Last updated 8/18/2026

# UNMC IRB Non-compliance

## What is Non-compliance?

**Non-compliance** is failure to follow federal regulations, HRPP policies, the requirements/determinations of the IRB/ORA, or the provisions of the IRB/ORA approved study.

## What events require prompt reporting to the IRB/ORA and which ones do not?

In general, events which were NOT known in advance by the research team (for example, were the result of noncompliance by the participant, or a result of an error or oversight by the research team or an ancillary service) **and** which meet the conditions below, do NOT need to be reported to the IRB/ORA.

### Events that generally are not reportable to the IRB/ORA:

1. ***Missed or Late Labs/Exams***

   Labs or examinations (including radiographs or scans) not performed, or performed outside of the protocol-defined window are **not reportable** if they:

   (a) are **not** intended to reduce risk to subjects or assess safety of the intervention; AND

   (b) are **not** related to the primary scientific aim of the research

2. ***Missed or Early/Late Study Interventions:***

   Administration of the intervention being studied in the research (drug, device, or biologic, or other intervention) is not performed or performed outside of the protocol-defined window, are **not reportable** if:

   (a) no additional labs and/or exams are needed to monitor for consequences of missed or early/late intervention; AND

   (b) missed or early/late intervention would **not increase risks** to subject; AND

   (c) missed or early/late intervention would **not have an adverse effect** on the ability of the research **to achieve the primary aim**

### Events that MUST be reported:

Report promptly to the IRB/ORA:

- Events which were known in advance by the research team or for which the research team gave permission without prior IRB/ORA review (e.g. the alteration of protocol activities or timing)
- Events which are the **same or substantively similar to** previous noncompliance events (such as events occurring more than twice for the same subject or more than three times in the same protocol).

## What should you do if there is a planned protocol deviation?

A **Single Subject Protocol Deviation** request must be submitted and approved by the IRB **before** implementing a one-time change to the IRB-approved application for one subject.

- Changes to eliminate or prevent an apparent, immediate hazard to the research subject may be instituted immediately (before IRB approval).
    - These actions are reported after the fact on an incident report.
    - Each single subject protocol deviation request is intended for a single occurrence and generally for one specific subject.
    - If the same deviation is submitted multiple times, the IRB may require a change in protocol.

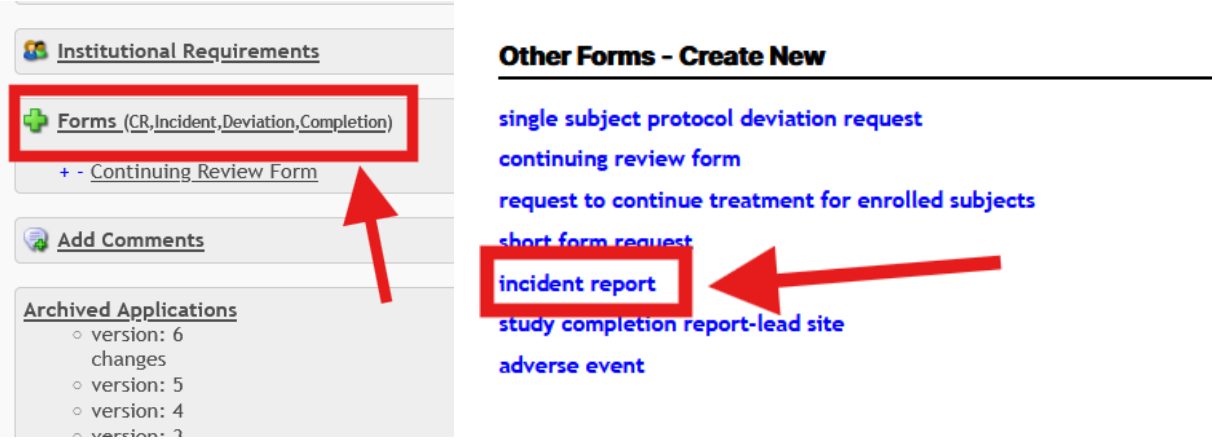
*Example*:
The protocol requires a subject have an MRI within 30 days prior to enrollment. An investigator may submit a single subject protocol deviation request to enroll a subject that had an MRI 35 days prior to enrollment but otherwise meets all other eligibility criteria.

If the request was submitted AFTER the subject had already been enrolled, this constitutes **noncompliance** and is submitted on an incident report.

## Non-compliance occurred; now what?

If the non-compliance needs to be promptly reported, as above, complete and submit an Incident Report through RSS.

1) Open the application in RSS
2) On the left-hand menu, click “Forms”. A pop-up will appear.
3) Click “incident report” in the pop-up menu.




**NOTE**: Some incidents may be combined on one report.

*Examples*:

- The same incident occurred with multiple subjects
- The same subject had multiple similar incidents occur

**NOTE:** For more information about completing and submitting an incident report, please refer to the RSS Training Guide titled “How to submit an Incident Report” available on the UNMC IRB Guidebook.

## When does the incident report need to be submitted?

- Within 10 business days of the research team becoming aware of the event, or
- Within 5 business days if **the noncompliance was associated with harm**.

## What if non-compliance occurs on a Central IRB study?

- Non-compliance must be reported to the reviewing IRB
    - If the reviewing IRB determines that the non-compliance is serious or continuing, or represents an Unanticipated Problem (UP), you **must** upload a copy of their findings/notification to RSS
    - Regardless of the determination, you are encouraged to upload the documentation from the CIRB