IRBIS changes, effective 6:00 PM, June 28, 2018

IRBIS 5.09.12 Update:

Progress Report, Question 7
Minor Deviations Reporting

This change will be activated at 6 PM on Monday, July 2.

Prior:

Have there been any deviations since the last renewal? * ○ Yes ○ No
Please summarize all deviations, including those documented in monitoring/audit reports, if applicable. Do not list individual events.

Revised:

7. Please review OHRE SOP 1401 on New Safety Information reporting
Select one of the following: *
1. ○ I have reported all deviations, identified within this review period, that qualify as New Safety Information per OHRE SOP 1401. All other deviations are documented in the Protocol Deviation Tracking Log.
2. ○ I have NOT reported all deviations, identified within this review period, that qualify as New Safety Information per OHRE SOP 1401.
   Please submit a New Safety Information (NSI) Submission(s) in IRBIS at this time and as applicable. In the NSI submission, include an explanation why the deviation(s) was not submitted promptly per OHRE SOP 1401 and a plan for ensuring timely submission going forward.

If a modification, renewal, or closure was generated for a study determined to be NHSR – the screening question would automatically be updated to be a full application. This automatic function has been deactivated, as it was a source of much confusion.

The consent template manager has been re-designed in IRBIS for better management of documents.

For stipulations that have been edited, IRBIS has been corrected to display both the original author and last edited by author on all screens where this information is available.
Multi-site Engagement Activities:

The role text has been revised to include new checkbox options to better clarify engagement status.

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Faculty Advisors (FA), who are also listed as Departmental Approvers, were being displayed the incorrect role certification text. This has been corrected such that the see the FA certification text. They continue to be unable to certify on behalf of the department for projects where they are a member of the research team. A secondary Departmental Approver is required.
IRBIS has been updated to include a hardstop for COIs generated for UNC Entities from Risk Manager COI system (similar to AIR hardstop). This will be turned on Friday afternoon, June 29.

As a reminder, in the event there is an issue with a COI and an override is needed, the following staff have the ability to override by entering an audit worthy justification:

- Elizabeth Kipp Campbell, Cassie Myers, Laura Cowan, Mike Matamoros, Jeanne Lovmo, Carter Church, and Cat Collins.

Override notifications are also sent to the appropriate COI office.

The expedited checklist has been revised:

*This change is still under development and may be delayed slightly*

New options include:

- **Criterion Not Applicable** option for question 5
- **Undetermined**
  - Selection of this option does not carry over to the next review. When responses to stipulations are re-submitted, you will be presented with a blank checklist, if applicable.
  - “Undetermined” should be used when no review or only an administrative review is completed. E.g. the information/documents provided in the submission are not sufficient for IRB to review the 111 criteria for approval; the application is returned to PI, at their request, to make changes after they submitted to the IRB.
- **111 Criteria met**
  - Selection of this option will consider the checklist requirement complete for this review and the rest of the submission unless it is de-selected. Subsequent review will NOT require the checklist item to be confirmed. If additional information is discovered affecting the 111 criteria, this option may be de-selected and the checklist will be re-instituted.
  - “111 criteria met” should be used once the criteria for approval are met and remaining stipulations are not related to the 111 criteria (i.e. administrative stipulations). E.g. the remaining stipulations are to provide a clean copy of the consent form, provide CITI training documentation for an investigator, etc.
- **Not required** (existing option, but included to describe proper use)
  - Selection of this option will turn off the checklist requirement for this review and the rest of the submission unless it is de-selected. This option requires a note as to why it is not required.
  - “Not required” should be used when the submission is not reviewed to determine the status of the 111 criteria. E.g. administrative modifications such as personnel changes; renewals for data analysis only when the appropriate confidentiality protections are documented.