CAMPBELL UNIVERSITY	**IRB SOP:** IRB New Protocol Submission		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-520	Miranda van Tilburg, PhD IRB Chair, IRB Office Campbell University	12/02/2020

Applies to Campbell faculty, faculty advisors, students and staff conducting or overseeing human subjects research.

Purpose

This procedure establishes the process for a Principal Investigators to submit a New Protocol Submission Form and Research Plan to the IRB for determination and/or approval for human subjects research.

Background

Principal Investigators must submit all new protocols or projects which involve human subjects as defined as Human Subject Research to the Campbell IRB for review and approval prior to initiation of research activities. See *Human Research Determination Worksheet* for further details if you are unsure if your research meets the criteria for human subjects research. The IRB will determine what type of review is required for the protocol based upon information provided in the submission and any attached documents. All proposals must be submitted to the CU IRB using the appropriate IRB application form available on the Campbell IRB website. In order to facilitate timely reviews and reduce paper waste, electronic applications are now used.

Lack of information or incomplete information on the IRB forms, may result in delays in the process of IRB review and approval. If you are unsure or require clarification contact the IRB Office. Please refer to the *IRB Investigator Manual for guidance* in completing an IRB application and submission.

Definitions

N/A

Principal Investigator Responsibility

It is the Principal Investigator's (PI's) responsibility to ensure that a New Protocol Submission and Research Plan is completed and submitted to allow the IRB adequate time to conduct its review of the project before conduct of the research begins. The PI bears the ultimate responsibility for knowing when IRB approval is required and securing IRB approval prior to beginning research activities.

Procedure for Protocol Submission

Use the *New Protocol Electronic Application Form* for the following listed project types:

1. **New Protocol Submission Form and Research Plan:**
   Please use this form for all projects meeting the definition of human subjects research.

   New Protocol Submission Form (found on the Campbell IRB website) which includes:

- Instructions
- Review Request
- Start and end dates
- Research Personnel
- Funding Information
- Risk Assessment
- Research Plan Information
- Recruitment and Subject Population
- Consent, Assent and Permissions
- Compensation and Reimbursement
- Other Institutions, Performance Sites and non-Campbell Personnel
- Additional Materials
- Clinical Trials
- Human Subjects Conflict of Interest
- New Protocol Submission Checklist
- Additional IRB Forms, including but not limited to Appendix A, B, and C may be required and can be found on the IRB website. All supplemental forms and documents should be attached to the *New Protocol Electronic Application Form*.

Research Plan

- The research plan describes the proposed research in sufficient detail so the IRB can determine if approval criteria for human subjects research defined in Campbell University's Registration Projects and FLEX Review Policy or in federal regulations (45 CFR Part 46) is met.
- The research plan is a narrative of the protocol and is a living document to be maintained over the life of the protocol.
- Please use the *Research Plan Template* and *Research Plan Guidance Document* which can be found on the IRB website.
- All documents should be attached to the *New Protocol Electronic Application Form*.

Here are some key points to remember when preparing your Research Plan:

- *Always keep an electronic copy. Electronic copies are also stored by the IRB in the protocol record.*
- *Note that not everything that is in the sponsor/agency project protocol will be relevant to the New Protocol Submission Form and Research Plan. You may not delete any of the primary sections in the New Protocol Submission Form or Research Plan. You may not involve any individuals who are members of the following populations as participants in your research unless you indicate this in your inclusion criteria as the inclusion of participants in these populations has regulatory implications.*
    - *Adults unable to provide legally effective consent*

- *Individuals who are not yet adults (infants, children, teenagers)*
- *Pregnant women*
- *Prisoners*

- *If you are conducting community-based participatory research, you may contact the IRB Office or the IRB website for information about:*
  - *Research studies using a community-based participatory research design*
  - *Use of community advisory boards*
  - *Use of participant advocates*
  - *Partnerships with community-based institutions or organizations*

Note:

If you received an Investigator Protocol from your project sponsor or lead project investigator for multi-site research, please complete the *New Protocol Submission Form* and *Research Plan* to document relevant local information not included in the sponsor or multi-site protocol. Upload received protocol with all other documents when completing the *New Protocol Electronic Application Form*.

2. Non Human Research (NHSR) Protocol Submission Form

Use for projects that do not meet the definition of human subjects research. The following are not considered Human Subject Research: Please see, IRB Investigator Manual.

NHSR Protocol Submission Form (found on the CU IRB website) which includes;

- Instructions
- Project & Investigator Information
- Purpose
- Data sources
- Data collected

IRB Review of New Protocol Submission

1. When a new project is received by the IRB, the IRB office will review the submission and attached documents for completeness and determine the appropriate type of IRB review based upon the risks and types of activities involved. The IRB reviews new research under the following categories:
   - Not Human Subjects Research Determination
   - FLEX Review for Registration Projects
   - Exempt Review
   - Exempt-Limited Review
   - Expedited Review
   - Convened Committee Review

In order for the IRB to approve a project, basic criteria as described in the federal regulations must be met. The determination that all criteria are met will be based upon information provided in the submission and any attached documents.

2. Protocols are assigned to next available Convened IRB Committee meeting. All protocols which do not qualify for convened IRB Committee review are assigned to a designated reviewer.
3. The IRB will notify PIs of its decision to approve or disapprove the proposed research project, or of modifications required to secure IRB approval of the research project by written notification. If the IRB decides to disapprove a research project, it will include in its written notification a statement of the reasons for its decision.
4. PIs and student researchers, if applicable, are notified of the status of a protocol within 5 business days following review by a designated reviewer or IRB Committee meeting.
5. A schedule of IRB Meetings is posted on the Campbell IRB website. During the summer months (May – August), no IRB meetings take place.
6. The IRB Coordinator should be contacted for questions related to the protocol or its review. Please reference the submission number (IRB#) and title assigned to the project when requesting assistance.

References

N/A