March 2021

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.
- Check the IRB website for the most up to date information.
- When submitting documents, please use the **original** format of the document. The IRB does not accept google format or MSWord documents reformatted as a pdf. document.
- While the IRB is constructing our new website some links may not be working properly. Please email or call the IRB Office and we will provide you with the information directly.

Do You Have a Question?

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

IMPORTANT INFORMATION

1. DETERMINATION TOOL If you are unsure if your project is research or is human subjects research please use the Human Subject Research Determination Sheet before submitting any documents to the IRB for determination or review.
2. REMINDER **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. There must be detailed, complete and adequate information in each area of the Research Plan to meet specific criteria before the IRB or IRB reviewer can make their decision. These criteria are in orange italicized print at the start of each section in the Research Plan Guidance document.
3. NOTICE The IRB sent notifications regarding exempt project status to investigators on 2/9 and 2/10 with IRB approved protocols. All Investigators with IRB Protocols approved prior to July 1, 2018 were to contact the IRB. The IRB requires an updated protocol status, if the protocol is ongoing, submit a Progress Report or if the research is complete, submit a Closure Form. The IRB will be sending reminder notification beginning 3/22/2021.

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:Why was my new protocol submission returned as inadequate?

A: The following chart provides the three main reasons and solutions for receiving an inadequate submission notification.

Reasons	Solutions	Tools
Lack of information to determine IRB approval criteria have been met.	• Provide clarification of specific research activities or circumstances surrounding the research activities. • Provide justifications for activities to be approved by the IRB. • Provide specific mechanisms to ensure privacy, confidentiality and safety of research activities and collected information.	• Research Plan Guidance & IRB Investigator Manual • Individual guidance documents and/or procedure documents regarding the specific type of research you are conducting. • Contact the IRB with questions or for consultation prior to submission.
Insufficient scientific justification for the research protocol or plan.	• Provide a clearly identified research purpose. • Provide all risks associated with the conduct of the research activities. • Ensure risks are not greater than the anticipated benefit of conducting the research. • Understand “minimal risk” does not mean “no risk”. • Some risks are unknown.	• Complete a through literature review prior to writing your Research Plan to enable you to identify a gap in the published research. Develop a specific research question to be answered. • Use information on the IRB website to identify risks associated with your specific research activities and how to reduce those risks.
Improper, missing and/or incorrect supporting documentation. *This is the most common reason for receiving an inadequate submission notification.*	• Plan accordingly and allow sufficient time to prepare your submission before submitting to the IRB. • Students should meet with Faculty Advisors prior to submission to ensure completeness. • Verify all study team members have completed human subjects research protection training.	• Use the checklist at the end of the new protocol submission form. • Organize submission documents prior to attaching to the electronic submission form. • Have study team member double check all documents are complete and available to submit.