

Information for Investigators and NIH IRBs Regarding Implementation of Revised Policies on Reportable Events and Allegations of Non-Compliance during the period of IRB transition

The NIH Office of Human Subjects Research Protections (OHSRP) has revised its policies on investigator reporting of research related events to the IRB and the process for evaluating allegations of non-compliance. This memo provides guidance as to the applicability of the revised policies during the transition of protocols from the existing IC specific IRBs to the central NIH Intramural (IM) IRB.

Effective date for policies 801 and 802 and this implementation memo: July 1, 2019

Reporting Requirements to the IRB

Relevant policies: *SOP 16 Reporting Requirements for Unanticipated Problems, Adverse Events and Protocol Deviations* and [*Policy 801, Reporting Research Events*](#). This transition should be implemented as follows:

Studies reviewed by the central NIH IM IRB:

- All aspects of Policy 801 apply, and it supersedes SOP 16.

Studies reviewed by an existing IC-specific IRB, (e.g., CNS IRB, NIAID IRB, etc.):

- Policy 801 applies except for the following:
 - When Policy 801 indicates to submit a Reportable Events Forms (REFs) to the OHSRP office of Compliance and Training, investigators should instead submit these REFs to their reviewing IRB through iRIS.
 - Section 5.2 (“Responsibilities of the OHSRP Office of Compliance and Training and the NIH IRB(s)”) – Section 5.2 does not apply.
 - Once investigators report an event as directed in Policy 801 and as described above, the IC-specific IRB will be responsible for evaluation of reportable events. REFs that include IRB determinations that require reporting to OHRP and, as applicable, FDA should be provided by the IC-specific IRB to the OHSRP office of Compliance and Training (just as these IRBs are currently providing PRFs to OHSRP).
 - Section 9 (“Supersedes dates”) – Section 9 does not apply.

Non-compliance in Human Subjects Research

Relevant policies: *SOP 16A Allegations of Non-compliance with Requirements of the NIH Human Research Protections Program (HRPP)* and [*Policy 802, Non-Compliance in Human Subjects Research*](#).

Studies reviewed by the central NIH IM IRB:

- All aspects of Policy 802 apply, and it supersedes SOP 16A.

Studies reviewed by an existing IC-specific IRB:

- Policy 802 does not apply. Allegations and investigations regarding non-compliance will continue to be handled consistent with existing SOP 16A and the overseeing IRB will continue to be the IC-specific IRB.
- Investigators should report allegations of non-compliance using the REF via iRIS.
- If the IRB determines the event or allegation of noncompliance constitutes serious and/or continuing non-compliance, IRBs should forward the completed REF to the OHSRP office of Compliance and Training (just as these IRBs are currently providing the PRFs to OHSRP.)

Note: When the existing IC-specific IRBs are assimilated into the central NIH IM IRB, all protocols previously under the oversight of the IC-specific IRB will become subject to all aspects of policies 801 and 802.