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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: 08-19-09

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, coordinating center, 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; and/or
- Serious or continuing noncompliance with the regulations or requirements of the IRB; and/or
- Suspension or termination of IRB approval for research due to noncompliance; and/or
- Department of Health and Human (DHHS) submitted or funded studies that are not otherwise approvable under 45 CFR 46 Subpart B, which include pregnant women, fetuses, and neonates; and/or
- DHHS submitted or funded studies which include prisoners; and/or
- Food and Drug Administration (FDA) regulated or DHHS or U.S. Department of Education submitted or funded studies which include children and are not otherwise approvable under applicable subparts; and/or
- Changes in IRB membership; and/or
- Certification of IRB approval; and/or
- Exceptions to informed consent in emergency medical research; and/or
- Veterans Affairs (VA) required reports (see VAMC/ORI/IRB Coordination SOP); and/or
- Regulatory agency requests for a report;
- Inquiries or sanctions from government oversight agencies.

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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, then 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 Prompt Unanticipated Problem Policy..

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 Coordinator, Veterans Affairs Medical Center (VAMC) Associate Chief of Staff (ACOS), VAMC Facility Director, VAMC Research Compliance Officer, Principal Investigator/Study Personnel

PROCEDURES

Unanticipated Problems Involving Risks to Subjects

1. When the IRB finds that UK research has experienced unanticipated problems involving risk to the subject or others, the RCO or designee prepares a report within fifteen days from the date the IRB conducts 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, approves the report, which the RCO sends through the IRB Chair and the VPR to the federal agency with a copy to the IRB, PI, and other University administrators as determined by the IRB. (See also Unanticipated/ Anticipated Problem/Adverse Event Reporting SOP.)

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2. If the research is regulated by the VAMC, ORI staff or the ORI RCO also send the report to the VAMC ACOS, who is responsible, in conjunction with the VAMC RCO, for sending the report to the appropriate VA official(s): the VAMC Facility Director; the Chair of the VA Research and Development Committee; the Regional Office of Research Oversight; the VAMC Privacy Officer (if an unauthorized use, loss, or disclosure of individually identifiable patient information resulted); and the Veterans Health Administration (VHA) Information Security Officer (if the report involves a violation of VA information security requirements). The VAMC Facility Director is responsible for sending the report to the Office of Human Research Protections (OHRP).
3. 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 to the IRB. If the PI is also the sponsor, then the IRB requires that the PI report to the FDA. The IRB may choose to prepare and send the report directly to the FDA.
4. If the DHHS conducts or funds the research, the RCO sends the report to the OHRP.
5. If an agency that is subject to the “Common Rule,” other than the DHHS, conducts or funds the research, the RCO sends the report to the agency as required by the agency and OHRP.
6. The RCO provides a copy of the federal report(s) and any final IRB actions to ORI staff, who are responsible for placing the report(s) in the IRB study file.

Serious or Continuing Noncompliance

1. When the IRB finds that research involves serious or continuing noncompliance, the ORI RCO or designee prepares a report within fifteen days from the date the IRB conducts 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, approves the report. The RCO sends the report through the IRB Chair and the VPR to the federal agency with a copy to the IRB, PI, and other University administrators as determined by the IRB. (See also Noncompliance SOP.)
2. If the research is regulated by the VAMC, ORI staff also send the report to the VAMC ACOS, who is responsible, in conjunction with the VAMC RCO, for sending the report to the appropriate VA official(s): the VAMC Facility Director; the Chair of the VA Research and Development Committee; the Regional Office of Research Oversight; the VAMC Privacy Officer (if an unauthorized use, loss, or disclosure of individually identifiable

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patient information resulted); and the VHA Information Security Officer (if the report involves a violation of VA information security requirements).

3. When research is FDA regulated, the IRB requires the PI to report to the sponsor, who must report to the FDA with a copy to the IRB. If the PI is also the sponsor, then the IRB requires the PI to report to the FDA. The IRB may choose to prepare and send the report directly to the FDA.
4. If the DHHS conducts or funds the research, the RCO sends the report to OHRP.
5. If an agency that is subject to the “Common Rule,” other than the DHHS, conducts or funds the research, the RCO sends the report to the agency as required by the agency and OHRP.
6. The RCO maintains all correspondence relating to the serious or continuing noncompliance. The RCO provides a copy of the federal report(s) and any final IRB actions to ORI staff, who are responsible for placing the report(s) in the IRB study file.

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 days from the date the IRB conducts 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, approves the report, which the RCO sends through the IRB Chair and the VPR to the federal agency with a copy to the IRB, PI, and other University administrators as determined by the IRB.
2. ORI staff send a copy of the report to the PI and other University administrators as determined by the IRB.
3. If the research is regulated by the VAMC, ORI staff also send the report to the Associate Chief of Staff (ACOS), who is responsible, in conjunction with the VAMC RCO, for sending the report to the appropriate VA official(s): the VAMC Facility Director; the Chair of the VA Research and Development Committee; the Regional Office of Research Oversight; the VAMC Privacy Officer (if an unauthorized use, loss, or disclosure of individually identifiable patient information resulted); and the VHA Information Security Officer (if the report involves a violation of VA information security requirements).
4. If the DHHS conducts or funds the research, the RCO sends the report to the OHRP.

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5. If an agency that is subject to the “Common Rule,” other than the DHHS, conducts or funds the research, the RCO sends the report to the agency as required by the agency and OHRP.
6. When research is FDA regulated, the IRB requires the PI to report to the sponsor, who must report to the FDA with a copy to the IRB. If the PI is also the sponsor, then the IRB requires the PI to report to the FDA. The IRB may choose to prepare and send the report directly to the FDA.
7. The RCO maintains all correspondence relating to the suspension or termination. The RCO provides a copy of the federal report(s) and any final IRB actions to ORI staff, who are responsible for placing the report(s) in the IRB study file.

