IRBIS 5.09.12 Update:

Progress Report, Question 7
Minor Deviations Reporting

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

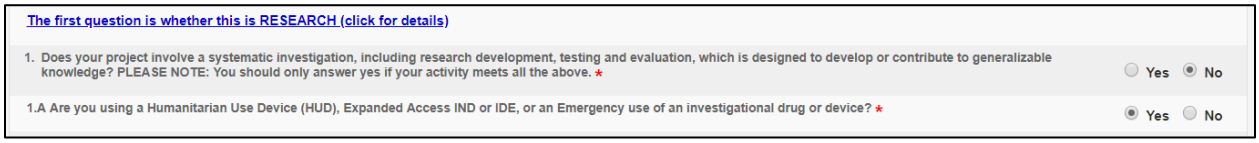
Prior:

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:

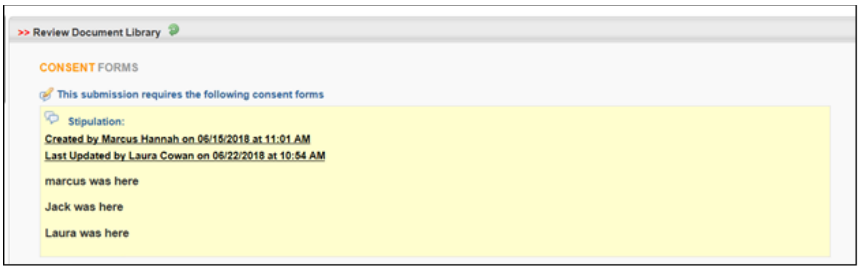
7. Please review OHRE SOP 1401 on New Safety Information reporting Select one of the following: * 1. ❍ I have reported all deviations, identified within this review period, that qualify as New Safety Information per OHRE SOP 1401. All other deviations are documented in the Protocol Deviation Tracking 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.



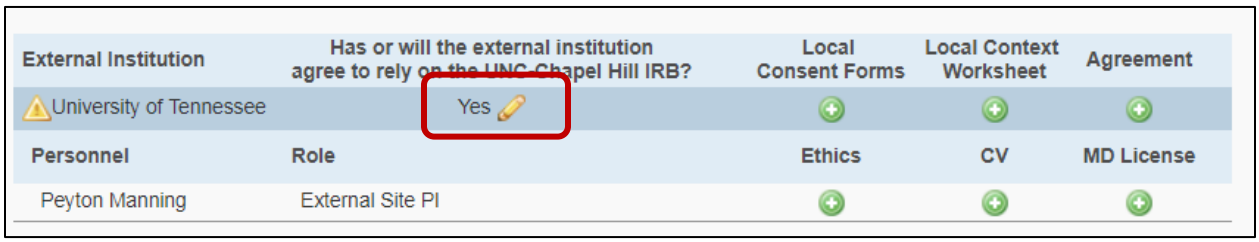
The consent template manager has been re-designed in IRBIS for better management of documents.

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.

