

**OFFICE OF HUMAN RESEARCH AFFAIRS (OHRA)**

**ISSUES GUIDANCE: RECORDING & REPORTING**

It is the expectation of the OHRA that all research protocols will include a plan for site monitoring and quality control to identify, document and report issues that occur during research. This guidance includes information about expectations for recording issues throughout the life of the project and appropriately reporting them to the OHRA for review.

Overview & Definitions

OHRA review of issues is divided into two main categories; Deviations & Reportable Events. The information needed for the OHRA to assess deviations and reportable events is very similar. The OHRA has simplified reporting by addressing them collectively as “Issues”. The OHRA will apply the following definitions during our review to determine whether an issue is a deviation or a reportable event and how to proceed with the review:

**Deviation:** is an unintentional error, action or process that departs from the IRB approved study protocol that is identified retrospectively (after the event occurred).

OHRA review of deviations is meant to identify instances of noncompliance. Noncompliance can then be further defined as serious noncompliance, continuing noncompliance or a combination. Instances of noncompliance may require reporting to internal institutional officials or external regulatory bodies (OHRP, FDA) depending on nature, severity and outcome. These determinations will set the stage for the corrective and preventative action plan.

**Reportable event:** is an adverse event or incident that occurs with a research participant (or participants) during the conduct of a research study.

OHRA review of reportable events is meant to identify unanticipated problems that pose risk to participants or others. Events that are found to be unanticipated problems that pose a risk to participants or others may require reporting to internal institutional officials or external regulatory bodies (OHRP, FDA) depending on severity and outcome. These determinations will set the stage for adjusting the protocol as necessary to protect those involved in the study.

Recording

Upon activation of a UnitedHealth Group affiliated research study site, the study files should be prepared with a mechanism/system for recording (documenting) all the issues that occur throughout the course of the project.

The level of detail and complexity necessary for the documentation method will be entirely dependent upon the complexity and level of risk posed by the research. Operational and Minimal risk research will likely have a simple system, while greater than minimal risk research will have a very robust documentation system.

An issues recording log template is available in the Resources Library of the OHRA website. Academic and Industry sponsors may require use of specific forms or systems for documenting issues. In those cases, the sponsor mechanisms should be utilized (and supplemented if necessary to meet the UHG OHRA reporting requirements.)

**General Expectations for recording**:

* If your research requires annual renewal, you will be required to submit documentation of your monitoring activities every year. Research that requires annual renewal would benefit from a highly organized and routine documentation process for all issues so that records received by the OHRA require little follow up or clarification during renewal.
* Please try to de-identify your issues records as much as possible to protect the confidentiality of participants
* You may maintain separate logs for tracking different types of issues, or compile them into one general issues log. The types information requested in the OHRA template log should be documented consistently regardless of what documentation method you employ:
  + When an issue is specific to an individual participant, identify that person without direct identifiers (e.g. subject ID)
  + A description of the issue
  + Date of occurrence
  + Date the PI was notified for assessment of the issue
  + Expectedness: Whether the issue is considered an expected occurrence/outcome of the research intervention/procedures/study population (yes or no is usually sufficient)
  + Relatedness: Whether the issue is directly related to participation in the research or could be explained by other factors(yes or no is usually sufficient)
  + The outcome of the issue and any corrective/preventative actions employed
  + Has this issue adversely impacted any one or more of the following OHRA Criteria:
    - Participant safety
    - Participant rights / willingness to participate
    - Participant welfare
    - The integrity of the study data
      * If the answer to any of these is YES, then the individual issue should be reported directly (“in real time”) to the OHRA via an Issue Report form. The date of your direct OHRA report should be documented in your log.

Reporting

**Individual Issue Reporting in “Real time”**

**What to report:**

For Deviations; the following should be reported to the OHRA as soon as possible after identification and PI assessment:

* Deviations that negatively affect participant safety or rights or welfare or willingness to participate.
* Deviations that negatively affect the data integrity of the study

For Reportable Events; an incident is determined to be reportable to the OHRA as soon as possible after identification and PI assessment when it is **both**:

1. Probably or definitely related to participation in the research
2. Unexpected in terms of nature, severity, or frequency

If you are Unsure: If you are unsure if an issue requires reporting, please contact the OHRA for assistance. The nature of research means new scenarios are occurring all the time and may not fall cleanly into a particular category.

**How to report in real time:**

If you have determined that an issue requires a real time OHRA Issue Report, please download the Issue report form from the Applications page of the OHRA website and submit it through the ON-RAMP portal for the associated protocol.

The Issues report form has been generalized to capture information about issues regardless of whether it is a deviation or an event or other occurrence. Please complete the form to the best of your ability. If some information is still pending at the time of your submission, please make that clear somewhere in the form and be sure to follow up.

Your ON-RAMP submission should include the completed issues report form and any documentation of review by external parties or other supporting documents to explain the issue.

**Routine / Aggregate Reporting**

Research that requires annual renewal must provide the OHRA with documentation representing the site monitoring activities annually at the time of renewal. It is expected that the OHRA will be provided with the most up to date log of all issues (or equivalent) for assessment.

Research that does not require annual renewal must provide the OHRA with final study issues log (or equivalent) with the closure submission.