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 the DHHS.
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 the DHHS based on the current guidance from OHRP. The IRB, in consultation with the ORI Director, approves the report, which ORI staff send through the VPR with a copy to the PI and to OHRP per OHRP guidance within fifteen days of IRB approval of the report.
3. ORI staff place a copy of all correspondence in the IRB protocol file and database.
4. If the OHRP disagrees with the IRB findings on 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. Upon receipt of an IRB application or request, ORI staff screen protocols for any inclusion of prisoners in research submitted to or funded by DHHS.
2. ORI staff notify the PI of the DHHS reporting requirement if it finds that the PI has submitted the protocol to DHHS or that the research is DHHS funded and includes prisoners.
3. With input from the IRB and/or the PI, ORI staff prepare a report to the DHHS based on the current guidance from OHRP on research which includes prisoners. ORI staff approve the

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report and send it to OHRP within fifteen days of IRB approval of the report. ORI staff place a copy of all correspondence in the IRB protocol file.

4. If the OHRP disagrees with the UK IRB classification of the research involving prisoner(s), ORI staff share the information from OHRP with the IRB and the PI.

Children

1. Upon receipt of an IRB application or request, ORI staff screen protocols for any inclusion of children in research submitted to or funded by DHHS or the U.S. Department of Education or regulated by FDA.
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, DHHS, or U.S. Department of Education subpart, ORI staff, with input from the IRB and the PI, prepare a report to the DHHS 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 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 DHHS through OHRP, Secretary of U.S. Department of Education, or Commissioner of FDA) based on current guidance from the agency. ORI staff place a copy of all correspondence in the IRB protocol file and database.
3. If the applicable federal agency disagrees with the IRB findings on the research involving children, ORI staff share the information from the agency with the IRB and the PI.

Changes in IRB Membership/Registration

1. When a change in IRB membership occurs, ORI staff notify OHRP/FDA via their online registration system. The ORI Associate Director or designee enters the required information regarding the changes in membership and submits the data to OHRP/FDA within fifteen days of receipt of the VPR's approval of the membership.
2. The ORI Associate Director is responsible for revising registration information such as changes in IRB member contact or Chair contact information within 90 days of the change, changes in the IRB's decision to review or discontinue review of types of FDA products or FDA clinical investigations within 30 days, or the University's decision to disband an IRB within 30 days of permanent cessation of the IRB's review of research.

Certification of IRB Approval

1. When a funding agency requires certification of IRB approval, the PI contacts the ORI to request that ORI staff prepare the certification document or indicates in the IRB application

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that the sponsor requires certification of IRB approval. The PI is responsible for requesting ORI documentation of IRB approval in accordance with the 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 obtain the signature of the UK authorized organizational representative for sponsored research or of an authorized IRB member.
3. ORI staff retain a copy of the certification form in the IRB protocol file 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) a copy.
5. To prepare a certification form for grants/contracts that fund more than one IRB protocol, the PI provides the 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 DHHS 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 DHHS 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 days of approval.
3. ORI staff place a copy of the report in the IRB files. (See Informed Consent SOP.)

VAMC Reporting Requirements

1. Procedures for VAMC reporting are outlined above in the procedures for reporting unanticipated problems, serious or continuing noncompliance, and suspension or termination of research and in the VAMC/ORI/IRB Coordination SOP.

Agency-Requested Reports

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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 or FDA or any 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 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, 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. ORI staff and/or the IRB are responsible for informing the ORI Director of any of the AAHRPP reportable events listed below. The ORI RCO prepares a report, the ORI Director reviews the report, and the VPR approves it. ORI staff submit the report to AAHRPP as follows:
 - Inquiries from a government oversight office, when the inquiry could result in a for-cause investigation, are reported within 72 hours.
 - Any findings or changes concerning the UK Human Research Protection Program that might affect the ability of the University to continue to meet AAHRPP standards are reported within 72 hours.
 - Any sanctions taken by a government oversight office are reported within 24 hours.
2. The Quality Improvement Coordinator prepares the AAHRPP annual report. The Quality Improvement Coordinator tracks changes in ORI policies and procedures. The ORI RCO or designee tracks noncompliance incidents, suggestions, concerns, and/or complaints received by the 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/VA Officials to Receive Copy of Reports

1. The IRB/ORI staff or the VPR determine appropriate institutional officials within UK or the VAMC 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

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with the policies outlined in the VAMC/ORI/IRB Coordination and the HIPAA in Research SOPs.

Examples of institutional officials who may receive copies of a report include, but are not limited to, the following:

- Vice President for Research;
- Dean of the College;
- Associate Dean of the College;
- Department Chair;
- VAMC Associate Chief of Staff who, as appropriate, is responsible for sending the report to: the Chair of the VA Research and Development Committee; the Regional Office of Research Oversight; the VAMC Privacy Officer (if an unauthorized use, loss, or disclosure of individually identifiable patient information resulted; the VHA Information Security Officer (if the report involves a violation of VA information security requirements); the VAMC Facility Director and Administrative Officer (if the study involves the VAMC) (See VAMC/ORI/IRB Coordination SOP.);
- VAMC Research Compliance Officer;
- Legal Counsel;
- Director of the Office of Sponsored Projects Administration;
- 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

38 CFR 16

Veterans Health Administration Handbook 1200.05

May 2003 OHRP Guidance on the Involvement of Prisoners in Research

May 2005 OHRP Guidance on the HHS 45 CFR 46.407 Review Process for Children Involved as Subjects in Research