Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2009-002.0
Policy Title: Reporting Non-Compliance to the Institutional Review Board (IRB)

Purpose

The purpose of this policy is to identify events that may constitute noncompliance that must be reported to the IRB, the time frame within which the reporting must occur, the elements of the report, and the mechanism for filing the report.

Definitions

See Policy 2011-007.0 for definitions of:

Non-Compliance Non-Compliance, Serious Non-Compliance, Continuing

Policy:

It is the policy of the HSPP that a Principal Investigator (PI) must report any instance of noncompliance that was within the control of the research team to the IRB within five business days of becoming aware of the occurrence.

While the IRB Chair may determine that an instance is not serious or continuing non-compliance, only the convened IRB will make the final determination as to whether an occurrence does constitute serious and/or continuing noncompliance. If the convened IRB determines that the occurrence does constitute serious and/or continuing noncompliance, the PI must also report the determination at the time of continuing review or study closure, whichever is first.

Procedure:

Occurrences that may constitute noncompliance with the approved protocol, regulations or directives of the IRB are reported to the IRB in one of two ways. Either the investigator self reports or the Director of the HSPP or an IRB Chair refers an audit finding to the IRB for determination.

Self Reporting:

PIs are to report to the IRB any noncompliance with the protocol or directives of the IRB that was within the control of the research team within 5 days of becoming aware of the event. An occurrence that may constitute noncompliance within the control of that research team is to be reported even if detected after a subject withdraws from a study, after a subject has completed the study intervention, or for up to 30 days after study completion.

The PI is to complete the Problem Report Form (PRF) for reporting to the IRB. The PRF addresses all information that is required for submission. If the PI proposes a corrective action that will require a change to the protocol or study related documents, the PI must also complete, sign and submit a request for modification form.

Upon receipt of a PRF, the IRB Regulatory Specialist (RS) will forward the report and any supporting documentation to the IRB Chair of the corresponding panel for review and determination of action. The IRB Chair has access to the complete IRB file of the study to which the occurrence relates.

The IRB Chair may determine that the occurrence does not constitute serious or continuing noncompliance or may refer the occurrence to the convened board for review and determination. In reviewing the PRF the Chair may also require the PI to take corrective actions. Any required actions will be communicated to the PI through correspondence from the IRB staff) as directed by the Chair. The Chair will determine whether an occurrence is not serious or continuing noncompliance by evaluating the reported occurrence in relation to the criteria in the section of the PRF in which the PI's judgment is entered. The determination of the Chair is documented on the reviewer form within the on-line IRB submission system.

Noncompliance that was not within the control of the research team and that does not pose any risk to subjects (e.g. a subject cancels an appointment that had been scheduled within the study window and cannot reschedule until 1 day out of study window) is to be reported at the time of continuing review or study closure, whichever comes first.

Self Reported Occurrences That Are Deemed Not to Be Serious or Continuing Non-Compliance: If the Chair determines that the occurrence does not constitute serious or continuing noncompliance, the Chair will note this determination on the reviewer form. The IRB RS will return the submission to the PI with an outcome noted of "Not Reportable". The determination will be presented for informational purposes to the convened board on the expedited and exempt agenda activity listing at the next convened meeting for which the submission deadline has not passed. Any member of the board may request that the convened board review the report and corresponding information. In such case, the determination of the convened board would stand.

Self Reported Occurrences Referred to the Convened Board: If the Chair refers the PRF to the convened board for review, the Chair will assign primary reviewers and direct the IRB RS to distribute the relevant information to each member of the appropriate IRB panel as part of the agenda for the next regularly scheduled meeting. The Chair will also determine whether any additional supporting documentation is required and direct the RS accordingly. The IRB RS will list the PRF as a discussion item on the agenda.

Referral of Audit Findings:

The RCM, who prepares the final audit correspondence for signature by the Director of the HSPP, is responsible for ensuring that audit letters containing a referral to the IRB are provided to the IRB RS for inclusion on the meeting agenda. The RCM will coordinate with the IRB Chair to determine whether documentation in addition to the audit letter and PI response letter, e.g., the audit intake form, should be included. The RCM is responsible for preparing the materials to be distributed to the board. For audit findings referred to the convened IRB, the Chair will assign primary reviewers and the IRB RS will list the item on the agenda as discussion items.

If the PRF or audit response is accompanied by a request for modification form, the IRB RS will list the modification and discussion item separately on the agenda. Procedures described elsewhere for the submission and review of modifications will be used for review and approval of the modification.

Actions of the IRB:

Upon initial review of a PRF or audit report, the Chair may elect to suspend the approval for the study, in whole or in part, until such time as the full board can review the information. (Refer to policy for imposing suspensions).

For any PRF referred to the convened board, at a minimum, all IRB members will have access to the PRF, the current consent form to orient them to the study, and copies of any supporting documentation that was submitted with the PRF. For audit findings IRB members will have access to, at a minimum, the audit letter and the response letter from the PI. Members also have access to the discussion item reviewer form. The complete IRB file will also be available for review. The Chair will lead the discussion at the meeting. The board will use the discussion item reviewer sheet as a guide in making its determinations and may require additional corrective actions of the PI.

The IRB may require corrective action including, but not limited to, a modification of the protocol or information disclosed in the informed consent document and process, that information be provided to past participants, that current participants be informed if the information may relate to their willingness to participate, re-consenting of currently enrolled subjects, more frequent continuing review, monitoring of the consent process or research project by a third party, or requiring additional education. The IRB may seek counsel from other institutional areas (e.g. legal counsel, risk management, research compliance) in determining corrective action plans. The IRB may make recommendations regarding employment status but has no authority over an individual's employment status.

When reviewing a PRF or audit finding, any member of the IRB may request additional information from the investigator, to review the complete IRB file, or to review previous minutes relating to the study. Requests for additional information from the investigator will be done through correspondence from the IRB member or from the IRB RS at the direction of the IRB member.

The IRB RS will note the outcome of the discussion and determination of the IRB in the minutes. The determinations of the board, including any required corrective actions, will be communicated to the PI in a letter prepared by the IRB staff and sent to the PI through the electronic IRB submission system. For determinations of serious and/or continuing non-compliance, the letter will first be routed the Chair for sign-off

If the IRB instructed the PI to make specific changes, the resulting request for modification may be reviewed through the expedited review process (i.e. the PI responds according to the directives provided by the IRB) or may require full board review (e.g. the responses provided by the PI do not match the directives of the IRB).

PRFs that are submitted to the IRB will be maintained in the IRB file(s) in electronic or paper format as applicable). The PI is also expected to keep copies of events in his/her study file.

The DHSPP may also review the underlying reason that caused the serious and/or continuing noncompliance to occur and may require that additional corrective action be taken to prevent subsequent occurrences. Corrective action may include, but is not limited to, requiring additional education of the investigator, clarifying existing policies or implementing new policies, or enhancing overall educational activities provided to investigators.

Additional Reporting From Investigators:
If the convened IRB determines that an occurrence is serious and/or continuing noncompliance, the PI must also report this at the time of continuing review on the continuation addendum form or at the time of study closure on the request for closure form, whichever comes first.

Related Policies

#2009-001 Reporting Unanticipated Problems to the IRB
#2009-003 Imposing a Suspension or Termination of IRB Approval
#2009 -004 Reporting to External Agencies and Institutional Officials

Basis

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

Document Attributes:

Date Created: 4/25/2017

Replaced Version: 5/2/13

Reviewed and Approved By:

Signed: Richard H. Simon **25 April 2017**
Richard Simon, MD **Date:**
Director Human Subjects Protection Office