approvable but presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children:

4.6.2.1. The RCA, in consultation with the PI and IRB Chair, finalizes a report based on the current guidance from OHRP.

4.6.2.2. The RCA sends the report to the IO and OHRP within fifteen (15) days of the report being finalized.

4.6.3. If the OHRP disagrees with the IRB findings of the research involving children, ORIO staff share the information from OHRP with the IRB and the PI.

4.6.4. The RCA provides a copy of the report and OHRP correspondence to ORIO staff, who are responsible for including the report(s) in the IRB study record.

4.7. Exception to Informed Consent in Emergency Medical Research

4.7.1. When the IRB approves an exception from the general informed consent requirements for emergency research under FDA and HHS regulations:

4.7.1.1. The PI provides the sponsor with a copy of the information publicly disclosed prior to the initiation and at the completion of the study.

4.7.2. When the IRB does not approve an exception from the general informed consent requirements for emergency research under FDA and HHS requirements:

4.7.2.1. The RCA, in consultation with the IRB Chair, finalizes a report outlining the reason why the IRB did not approve the exception.

4.7.2.2. The RCA sends the report to the IO, PI, and sponsor within fifteen (15) days of the report being finalized.

4.7.3. The RCA provides a copy of the report and OHRP correspondence to ORIO staff, who are responsible for including the report(s) in the IRB study record.

4.8. Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) Reporting Requirements

4.8.1. ORIO staff, investigators, and/or the IRB are responsible for informing the RCA of any AAHRPP reportable events.

4.8.2. When notified of 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-U.S. authorities related to human research protections:

4.8.2.1. The RCA sends a report outlining the event to AAHRPP within forty-eight (48) hours of being notified.

4.8.3. When notified of any litigation, arbitration, or settlements initiated related to human research protections:

4.8.3.1. The RCA sends a report outlining the event to AAHRPP within forty-eight (48) hours of being notified.

4.8.4. When notified of any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the USM's Human Research Protection Program (HRPP):

4.8.4.1. The RCA sends a report outlining the event to AAHRPP within forty-eight (48) hours of being notified.

5. 0 <u>References</u>

5.1. 45 CFR 46 Subpart B
5.2. 45 CFR 46 Subpart C
5.3. 45 CFR 46 Subpart D
5.4. 21 CFR 50 Subpart D
5.5. OHRP Guidance on the Involvement of Prisoners in Research
5.6. OHRP Guidance on the HHS 45 CFR 46.407 Review Process for Children Involved as Subjects in Research.