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



REMINDERS

- Use Wufoo not email to submit your protocol:

 All types of protocol submission are required to 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, make sure your submissions are complete and contain all 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 or approval.
- When submitting documents, please use the <u>original</u> format of the document. The IRB does not accept google format or MSWord documents reformatted as a pdf. document.

Do You Have a Question?

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

IMPORTANT INFORMATION

- 1. <u>UPDATE</u> Dr. van Tilburg is no longer the IRB Chair. Dr. Alfred Bryant is now the Vice Chair and a new IRB Chair will be appointed soon.
- 2. <u>UPDATE</u> Make sure to update your IRB website address on your browser each time you open the site to ensure access to the newest information and forms.
- 3. <u>NEW</u> The IRB website has been updated and has a new look. Look under <u>For Investigators</u> for almost anything you need. There are special pages for <u>New Investigators</u> and <u>Determining If Your Project Requires IRB Review</u>.
- 4. <u>NEW</u> IRB submission forms, submission attachment forms, and consent documents have been updated. Please use the revised forms when submitting for IRB review.
- NEW <u>Fundamentals of Qualitative Research Methods</u> a six module educational information video presentation conducted by Leslie Curry, PhD, MPH in association with Yale Global Health Leadership Institute has been added to the <u>Resources for Investigators</u> page of the IRB website.
- 6. <u>REMINDER</u> Undergraduate research for *education only* in the classroom submissions are due at least one month prior to the anticipated project(s) start date.

As always, the use of the most current version of IRB documents (found on the IRB website) will improve the speed of the IRB review process. This allows researchers to receive an IRB decision and start research activities sooner.

Q:What is the difference between Registration/FLEX review and Exempt or Expedited Review?

A: All of these review types are for no greater than *minimal risk* research and there are several differences between the 3 types of reviews. The important difference is Exempt & Expedited review apply to research that is funded by a federal agency or the research is required to be reviewed under federal regulations.

Registration/FLEX research categories are a combination of activities that would normally meet the criteria of Exempt and a few that would normally be considered Expedited.

If your research is **NOT** federally funded or regulated check to see if it meets all 8 criteria for FLEX review. If all criteria are met, then check if your research meets 1 or more of the 10 categories. If your research does, this is how you should be submitting your research protocol to the IRB for determination/approval. Please refer to the IRB website for further details regarding consenting requirements for Registration/FLEX projects.

Registration Project/FLEX criterial

- Project activities no greater than minimal risk
- No/has never been federal support for project
- 3. No Student/Fellow federally funded support (directly or indirectly)
- 4. Without contractual obligations or restrictions prohibiting this type of review
- 5. No prisoner involvement
- 6. No reliance agreement involved
- 7. No data/biospecimen local banking involved
- 8. Not an international project

Registration Project/FLEX Categories

- 1. Educational research
- 2. Surveys, interviews & focus groups & some observational research
- 3. Biospecimens collected/to be collected solely for non-research purposes
- 4. Taste & food quality evaluations
- 5. Blood draws via venipuncture, finger, heal or ear-stick
- 6. Prospective collection of biospecimens via non-invasion procedures
- 7. Prospective collection of data via non-invasive procedures
- 8. Materials (data, documents, etc.) that have been or will be collected for research or non-research purposes
- 9. Collection if images, video, or audio recordings solely for research
- 10. Psychosocial interventions, including benign behavioral intervention which may or may not involve deception