

Serious or Continuing Noncompliance or Unanticipated Problems Involving Risks: IRB Reporting to Federal Agencies

The University of Kentucky (UK) requires that the UK Institutional Review Board (IRB) report the following:

1. continuing noncompliance; 2. serious noncompliance; 3. unanticipated problems/ adverse events involving risk to subjects or others in human subjects research to a federal agency, if applicable. *See also Mandated Reporting to External Agencies SOP or if applicable, the VAMC/IRB/ORI Coordination SOP for a complete list of required reports that must be submitted to external agencies.*

When the IRB finds that human subjects research involves **serious or continuing noncompliance and/or unanticipated problems/ adverse events involving risk to subjects or others**, the Research Compliance Officer (RCO) or designee prepares a report to the applicable regulatory agency (e.g., Office of Human Research Protection (OHRP) and other Common Rule agencies) and sends the report to that agency. When research is FDA regulated, the IRB requires the PI to report to the sponsor who must report to the FDA. If the PI is also the sponsor, then the PI is required to report to the FDA. The IRB can choose to prepare and send the report directly to the FDA, if deemed appropriate. *See also Noncompliance SOP and Unanticipated Problem SOP*

Noncompliance is defined as conducting research in a manner that disregards or violates federal regulations or institutional policies and procedures applicable to human subjects research. It includes noncompliance with the requirements of the VA Handbook 1200.05 as applicable. Noncompliance with IRB and/or federal requirements may involve a range of issues from relatively minor or technical violations which result from inadvertent errors, inattention to detail, or inadequate training and supervision of research staff to more serious violations which pose risk to subjects and/or violations of their rights and welfare.

Continuing noncompliance is defined as persistent failure to adhere to the laws, regulations, or policies governing human research.

Serious noncompliance is defined a failure to adhere to the laws, regulations, or policies governing human research that may reasonably be regarded as:

- (1) Involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others; or
- (2) Substantively compromising the effectiveness of a facility's human research protection or human research oversight programs.

See also the Noncompliance SOP.

An **Unanticipated problem** is any unforeseen or unexpected incident or experience (including an unanticipated adverse event) which is not described in the general investigational plan or elsewhere in the current application or with the current investigator brochure, or in the consent document.

An **Unanticipated problem involving risk to subjects or others** is any unforeseen or unexpected event or experience that adversely affects the rights, safety, or welfare of subjects or others (which is not described in the general investigational plan or elsewhere in the current application or with the current investigator brochure, or in the consent document). The event or experience could involve physical harm/risk (e.g., adverse event), social harm/risk (i.e., inappropriate breach in confidentiality, harm to a subject's reputation, or invasion of privacy), psychological harm/risk or legal harm/risk. The experience could also involve events not previously identified in severity or degree of incidence. An adverse event could be considered an "unanticipated problem involving risk to subjects or others".

- A **serious problem/adverse event** is any incident that results in significant harm to or increased risk for the subject or others. Examples of events which are serious would include but are not limited to, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse event when, based upon appropriate medical judgment, they may jeopardize the subject's health or welfare and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse. A disability is a substantial disruption of a person's ability to conduct normal life functions.

See also the Unanticipated/Anticipated Problem/Adverse Event Reporting SOP or if applicable the VA Unanticipated/Anticipated Problem/Adverse Event Reporting SOP and VA Research Internal Prompt Reporting Form.

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