University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
Revision #10	**TITLE: Mandated Reporting to External Agencies**		**Page 1 of 8**
Approved By: ORI Director	Signature	Date	Date First Effective: 07-08-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	Revision Date: 05-14-2023

OBJECTIVE

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

GENERAL DESCRIPTION

University of Kentucky (UK) policy requires compliance with all applicable accreditation, local, state, and federal reporting requirements in the conduct of research involving human subjects. The IRB/ORI notifies appropriate officials when research falls under the purview of a federal regulatory agency and one or more of the following occurs:

- Unanticipated problems involving risks to subjects or others;
- Serious or continuing noncompliance with the regulations or requirements of the IRB;
- Suspension or termination of IRB approval for research due to noncompliance;
- Department of Health and Human Services (HHS) submitted or funded studies that are not otherwise approvable under 45 CFR 46 Subpart B, which include pregnant women, fetuses and neonates;
- HHS submitted or funded studies which include prisoners;
- Food and Drug Administration (FDA) regulated, HHS, or U.S. Department of Education submitted or funded studies which include children and are not otherwise approvable under applicable subparts;
- Certification of IRB approval;
- Exceptions to informed consent in emergency medical research;
- Regulatory agency requests for a report; and/or
- Inquiries or sanctions from government oversight agencies.

Reporting to regulatory federal agencies is not required if the principal investigator (PI) voluntarily closes down a study to new subject accrual or temporarily halts the research procedures. The IRB, IRB Chair, ORI, or administrative officials may recommend voluntary closure to the PI, but the PI makes the decision whether closure is appropriate. However, if the IRB or IRB Chair requires suspension or termination, the incident may be reportable under this policy.

Lapses of approval as outlined in the Continuation Review SOP are not reportable under provisions of the SOP.

Definitions

Unanticipated Problem Involving Risks: See UK Policy on Unanticipated Problem and Safety Reporting.

Serious Noncompliance: See Noncompliance SOP.

Continuing Noncompliance: See Noncompliance SOP.

RESPONSIBILITY

Execution of SOP: IRB Chair, IRB, ORI Staff, ORI Director, Vice President for Research (VPR), ORI Research Compliance Officer (RCO), Quality Improvement Program (QIP) Coordinator, Principal Investigator (PI)/Study Personnel

PROCEDURES

Unanticipated Problems Involving Risks to Subjects

1. When the convened IRB determines that an unanticipated problem involving risks to the subject or others occurred on a research protocol, the ORI RCO or designee prepares a report within fifteen (15) days from the date the IRB conducts the final review of the unanticipated problem. The report includes the title of the research protocol and/or grant proposal; name of the PI on the protocol; IRB number assigned to the research protocol; the number (project identifier) of any applicable federal award(s) (grant, contract, or cooperative agreement); the nature of the event; the findings of UK or the IRB; and actions taken by the PI, UK, and/or the IRB to address the issue. The ORI Director, in consultation with the IRB Chair, finalizes the report, which the ORI RCO sends to the federal agency with a copy to the IRB Chair, VPR, PI, and other University administrators as determined by the IRB. (See also Unanticipated/ Anticipated Problem/Adverse Event Reporting SOP.)

2. When research is regulated by the FDA, the IRB requires the PI to report to the sponsor, who must report to the FDA with a copy provided to the IRB. If the PI is also the sponsor, the IRB requires that the PI report to the FDA. The IRB may choose to prepare and send the report directly to the FDA.

3. If HHS conducts or funds the research, the ORI RCO sends the report to OHRP.

4. If an agency other than HHS, that is subject to the "Common Rule", conducts or funds the research, the ORI RCO sends the report to the agency as required by the agency and OHRP.

5. The ORI RCO provides a copy of the federal report(s) and any final IRB actions to ORI staff, who are responsible for including the report(s) in the IRB study record.

Serious or Continuing Noncompliance

1. When the convened IRB determines that serious or continuing noncompliance occurred on a research protocol, the ORI RCO 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. The report includes the title of the research protocol and/or grant proposal; name of the PI on the protocol; IRB number assigned to the research protocol; the number (project identifier) of any applicable federal award(s) (grant, contract, or cooperative agreement); the nature of the event; the findings of UK or the IRB; and actions taken by the PI, UK, and/or the IRB to address the issue. The ORI Director, in consultation with the IRB Chair, finalizes the report. The ORI RCO sends the report to the federal agency with a copy to the IRB Chair, VPR, PI, and other University administrators as determined by the IRB. (See also Noncompliance SOP.)

2. When research is FDA regulated, the IRB requires the PI to report to the sponsor, who must report to the FDA with a copy provided to the IRB. If the PI is also the sponsor, the IRB requires the PI to report to the FDA. The IRB may choose to prepare and send the report directly to the FDA.

