

## 10.0 PROMPT INSTITUTIONAL REVIEW BOARD REPORTING

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### 10.1 OBJECTIVE

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

### 10.2 GENERAL DESCRIPTION

Howard University (HU) policy requires compliance with all applicable accreditation, local, state, and federal reporting requirements in the conduct of research involving human subjects. The IRB/ORRC 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 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
- Regulatory agency requests for a report;
- 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, ORRC, 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 SOPP are not reportable under provisions of the SOPP.

### 10.3 DEFINITIONS

*Unanticipated Problem Involving Risks:* See Prompt Unanticipated Problem Policy.

*Serious Noncompliance:* See Noncompliance SOPP.

*Continuing Noncompliance:* See Noncompliance SOPP.

### 10.4 RESPONSIBILITY

Execution of SOPP: IRB Chair, IRB, ORRC Staff, ORRC Director, Associate Vice President (AVP) for Regulatory Research Compliance (RRC), ORRC Research Compliance Officer (RCO), Principal Investigator/Study Personnel

### 10.5 PROCEDURES

Unanticipated Problems Involving Risks to Subjects

- When the IRB finds that HU 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 HU or the IRB; and actions taken by the PI, HU, and/or the IRB to address the issue. The ORRC Director, in consultation with the IRB Chair, approves the report, which the RCO sends through the IRB Chair and the AVP for RRC 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 SOPP).
- 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.

- If the DHHS conducts or funds the research, the RCO sends the report to the OHRP.
- 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.
- The RCO provides a copy of the federal report(s) and any final IRB actions to ORRC staff, who are responsible for placing the report(s) in the IRB study file.

#### 10.5.1 Serious or Continuing Noncompliance

- When the IRB finds that research involves serious or continuing noncompliance, the ORRC 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 HU or the IRB; and actions taken by the PI, HU, and/or the IRB to address the issue. The ORRC Director, in consultation with the IRB Chair, approves the report. The RCO sends the report through the IRB Chair and the AVP for RRC to the federal agency with a copy to the IRB, PI, and other University administrators as determined by the IRB (See also Noncompliance SOPP).
- 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.
- If the DHHS conducts or funds the research, the RCO sends the report to OHRP.
- 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.
- 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 ORRC staff, who are responsible for placing the report(s) in the IRB study file.

#### 10.5.2 Suspension or Termination of Research

- When the IRB suspends or terminates approval of a research protocol, the ORRC 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 HU or the IRB; and actions taken by the PI, HU, and/or the IRB to address the issue. The ORRC Director, who may consult with the IRB Chair, approves the report, which the RCO sends through the IRB Chair and the AVP for RRC to the federal agency with a copy to the IRB, PI, and other University administrators as determined by the IRB.

- ORRC staff sends a copy of the report to the PI and other University administrators as determined by the IRB.
- If the DHHS conducts or funds the research, the RCO sends the report to the OHRP.
- 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.
- 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.
- 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 ORRC staff, who are responsible for placing the report(s) in the IRB study file.

### **10.5.3 Fetuses, and Neonates**

- Upon receipt of an IRB application or request, ORRC staff screen protocols for any inclusion of fetuses, or neonates in research submitted to or funded by the DHHS.
- If the IRB finds that the research is not otherwise approvable for fetuses, 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 fetuses, or neonates, ORRC 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 ORRC Director, approves the report, which ORRC staff sends through the AVP for RRC with

a copy to the PI and to OHRP per OHRP guidance within fifteen days of IRB approval of the report.

- ORRC staff place a copy of all correspondence in the IRB protocol file and database.
- If the OHRP disagrees with the IRB findings on the research involving fetuses, nonviable neonates, or neonates of uncertain viability, ORRC staff share the information from OHRP with the IRB and the PI.

