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New IAA with NCI CIRB
A new IRB Authorization Agreement (IAA) with the NCI Central IRB (CIRB) was executed by Dr. Norton, the UF Vice President for Research, on 7/31/19. Updates were made to address the responsibilities of institutions when participants become incarcerated while participating in a research study.

- The responsibilities of the NCI CIRB are to:
  - Review investigator requests for enrolled participants to continue on a CIRB-approved study while incarcerated.
  - Conduct a convened review for enrolled participants on a study to fulfill the regulatory requirements of 45 CFR 46 Subpart C.

- The responsibilities of the Signatory Institution are to:
  - Notify the CIRB if a study participant becomes incarcerated while enrolled in a study under the CIRB’s purview. If the investigator deems it in the best interest of the study participant to remain on the study while incarcerated, provide justification to the CIRB.

*Researchers: Please attach a copy of the updated IAA in Q5.0 of the sIRB Ceded Site SmartForm.*

Status Report vs Continuing Review
As of January 21, 2019, continuing review of minimal risk research is no longer required for protocols approved under an Expedited research category. Such minimal risk research will be moved to Status Report and receive approval for 3 years in lieu of submitting an annual continuing review.

What is a Status Report?
This is the University of Florida’s way of implementing the Common Rule by approving follow-up reporting. Principal Investigators (PIs) will be prompted every three years to indicate whether a study is continuing or closing, nothing more. Also, a PI does not need to wait the 3 years to submit a Status Report to close the study; this can occur at any time.

What about revisions and reportable events?
PIs will still be responsible for submitting any revisions and reportable events per our reporting guideline. The responsibility for tracking events does not disappear with continuing reviews going away. PIs still need to continue to track events that individually would not be reportable in order to determine any changes in frequency and/or severity that might need to be reported.
Our expedited study is due to expire in three weeks, are we automatically moved to a Status Report?
If your study was approved prior to the implementation of the Common Rule changes in January, you will need to submit a continuing review in myIRB prior to the expiration date. If the reviewer deems that your study no longer requires continuing review, it will be moved to a Status Report.

Help! The PI wants me (a coordinator) to create a study closure for an expedited student survey study, but I do not see an option to close the study.
If this study was approved before January 21, 2019, the coordinator will not see the New Continuing Review/Closure button below the My Activities heading if there is a revision in pre-submission because a revision and Continuing Review/Closure cannot be in process at the same time;

OR

If the study was approved after January 21, 2019, the coordinator will not see the Status Report button because it can only be seen and submitted by the PI.

If a Full Board study is moved to longitudinal status (i.e., long-term follow-up) is it also moved to Status Report?
It depends. If a Full Board study is under “FDA Oversight” (a study involving a drug or medical device) is moved to longitudinal status, it can move to Executive Review/Expedited Review, but it must have a continuing review each year.

For additional information, please refer to the:

Investigator Guideline Updates
New
- Approved Human Research Roles - University of Florida
- External-Faculty-Joining-UF - New Hires Guideline

Updated
- Event-Reporting Guideline – The intent of this guideline was not changed. The language was tweaked to help clarify when reportable events and deaths should be reported.

HIPAA Waiver of Authorization SmartForm Reminder
When asked to provide the protected health information (PHI) that you will collect, create, use or disclose (disclose=outside the covered entity), under this waiver in Q1.0, please do not just list the HIPAA identifiers (i.e., name, medical record number and dates). Please include the health information; PHI = identifiers + health information (i.e., medical record number, dates + test results, diagnosis, etc.).

Supported Browsers for myTraining
Chrome, Firefox, and Internet Explorer 11 are supported browsers for myTraining. EDGE is not supported, and Safari is not recommended.