November 2021

Human Research Protection Program (HRPP) And Institutional Review Board (IRB) Newsletter

REMINDERS

- **Use Wufoo to submit your protocol:** All types of protocol submission should be submitted using the appropriate Electronic Application Form in Wufoo. Emailed protocol submissions will be returned. Links to the electronic application forms can be found in the instructions at the top of each submission form.
- **To speed up IRB review, ensure your submissions are complete and contain all requested information.** When completing your Research Plan use the Research Plan Guidance document to ensure you provide all the information the IRB requires when making a determination/approval.
- When submitting documents, please use the **original format** of the document. Google and pdf. documents are not editable by the IRB.

Do You Have a Question?

Contact the HRPP/IRB Office at 910-893-7780 or email us at irbadmin@campbell.edu

IMPORTANT INFORMATION

1. NEW Two new guidance documents regarding retention of human subjects research regulatory documentation (see below) can be found in the Guidance Library on the IRB website.
2. UPCOMING Research Banking Project Information & Training Educational Video will be available soon.
3. REMINDER Due to Winter Break the IRB will not be processing new submissions between 12/19/21 – 1/1/22. The deadline to secure IRB determination/approval by the start of Winter Break is 12/10/21. The IRB will continue to work on submissions but is unable guarantee a final determination/approval submitted after 12/10.
4. REMINDER Check the IRB website routinely as new educational videos, presentations and guidance is being added continually.
5. REMINDER Faculty with students conducting human subjects research projects during the Spring Term should submit their IRB applications as soon as possible. The IRB advises Spring Term projects which require completion by 6/2022 to be submitted prior to 2/28/2022.

As always, the use of the most current version of an IRB document (found on the IRB website) will improve the speed of the IRB review process. Remember to set your browser to refresh, this will ensure you are viewing current information and documents.

Q:Do you know what IRB regulatory documentation to retain?

A: The regulatory documentation an investigator is required to retain is dependent on which regulatory statute or institutional policy the IRB granted approval. FDA regulated research requires more regulatory documentation to be kept as compared to research approved by institutional FLEX review. At Campbell the IRB expects investigators to retain the following for each IRB-approved project:

- All IRB submission forms (New Protocol, Amendments, Closures, etc.)
- All versions of the IRB-approved Research Plan & informed consent documents with the IRB approval watermark.
- All IRB letters
- All documents submitted to the IRB for approval and/or approved (e.g., recruitment materials, surveys, data collections tools, DUAs, Reliance Agreements, Letters of Support, etc.)
- Human Subject Research Protection Training documents
- Any Conflict of Information Documentation.
- Other research materials associated with the project, such as but not limited to, signed consent forms, paper surveys, field notes, data spreadsheets, transcripts, screening logs, subject shadow files, etc.

The documents listed above except for the last item, must be found in a Regulatory File/Binder for each IRB-approved protocol. Regulatory Binders can be retained in paper or electronically. Other research materials may be retained in either paper (e.g., paper survey or research written notes) or electronically, if appropriate.

All protocol documentation, including source documents, must be retained for a minimum of 3 years or 6 years (HIPAA covered information) after the IRB has approved the project closure.

Please see IRB Guidance: Regulatory File/Binder Checklist and Guidelines for Documentation of Human Subject Research for a detailed list of documents.