

Standard Operating Procedures		
SOP #404.5 Revision 5	TITLE: Mandated Reporting to External Agencies	Effective Date: 2/12/2019
Approved By: OIRB Director	Signature 	Date 2/12/2019
Approved By: IRB Chair	Signature 	Date 2/12/2019

PURPOSE

To describe the process to ensure prompt reporting by the IRB to appropriate institutional officials, sponsors, coordinating centers, and the appropriate regulatory and accrediting agency heads.

REVISIONS FROM PREVIOUS VERSION

Added DoD reporting requirements

POLICY

University of New Mexico (UNM) policy requires compliance with all applicable local, state, and federal reporting requirements in the conduct of human research. The IRB/OIRB 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 participants 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 projects that are not otherwise approvable under 45 CFR 46 Subpart B, which include pregnant women, fetuses, and neonates; and/or
- DHHS submitted or funded projects which include prisoners; and/or
- Food and Drug Administration (FDA), DHHS or U.S. Department of Education submitted or funded projects which include children and are not otherwise approvable under applicable subparts; and/or
- Certification of IRB approval; and/or
- 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 project to new participant accrual or temporarily halts the research procedures. The IRB, IRB Chair, OIRB, 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.

An expiration of IRB approval as outlined in the Expiration of IRB Approval SOP is not reportable under provisions of this SOP.

Researchers may also have mandated reporting responsibilities outside of the IRB based on federal or other funding requirements (see Guidance on Additional Requirements for Federally Funded Research).

Definitions

Reportable events include unanticipated problems involving risks to participants or others, non-compliance determined to be serious or continuing, and suspensions and terminations of approved research by the IRB.

RESPONSIBILITIES

Execution of SOP: Researchers, IRB Chair, IRB, OIRB, Institutional Official (IO).

PROCEDURE

General Compliance Reporting

1. When the IRB finds that UNM research has experienced unanticipated problems involving risk to the participants or others; serious or continuing noncompliance; or suspension or termination of research, the OIRB Director or designee prepares a report within fifteen days from the date the IRB conducts final review of the unanticipated problem.
2. 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 UNM or the IRB; and actions taken by the PI, UNM, and/or the IRB to address the issue. The OIRB Director, in consultation with the IRB Chair, approves the report, which the Director sends to the federal agency with a copy to the IRB Chair, IO, PI, and other University administrators as determined by the IRB.
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 report is sent to the OHRP.
5. If Department of Defense (DoD) supports the research, the report is sent to the DoD human research protection officer within 30 days.
6. If an agency that is subject to the "Common Rule," other than the DHHS, conducts or funds the research, the report is sent to the agency as required by the agency and OHRP.
7. If the project has no federal funding, the report will be provided to the IO or designee.
8. Reports are provided to the appropriate federal agency no later than 30 days after discovery of the event.
9. The OIRB Director provides a copy of the report(s) and any final IRB actions to OIRB staff, who are responsible for placing the report(s) in the IRB file and database.

Prisoners

1. Upon receipt of an IRB application or request, OIRB staff screen protocols for any inclusion of prisoners in research submitted to or funded by DHHS.
2. OIRB staff notify the PI of the DHHS reporting requirement (aka "certification") 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, OIRB staff prepare a report to the DHHS based on the current guidance from OHRP on research which includes prisoners. OIRB staff approve the report and send it to OHRP within fifteen days of IRB approval of the report. OIRB staff place a copy of all correspondence in the IRB file and database.
4. If the OHRP disagrees with the UNM IRB classification of the research involving prisoner(s), OIRB staff share the information from OHRP with the IRB and the PI.

5. The IRB will not issue final approval of the protocol until the OIRB receives final certification from OHRP.

Children

1. Upon receipt of an IRB application or request, OIRB staff screen protocols for any inclusion of children in research submitted to or funded by DHHS or the U.S. Department of Education.
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, OIRB staff, with input from the IRB and the PI, prepare a report to the applicable federal agency based on the current guidance from the applicable agency. The IRB, in consultation with the OIRB Director, approves the report and sends a copy to the PI within fifteen days of IRB approval of the report. OIRB 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. OIRB staff place a copy of all correspondence in the IRB file and database.
3. If the applicable federal agency disagrees with the IRB findings on the research involving children, OIRB staff share the information from the agency with the IRB and the PI.
4. The IRB will not issue final approval of the protocol until the OIRB receives final approval from the relevant regulatory agency.

Agency-Requested Reports

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

Accreditation Reporting

1. UNM will report to its accrediting body (AAHRPP) as soon as possible but within 48 hours after the IRB or any researcher (if the researcher is notified directly rather than the IRB) becomes aware of:
 - a. 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-US authorities related to human research protections.
 - b. Any litigation, arbitration, or settlements initiated related to human research protections;
 - c. Any press covering (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding UNM's human research protections program.

REFERENCES

45 CFR 46 Subparts B, C, D
21 CFR 50 Subpart D



28 CFR 512.19,20

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

DoD Instruction 3216.02