Reporting to Regulatory and Oversight Agencies

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Policy Statement

The UIW ORSPO will promptly report, no more than 30 days after identifying a reportable event, the following to relevant regulatory and oversight agencies for non-exempt research, regardless of funding:

- unanticipated problems involving risks to research participants or others,
- serious and/or continuing noncompliance with the requirements or determinations of the IRB, and
- suspension or termination of previously approved research.

Description and Procedures

A. Report Preparation

Official written reports for official reporting to oversight agencies are to be prepared as follows:

1. The report is drafted by ORSPO staff.
2. If the report is related to a protocol approved by an external IRB, the ORSPO coordinates the drafting and review of the report with the counterpart at the external IRB in accordance with the agreed-upon terms of the reliance agreement.
3. The report must be drafted as soon as information is available that confirms or clarifies the issue to be reported.
4. The report is reviewed for comments, as appropriate, by the IRB Chair/designee, Director of ORSPO, the Principal Investigator, and others.
5. The report is signed by the Associate Provost for Research and Graduate Education, the Institutional Official, or designee.

B. Elements of the Report

The report should be concise and include only detail which directly supports the actions taken. The following elements must be included in the report:

1. name of the institution conducting the research;
2. title of the research project and/or grant proposal;
3. name of the Principal Investigator on the protocol;
4. the IRB approval number;
5. the number of any applicable federal award(s);
6. for FDA reports of suspension or termination: the name of the drug, biologic, or device and the IND number or the IDE number/non-significant risk (NSR) status of the device;

7. a description of the event or events resulting in the unanticipated problem, serious/continuing noncompliance, and/or suspension or termination;
8. the findings of the organization;
9. actions taken by the organization, including any IRB actions taken related to the matter, and reasons for those actions; and
10. clear identification that the issue is resolved or specific plans for continued investigation or action.

C. Distribution of the Report

The distribution of the written report begins with federal and/or non-federal agencies that have oversight due to funding, conduct, or an assurance of compliance. A report is always sent to OHRP, the FDA if FDA-regulated research, and other "Common Rule Signatories" that require reporting separate from OHRP. A UIW report may not be sent to federal agencies already made aware of the event by way of the investigator, sponsor, or another organization, as determined by the ORSP Director and/or IRB Chair.

For research supported by the Department of Defense (DoD), the ORSPO is responsible for notifying, within 30 days of identifying a reportable event, the Human Research Protection Office of the DoD, the Department of Navy Human Research Protections Program (HRPP) Office, and supporting DoD component of the following:

- all suspensions or terminations of previously approved research protocols,
- the initiation and results of investigations of alleged non-compliance with human participant protections,
- unanticipated problems involving risks to participants or others,
- any for-cause investigations of DoD-supported research conducted by any Federal department of agency or national organization, and/or
- all restrictions, suspensions, or terminations of institutions' assurances.

Copies of the report are directed to:

- the Principal Investigator,
- the UIW IRB Chair(s),
- the UIW Institutional Official,
- the supervisor and/or the Department Chair or Dean of the Principal Investigator, and
- other sites involved in the research, as appropriate.

The timing for official distribution of the report to oversight agencies should be as soon as practicable, with the primary attention first given to taking any actions (if necessary) to ensure the ongoing protection of human research participants. For more serious incidents, the report will be filed as soon as practicable. It may be necessary to contact an agency prior to filing a report in order to alert the agency to a serious problem.

Effective Date

August 24, 2020

Revision History