

# 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

## Do You Have a Question?

Contact the HRPP/IRB Office at 910-893-7780 or email us at [irbadmin@campbell.edu](mailto:irbadmin@campbell.edu)

## IMPORTANT INFORMATION

1. **NEW** Dr. Stephen Holly from Pharmaceutical Sciences is the new IRB Chair and can be reached at [irbchair@campbell.edu](mailto:irbchair@campbell.edu).
2. **NEW** Educational Opportunity for potential & current NIH Investigators. 2021 [NIH Virtual Seminar on Program Funding and Grants Administration](#) is being held November 1 - 4 and registration is free. Check out the [Agenda!](#)
3. **ADDED** The following educational videos have been added to the "Resources for Investigators" page on the IRB website.
  - [When PI's Come A-Knockin': Everything Investigators Want to Know but are Afraid to Ask](#)
  - [When Does the Common Rule Apply](#)
  - [Institutional Engagement in Human Subjects Research](#)
  - [Regulatory Options for Secondary Research with Private Info and Biospecimens Pt. 1](#) and [Pt. 2](#)
  - [Webinar: What You Should Know About IRB Review of Research](#)
4. **ADDED** Guidance on [FERPA Data De-identification: An Overview of Basic Terms](#) on the "Guidance Library & FAQ" page of the IRB website.
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 submission prior to the beginning of the Spring term.

*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.*

## Q:What type of review is required for an interventional research study?

A: Most interventional studies require Expedited or Full Committee review. At Campbell most interventional studies are "no greater than minimal risk" requiring Expedited review. There are two exceptions for reviewing "no greater than minimal risk" studies on adults which do not require Expedited review. They are:

1. If the project **IS** federally funded or research activities require review under federal regulations.
  - Exempt, Category 3: May be used if the research is not greater than minimal risk and the study meets the criteria for Benign Behavioral Intervention\*; **or**
2. If the project is **NOT** federally funded or research activities **DO NOT** require review under federal regulations and the study meets the criteria for Registration Project/FLEX review.
  - Registration, Category 10: May be used if the research is not greater than minimal risk and is a psychosocial intervention that meets the same criteria as for Benign Behavioral Intervention\*.

*\*Benign Behavioral Interventions* "are brief in duration, harmless, painless, not physically invasive, not likely to have significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing." The brief in duration requirement only pertains to the intervention itself, and not the data collection. If the research involves deceiving the subjects regarding the nature or purposes of the research, the subject must authorize the deception through a prospective agreement. The subject is to be informed that they will be unaware of or misled regarding the nature or purpose of the research.

This type of interventional research does not apply to children. For further details and examples of benign behavior interventions please see [IRB Guidance: Benign Behavioral Intervention](#).