#### 10.5.4 Prisoners

- Upon receipt of an IRB application or request, ORRC staff screen protocols for any inclusion of prisoners in research submitted to or funded by DHHS.
- ORRC staff notifies 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.
- With input from the IRB and/or the PI, ORRC staff prepares a report to the DHHS based on the current guidance from OHRP on research which includes prisoners. ORRC staff approves the report and send it to OHRP within fifteen days of IRB approval of the report. ORRC staff place a copy of all correspondence in the IRB protocol file.
- If the OHRP disagrees with the HU IRB classification of the research involving prisoner(s), ORRC staff share the information from OHRP with the IRB and the PI.

#### 10.5.5 Children

- Upon receipt of an IRB application or request, ORRC 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.
- 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, ORRC 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 ORRC Director, approves the report and sends it through the AVP for RRC with a copy to the PI within fifteen days of IRB approval of the report. ORRC staff submits a copy to the institutional official of the applicable federal agency (e.g., Commissioner of FDA) based on current guidance from the agency. ORRC staff place a copy of all correspondence in the IRB protocol file and database.

- If the applicable federal agency disagrees with the IRB findings on the research involving children, ORRC staff share the information from the agency with the IRB and the PI.

#### **10.5.6 Changes in IRB Membership/Registration**

- When a change in IRB membership occurs, ORRC staff notifies OHRP/FDA via their online registration system. The ORRC 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 AVP for RRC's approval of the membership.
- The ORRC 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.

#### **10.5.7 Certification of IRB Approval**

- When a funding agency requires certification of IRB approval, the PI contacts the ORRC to request that ORRC 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 ORRC documentation of IRB approval in accordance with the funding agency requirements.
- The PI may provide ORRC staff with a copy of the agency certification form. ORRC staff prepares the required agency form(s) and obtain the signature of the HU authorized organizational representative for sponsored research or of an authorized IRB member.
- ORRC staff retains a copy of the certification form in the IRB protocol file and forward the Original certification form to the investigator.
- The PI transmits the certification of IRB approval to the funding agency within the time period specified by the agency and provides the Research Administrative Services (RAS) a copy.

Secretary of DHHS through OHRP, Secretary of U.S. Department of Education, or To prepare a certification form for grants/contracts that fund more than one IRB protocol, the PI provides the ORRC with a list of pertinent IRB protocol numbers. ORRC staff verifies the IRB numbers and IRB approval prior to preparing and issuing the certification document. The PI transmits the

certification to the agency and provides the Office of Sponsored Research Projects with a copy.

#### **10.5.8 Exception to Informed Consent in Emergency Medical Research**

- 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.
- When the IRB does not approve an exception from the general informed consent requirements for emergency research under FDA and DHHS requirements, ORRC staff, with input from the IRB, prepares a report of the reasons why the IRB did not approve the exception. The IRB Chair, in consultation with the ORRC Director, approves the report. ORRC staff submits the report to the sponsor and the PI within fifteen days of approval.
- ORRC staff place a copy of the report in the IRB files (See Informed Consent SOPP).

#### **10.5.9 Agency-Requested Reports**

- A federal agency may periodically ask the IRB or HU for a specific report on a variety of issues (e.g., alleged noncompliance submitted to a federal agency). ORRC staff is responsible for informing the ORRC Director of any inquiries from a government oversight office, such as OHRP or FDA or any other agencies. The ORRC Director or designee reviews the request and designates an ORRC staff member to assist the IRB/HU with preparation of the report (e.g., the RCO oversees noncompliance report preparation).
- The designated ORRC staff member prepares the report in accordance with the agency's request relative to content and timing.
- The AVP for RRC, in consultation with the ORRC Director, approves the report. The ORRC Director and/or IRB Chair or AVP for RRC determines who receives a copy of the report depending on the nature of the request.

## **10.6 REFERENCES**

45 CFR 46 Subpart B  
45 CFR 46 Subpart C  
45 CFR 46 Subpart D  
21 CFR 50 Subpart D  
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.