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?

1. All non-compliance events which include, but not limited to, events which:
    a. cause harm to subjects or others
    b. increase risks to subject
    c. have an adverse effect on the ability of the research to achieve the primary aim
    d. the research team gave "permission" for the labs/exams or interventions to be missed or to be performed early/late, without prior IRB/ORA review
2. Non-compliance events which are the **same or substantively similar to** prior non-compliance events. This includes the same or substantively similar events:
    a. occurring **more than twice for the same subject**, or
    b. occurring **more than three times for the same protocol** (even if individual events would otherwise satisfy the conditions for delayed reporting otherwise)

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.

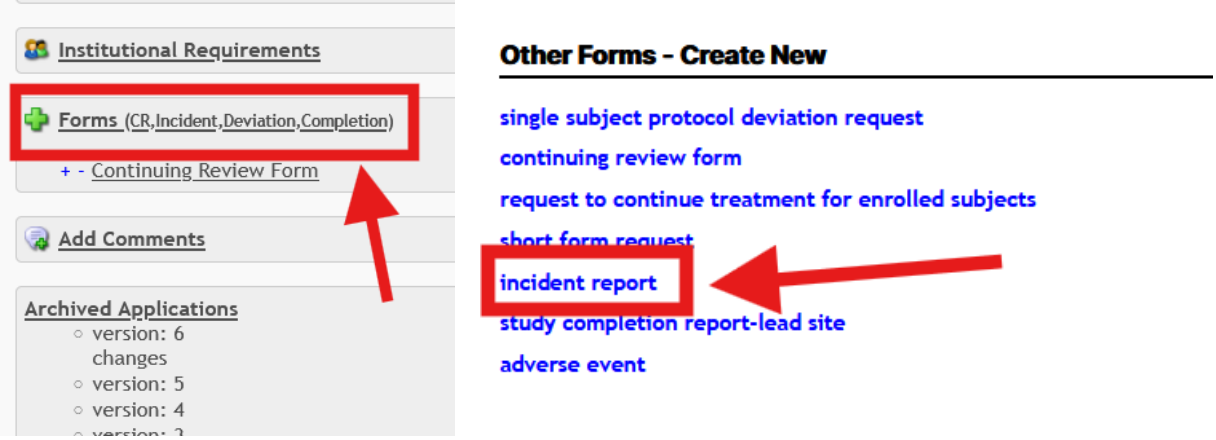
Example:
The protocol requires a subject have an MRI within 30 days prior to enrollment. An investigator may submit a single subject protocol deviation request to enroll a subject that had an MRI 35 days prior to enrollment but otherwise meets all other eligibility criteria.

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