Human Subjects Research Protection Program (HRPP)
and Institutional Review Board (IRB)
October 2020 Newsletter

Below are reminders and updates from the Campbell IRB. Please reach out to us for any questions at irbadmin@campbell.edu. before you initiate research, especially if students are involved.

REMINDERS:

- COVID 19 and Human Subjects Research is still in effect.
- 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.
- Check the IRB website for the most up to date information.

UNDERGRADUATE RESEARCH IN THE CLASSROOM?

If you are planning any research in the classroom for undergraduate courses, please contact the IRB as soon as possible but in no later than 1 month before your class starts. Please read the standard operating procedure on undergraduate classroom research.

EFFECTIVE JULY 2, 2020:

1. NEW Protocol Submission Form, Research Plan Template & Research Plan Guidance: The New Protocol Submission Form, Research Plan Template and Research Plan Guidance have been published on the IRB website and **must** be used for all new submissions starting 7/2/2020. The research plan should describe the proposed research in sufficient detail so that the IRB can determine if approval criteria for humans subjects research is met. The research plan document will be a living document throughout the life-time of the protocol and will need to be updated with the submission of amendments and continuing reviews, if applicable. The IRB highly recommends using the Research Plan Guidance document when completing your research plan. The following Research Plan supplemental documents have been added to the IRB website: Research Plan Appendix A: HIPAA-Use of PHI, Research Plan Appendix-B: Banking-Projects, and Research Plan Appendix-C: Genetic Materials/ Information/Tests.

2. NEW Banking Projects: A new type of research project, called “Banking” is now available for researchers wishing to collect information and/or biospecimens for unspecified, future research with use of an Academic Banking Consent, Biomedical Banking Consent or Distant Banking Consent Module Template. This type of project can be in addition to a researcher’s main project, can be a stand-alone project. Examples of banking projects:
    - Recruitment banks for collection names and contact information
    - Academic banks for collection of student records for future research use.

3. NEW Students may no longer be PIs: In a recent IRB meeting it has been decided that students can no longer be principal investigator (PI) at Campbell. The student’s faculty advisor will be required to serve as the PI. This is to protect the students, faculty and institution as well as to ensure appropriate oversight of student-led projects. Students are allowed and encouraged to be co-investigators on research projects. This change will not affect the scientific contributions of students to research projects and students can still be primary authors on any presentation or publication resulting from a research project.

4. NEW IRB Conflict of Interest in Research and Disclosure: Federal regulations require the IRB to review human subjects research protocols for potential conflicts of interest (COI). Currently at Campbell this only applies to human subject research managed or funded by the Public Health Service (PHS) and their components, which includes NIH, and the National Science Foundation (NSF). Detailed information regarding COI can be found in HSR311-IRB SOP: Conflict of Interest (COI) in Human Subjects Research and must be reported to the IRB using IRB Investigator Conflict of Interest (COI) Disclosure Form.

5. The following additional documents have been added or revised and can be found on IRB website:
    - HSR330-IRB SOP: Human Subject Research Protections Training Requirements
    - HSR380-IRB SOP: Compensation of Research Subjects
    - HSR750-IRB SOP: Banking Projects
    - Institutional Consent Template
    - Campbell HIPAA Authorization-Form Template
    - IRB Guidance: Compensation in Human Subjects Research
    - IRB Guidance: Informed Consent and Waivers
    - IRB Guidance: HIPAA and Human Subjects Research
    - IRB Guidance: Identification Levels in Research
    - IRB Guidance: Use of Internet Survey Platforms in Research
    - Human Subjects Research Determination Worksheet
    - Not Human Subjects Research (NHSR) Submission Form
    - Investigator Agreement Form

Continue to check the IRB website for revised documents. The changes listed above will require revisions to many associated IRB documents, guidance and forms. As always, the use of the most current version of an IRB document will improve the speed of the IRB review process.