Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2009-004.0
Policy Title: Required Reporting to Institutional Officials and External Agencies

Purpose

The purpose of this policy is to identify the individual responsible for reporting instances of serious non-compliance, continuing non-compliance, unanticipated problems involving risk to subjects or others (unanticipated problems), and/or any suspension or termination of IRB approval to appropriate institutional officials (also referred to as administrative officers) and, as applicable, federal department or agency heads, the mechanism for reporting and the time frame within which such reports are to be filed.

Definitions

See policy 2011-007.0 for definitions of:

IRB Approval Non-compliance, Continuing Non-compliance, Serious
Suspension Termination
Unanticipated Problem Involving Risk to Subjects or Others

Policy

It is the policy of the HSPP that the Director of the HSPP (DHSPP) is responsible for informing relevant institutional officials and, as applicable, external agencies of determinations of serious non-compliance, continuing non-compliance, unanticipated problems, suspensions of IRB approval (in whole or in part) and/or terminations of IRB approval.

Procedure

Suspensions of IRB approval, terminations of IRB approval, or determinations of unanticipated problems, serious non-compliance or continuing non-compliance are communicated to the DHSPP either by copy of a suspension or termination letter, and/or by copy of the IRB minutes.

As applicable, the DHSPP will report in letter format to the to the relevant agency (i.e. the Office for Human Research Protections, the FDA, or to any other regulatory agency with oversight due to conduct or an assurance of compliance) with copy to relevant institutional officials identified in Institutional Policy 2002-42 (Review and Approval of Research Involving Human Subjects) and the Department Chair of the PI. As applicable, the letter may also be sent to other sites involved in the research if the findings and corrective actions impact that site, and the study sponsor. HSPP staff will place a copy of the letter in the applicable study file. If the study file exists only in an electronic format, the letter will be uploaded to the electronic study file. If the study is funded by a federal agency the Office for Human Research Protections Incident Report Form will also be completed and the letter will be uploaded to that form. The incident report form may be completed by the Director or staff within the HSPP. (Form available at https://oash.force.com/ohrpwebforms/s/incident-web-form)

The letter may be written by the DHSPP or delegated to HSPP staff with review, approval and signature of the DHSPP. The letter will be sent by the HSPP staff by e-mail if available or US post if no e-mail is available or uploaded as an attachment to the OHRP incident report template. The letter will contain:

- the number and title of the study;

- the name of the principal investigator;
- a summary description of the problem and the cause;
- the date of occurrence;
- determinations of the IRB
- the corrective actions taken or to be taken;
- the reason for the corrective action (e.g. to remedy specific situation, to prevent subsequent occurrence, to ensure data integrity, etc.)
- and any plans for ongoing monitoring.

Reporting to federal agencies or institutional officials is not required if the agency or official is already made aware of the event through other mechanisms, such as by receiving a copy of the IRB minutes, reporting by the investigator, sponsor or another organization. If no external reporting is required (e.g. no federal funding, no FDA regulated product involved), the letter may be replaced by an email communication sent from the DHSPP or designee.

Unless there are extenuating circumstances, letters will be issued within three weeks of the IRB determination that an event constitutes an UP, serious and/or continuing non-compliance, or from when the suspension or termination is imposed. An example of an extenuating circumstance would be the requests of the IRB for a full audit of a study in which case reporting may be delayed until the audit is completed and reviewed by the convened board.

Related Policies

#2009-001 –Reporting Unanticipated Problems to the IRB
#2009-002 – Reporting Non-compliance to the IRB
#2009-003 – Imposing and Lifting Suspensions or Terminations

Basis

45 CFR 46 – Protection of Human Subjects
21 CFR 56 – Institutional Review Boards

Document Attributes

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Reviewed and Approved By:

Richard Simon **12/30/2021**

Richard Simon, MD **Date:**
Director Human Subjects Protection Program