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### Stamped Consent Forms

According to the Code of Federal Regulations 45 CFR 46.116, researchers must obtain legally effective informed consent from human subjects or their legally responsible representative before any research-related screening or intervention commences using only the currently approved, stamped Informed Consent Form, when applicable. Researchers are reminded to use a stamped consent form in their approval letters; however, reviewers are finding that unstamped consent forms are being attached at continuing review.

To prevent reporting a reportable event for non-compliance for using an unstamped consent form and potentially not being permitted to use the data, please access the stamped informed consent form(s) correctly from the Stamped Docs tab in myIRB.
Certificates of Confidentiality

A new Certificate of Confidentiality (CoC) policy went into effect on October 1, 2017; whereas, NIH awardees no longer have to apply for a CoC. All ongoing or new research funded by the NIH as of December 13, 2016 that is collecting or using identifiable, sensitive information is automatically issued a CoC through a term and condition of award.

CoCs, however, are not limited to federally funded research. CoCs may be issued to cover any research that is considered “sensitive” and eligible for CoC protection if the non-federally funded study involves the collection of identifiable information (including enrollment), which, if revealed, could harm the financial standing, employability, insurability, or reputation of a research subject (i.e., collection of information pertaining to illicit drug use, HIV status, etc.). The investigators can seek a CoC for their research on their own and inform the IRB of this in the myIRB application to the IRB, or the IRB can require an investigator to obtain a CoC.

In an effort to assist IRB reviewers with CoC determination, a Certificate of Confidentiality Determination SmartForm was added as part of the 3/8/2018 myIRB upgrade. Unbeknownst to IRB staff and reviewers, Q1.0 defaulted to “No”; whereas, multiple research projects were sent back to researchers to change their response to “Yes” because they were collecting HIPAA identifiers and to answer Q1.1 (which will only blow in if “Yes” is selected) appropriately so the reviewer could determine if your research involves identifiable, sensitive information.

This issue has been corrected; however, it is recommended that you click on the 18 HIPAA Identifiers link in Q1.0 to ensure that you select “Yes” or “No” accordingly.

For more CoC policy and application instruction information, please refer to the Certificates of Confidentiality Guideline.
**Expedited Review**
The IRB office receives frequent inquiries regarding the status of expedited submissions. Please note that Expedited Review means a review by an executive IRB reviewer rather than by the Full Board at a convened meeting. It does not mean “fast”. Researchers, however, can “quicken” the review and approval process by referring to the [myIRB Researcher Manual](http://research.ufl.edu/myirb), the [guide for requesting the correct review type](http://research.ufl.edu/myirb), the IRB policies, guidelines and guidances, and by contacting the appropriate IRB office listed in the header of this newsletter.

**For your research information**

a. Office of Research Portal ([http://research.ufl.edu/researchportal/](http://research.ufl.edu/researchportal/)): one stop shop with contact information for most institutional level research resources.

b. Transferring /New Investigator at UF form ([http://research.ufl.edu/forms/newresearcher.html](http://research.ufl.edu/forms/newresearcher.html)): help new researchers to facilitate research at UF.

c. Leaving UF form ([http://research.ufl.edu/forms/notification-of-departing-pi.html](http://research.ufl.edu/forms/notification-of-departing-pi.html)): help all impacted units close out or transfer research for departing researchers.

d. Human Research Protection Program (HRPP) ([http://research.ufl.edu/hrpp.html](http://research.ufl.edu/hrpp.html)).