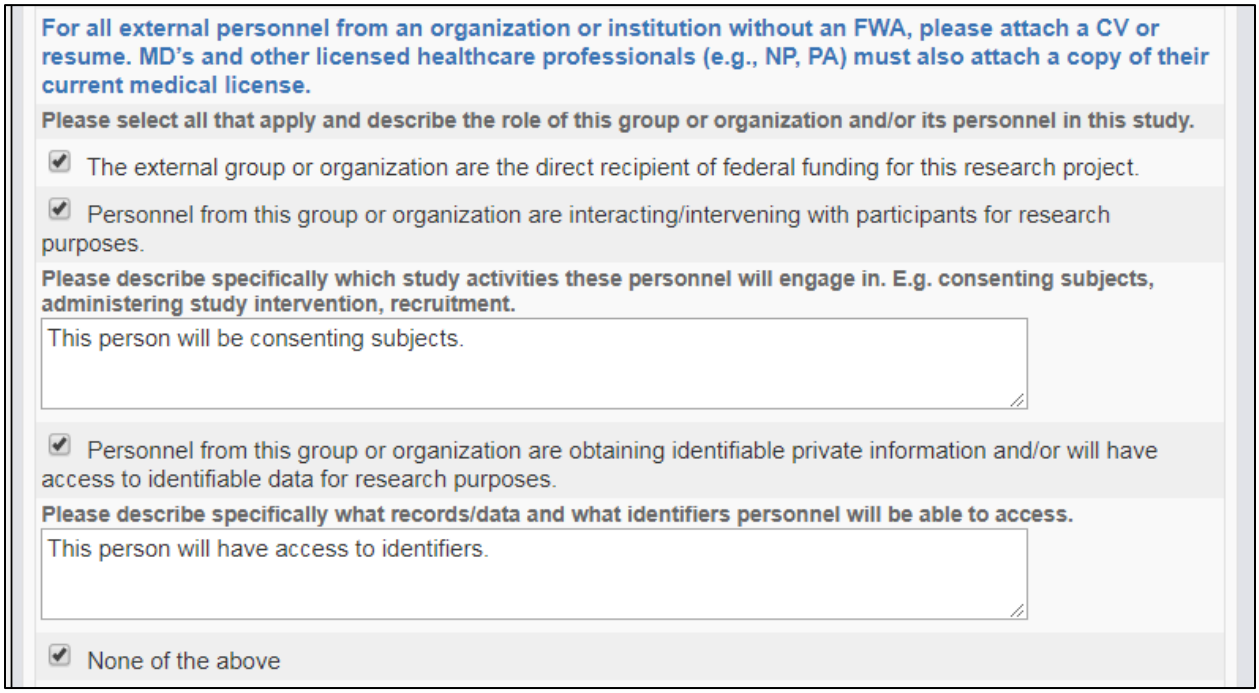


Multi-site Engagement Activities:

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



External Institution	Has or will the external institution agree to rely on the UNC-Chapel Hill IRB?	Local Consent Forms	Local Context Worksheet	Agreement
University of Tennessee	Yes			
Personnel	**Role**	**Ethics**	**CV**	**MD License**
Peyton Manning	External Site PI			



For all external personnel from an organization or institution without an FWA, please attach a CV or resume. MD's and other licensed healthcare professionals (e.g., NP, PA) must also attach a copy of their current medical license.

Please select all that apply and describe the role of this group or organization and/or its personnel in this study.

- [x] The external group or organization are the direct recipient of federal funding for this research project.
- [x] Personnel from this group or organization are interacting/intervening with participants for research purposes.

Please describe specifically which study activities these personnel will engage in. E.g. consenting subjects, administering study intervention, recruitment.

This person will be consenting subjects.

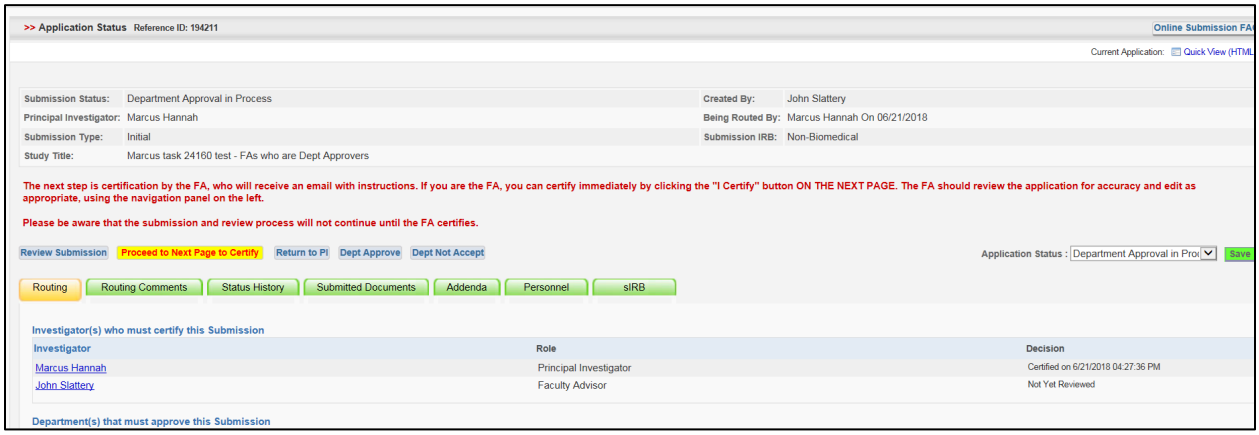
- [x] Personnel from this group or organization are obtaining identifiable private information and/or will have access to identifiable data for research purposes.

Please describe specifically what records/data and what identifiers personnel will be able to access.

This person will have access to identifiers.

- [x] None of the above

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.



>> Application Status Reference ID: 194211

Online Submission FA

Current Application: Quick View (HTML

Submission Status:	Department Approval in Process	Created By:	John Slattery
Principal Investigator:	Marcus Hannah	Being Routed By:	Marcus Hannah On 06/21/2018
Submission Type:	Initial	Submission IRB:	Non-Biomedical
Study Title:	Marcus task 24160 test - FAs who are Dept Approvers		

The next step is certification by the FA, who will receive an email with instructions. If you are the FA, you can certify immediately by clicking the "I Certify" button ON THE NEXT PAGE. The FA should review the application for accuracy and edit as appropriate, using the navigation panel on the left.

Please be aware that the submission and review process will not continue until the FA certifies.

Review Submission | Proceed to Next Page to Certify | Return to PI | Dept Approve | Dept Not Accept

Application Status : Department Approval in Pro Save

Routing | Routing Comments | Status History | Submitted Documents | Addenda | Personnel | sIRB

Investigator(s) who must certify this Submission

Investigator	Role	Decision
Marcus Hannah	Principal Investigator	Certified on 6/21/2018 04:27:36 PM
John Slattery	Faculty Advisor	Not Yet Reviewed

Department(s) that must approve this Submission

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.