3. If HHS conducts or funds the research, the ORI RCO sends the report to OHRP.

4. If an agency other than HHS, that is subject to the "Common Rule," conducts or funds the research, the ORI RCO sends the report to the agency as required by the agency and OHRP.

5. The ORI RCO maintains all correspondence relating to the serious or continuing noncompliance. The ORI RCO provides a copy of the federal report(s) and any final IRB actions to ORI staff, who are responsible for including the report(s) in the IRB study record.

Suspension or Termination of Research

1. When the IRB suspends or terminates approval of a research protocol, the ORI RCO or designee prepares a report to the applicable federal agency within fifteen (15) days from the date the IRB conducts the final review of the suspension or termination. The report includes the title of the research protocol and/or grant proposal; name of the PI on the protocol; IRB number assigned to the research protocol; the number (project identifier) of any applicable federal award(s) (grant, contract, or cooperative agreement); the nature of the event; the findings of UK or the IRB; and actions taken by the PI, UK, and/or the IRB to address the issue. The ORI Director, who may consult with the IRB Chair, finalizes the report, which the ORI RCO sends to the federal agency with a copy to the IRB Chair, VPR, PI, and other University administrators as determined by the IRB.

2. When research is FDA regulated, the IRB requires the PI to report to the sponsor, who must report to the FDA with a copy provided to the IRB. If the PI is also the sponsor, the IRB requires the PI to report to the FDA. The IRB may choose to prepare and send the report directly to the FDA.

3. If HHS conducts or funds the research, the ORI RCO sends the report to OHRP.

4. If an agency other than HHS, that is subject to the "Common Rule", conducts or funds the research, the ORI RCO sends the report to the agency as required by the agency and OHRP.

5. The ORI RCO maintains all correspondence relating to the suspension or termination. The ORI RCO provides a copy of the federal report(s) and any final IRB actions to ORI staff, who are responsible for including the report(s) in the IRB study record.

Pregnant Women, Fetuses and Neonates

1. Upon receipt of an IRB application or request, ORI staff screen protocols for any inclusion of pregnant women, fetuses or neonates in research submitted to or funded by HHS.

2. If the IRB finds that the research is not otherwise approvable for pregnant women, nonviable neonates or neonates of uncertain viability under 45 CFR 46 Subpart B and the research 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, ORI staff, with input from the IRB and the PI, prepare a report to HHS based on the current guidance from OHRP. The IRB, in consultation with the ORI Director, approves the report, which ORI staff send to OHRP per OHRP guidance within fifteen (15) days of IRB approval of the report, with a copy provided to the VPR and PI.

3. ORI staff maintain copies of all correspondence.

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

Prisoners

1. ORI staff screen protocols for any inclusion of prisoners in research.

2. ORI staff notify the PI of HHS reporting requirements if the protocol involves prisoners.

3. With input from the IRB and/or the PI, ORI staff prepare a report to HHS based on the current guidance from OHRP on research which includes prisoners. ORI staff approve the report and send it to OHRP within fifteen (15) days of IRB approval of the report.

4. ORI staff ensure a copy of all correspondence is included in the IRB study record.

5. If OHRP disagrees with the IRB classification of the research involving prisoners, ORI staff share the information from OHRP with the IRB and PI.

Children

1. ORI staff screen protocols submitted to/funded by HHS or the U.S. Department of Education or those regulated by FDA for any inclusion of children in research.

2. If the IRB finds that the research is not otherwise approvable but presents an opportunity to understand, prevent, or alleviate serious problems affecting the health or welfare of children under the applicable FDA, HHS, or U.S. Department of Education subpart, ORI staff, with input from the IRB and the PI, prepare a report to HHS based on the current guidance from the applicable agency. The IRB, in consultation with the ORI Director, approves the report and sends it through the VPR with a copy to the PI within fifteen (15) days of IRB approval of the report. ORI staff submit a copy to the institutional official of the applicable federal agency (e.g., Secretary of HHS through OHRP, Secretary of U.S. Department of Education, or Commissioner of FDA) based on current guidance from the agency.

3. ORI staff include all correspondence in the IRB study record.

4. If the applicable federal agency disagrees with the IRB findings of the research involving children, ORI staff share the information from the agency with the IRB and the PI.

Certification of IRB Approval

1. When a funding agency requires certification of IRB approval, the PI contacts ORI to request that ORI staff prepare the certification document or indicates in the IRB application that the sponsor requires certification of IRB approval. The PI is responsible for requesting ORI documentation of IRB approval in accordance with funding agency requirements.

