December 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. 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 has passed.
2. REMINDER Faculty with students conducting human subjects research projects during the Spring Term should submit their IRB applications as soon as possible. Faculty with expired IRB-approved protocols must submit a Closure Form or Progress Report for those projects before the IRB will accept any new submissions.
3. NEW Information on the 2021 NIH Virtual Seminar can be found on the IRB website under Resources for Investigators. There are many presentation topics available. The IRB suggests viewing *OHRP: What is Human Subjects Research Part I & Part II*.
4. REMINDER Check the IRB website routinely as new educational videos, presentations and guidance is being added continually.
5. CHANGE The *Continuing Review Submission Form* has been removed from the website. Currently the IRB does not have any projects approved that require the use of this form.

Remember to set your browser to refresh, this will ensure you are viewing current information and documents.

Q: Does data collected during a retrospective record review qualify for review as Exempt, Category 4: Secondary research for which consent is not required?

A: It depends on how the researcher will record the data collected from the medical record.

To qualify as *Exempt, Category 4* the investigator must be accessing the medical record containing identifiable private information/biospecimens and recording/collecting the information in a way that the identity of the subjects cannot be readily ascertained directly or through identifiers linked to the subjects and the investigator does not contact or try to re-identify the subjects. This would qualify as secondary research and no consent would be required but a HIPAA authorization or waiver of HIPAA granted by the IRB is required.

If an investigator is accessing identifiable medical records and recording identifiers, the project is not secondary research, it is primary research and requires obtaining consent or waiver of consent and a HIPAA authorization or waiver of HIPAA to be granted by the IRB. Typically the IRB would grant approval under an *Expedited Review, Category 5*.

Secondary research typically involves the use of data/biospecimens that has been collected for non-research purposes, such but not limited to, patient treatment records, pharmacy records, registry information, data/biospecimens collected for another previously conducted research project.

Note: if your project is not federally funded and meets the criteria for **FLEX Review the IRB will use the FLEX review process**. The FLEX Review categories allow for the collection of information in both a de-identified manner and identified manner (combination of Exempt, Cat.4 and Expedited, Cat. 5). For detailed information on Medical Record/Chart review, review criteria and submission information please see IRB Guidance: Medical Record/Chart Reviews.