2. The PI may provide ORI staff with a copy of the agency certification form. ORI staff prepare the required agency form(s) and obtains the signature of either the UK authorized organizational representative for sponsored research or an authorized IRB member.

3. ORI staff retain a copy of the certification form in the IRB protocol record and forward the original certification form to the investigator.

4. The PI transmits the certification of IRB approval to the funding agency within the time period specified by the agency and provides the Office of Sponsored Projects Administration (OSPA) with a copy.

5. To prepare a certification form for grants/contracts that fund more than one IRB protocol, the PI provides ORI with a list of pertinent IRB protocol numbers. ORI staff verify the IRB numbers and IRB approval prior to preparing and issuing the certification document. The PI transmits the certification to the agency and provides OSPA with a copy.

Exception to Informed Consent in Emergency Medical Research

1. When the IRB approves an exception from the general informed consent requirements for emergency research under FDA and HHS regulations, the PI provides the sponsor with a copy of the information publicly disclosed prior to the initiation and at the completion of the study. The PI is responsible for maintaining a copy of the report.

2. When the IRB does not approve an exception from the general informed consent requirements for emergency research under FDA and HHS requirements, ORI staff, with input from the IRB, prepare a report of the reasons why the IRB did not approve the exception. The IRB Chair, in consultation with the ORI Director, approves the report. ORI staff submit the report to the sponsor and the PI within fifteen (15) days of approval.

3. ORI staff include a copy of the report in the IRB study record. (See Informed Consent SOP.)

Agency-Requested Reports

1. A federal agency may periodically ask the IRB or UK for a specific report on a variety of issues (e.g., alleged noncompliance submitted to a federal agency). ORI staff are responsible

for informing the ORI Director of any inquiries from a government oversight office such as OHRP, FDA, or other agencies. The ORI Director or designee reviews the request and designates an ORI staff member to assist the IRB/UK with preparation of the report (e.g., the ORI RCO oversees noncompliance report preparation.)

2. The designated ORI staff member prepares the report in accordance with the agency's request relative to content and timing.

3. The VPR or designee, in consultation with the ORI Director, approves the report. The ORI Director and/or IRB Chair or VPR determines who receives a copy of the report depending on the nature of the request.

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

1. In order to report to AAHRPP within 48 hours as required, ORI staff, researchers, and/or the IRB inform the ORI Director of any of the reportable events listed below. The ORI Quality Improvement Program (QIP) Coordinator or designee prepares a report, the ORI Director reviews the report, and the VPR approves the report. ORI staff submit reports as follows:
   - Within 24 hours of being notified or becoming aware of any negative actions taken by a government oversight office including but not limited to OHRP Determination Letters, FDA Warning Letters, and FDA restrictions placed on IRBs or Investigators.
   - Within 24 hours of being notified or becoming aware of any lawsuits (i.e., litigation, arbitration, or settlements initiated) related to human subjects research protections.
   - Within 24 hours of being notified or becoming aware of any press coverage (including not but limited to radio, TV, newspaper, online publications) of a negative nature regarding the UK HRPP.

   If it is unclear whether a particular item is reportable to AAHRPP, the QIP Coordinator or designee contacts the AAHRPP office for further advice.

2. The QIP Coordinator prepares the AAHRPP annual report. The QIP Coordinator or designee tracks information for inclusion in the annual report including but not limited to substantive organizational changes, changes in resources, program scope, and/or ORI policies and procedures. The ORI RCO or designee tracks noncompliance incidents, suggestions, concerns, and/or complaints received by ORI and makes recommendations to the ORI Director for inclusion in the AAHRPP annual report. The ORI Director reviews the report, and the VPR approves it.

Reports: IRB Determination of UK Officials to Receive a Copy of Reports

1. The IRB/ORI staff or the VPR determine appropriate institutional officials within UK who will receive a copy of a report on a case-by-case basis when the IRB/ORI staff send any of the federally mandated reports discussed in this SOP to a federal agency. These determinations are in accordance with applicable federal requirements and in accordance with the policies outlined in the HIPAA in Research SOP.

   Examples of institutional officials who may receive copies of a report include but are not limited to the following:
   - Vice President for Research (VPR);
   - Dean of the College;
   - Associate Dean of the College;
   - Department Chair;
   - Legal Counsel;
   - Director of the Office of Sponsored Projects Administration (OSPA);
   - UK Privacy Officer;
   - Other University administrators as determined by the IRB /ORI Director.

REFERENCES

45 CFR 46 Subpart B
45 CFR 46 Subpart C
45 CFR 46 Subpart D
21 CFR 50 Subpart D
OHRP Guidance on the Involvement of Prisoners in Research
OHRP Guidance on the HHS 45 CFR 46.407 Review Process for Children Involved as Subjects in Research
AAHRPP Accreditation Procedures