HSR-030

HRPP Policy: Registration Projects and FLEX Review

Date of Current Revision: 11/04/2020

Primary Responsible Officer: Institutional Official, Vice President
Vice President for Academic Affairs and Provost

Policy Number:	HSR-030	**Effective Date:**	12/04/2020
Policy Title:	HRPP Policy: Registration Projects and FLEX Review	**Revised Date(s):**	11/04/2020
Policy Type:	☐Board ☐Administrative ☐Academic ☐Student ☒Other: HRPP	**Contact:**	Shawn Leming, BA, CIP Institutional Review Board Office

Policy Statement

This policy establishes flexibility in review, administration, and oversight of human subjects research. As defined below, all registration projects must meet the listed criteria to qualify under the equivalent protections and processes (FLEX Review) as defined and outlined in this policy.

Requirements

1.0 This policy is limited to projects which meet the following criteria:

1. All project activities are no greater than minimal risk;
2. There is no/has never been federal support for this project;
3. The project does not include a student/fellow supported via a federal training grant or other federal funding including support from Faculty Advisor's federal funding;
4. Projects without contractual obligations or restrictions that preclude eligibility with this policy. For example, a project would not qualify if the sponsor's contract requires the project to be reviewed under FDA or Department of Health and Human Services (DHHS) regulations;
5. Project does not involve prisoners as subjects;
6. Project does not have an executed Inter-Institutional Reliance Agreement in place;
7. Project is not a data information or biospecimen local banking project;
8. Project may not include international site(s) under the supervision of the PI.

Application of this policy to any human subject research project will be at the discretion of the Campbell University Chair of the Institutional Review Board.

2.0 Registration Categories

This policy creates new Campbell University IRB-specific registration categories which are not defined in the federal regulations for research projects. These categories will only be applied to research projects which fall outside of the scope of Campbell University Federalwide Assurance (FWA) for the Protection of Human Subjects

- Category 1: Evaluation or comparison of educational techniques or instructional curriculum
- Category 2: Conducting surveys, questionnaires, focus groups, or interviews
- Category 3: Use of biospecimens that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis)
- Category 4: Taste and Food Quality evaluations
- Category 5: Blood draws via venipuncture, finer, heel, or ear stick*
- Category 6: Prospective collection of biospecimens via non-invasive procedures
- Category 7: Prospective collection of data via non-invasive procedures

- Category 8: Research involving materials (i.e., data, documents, or records) that has been collected, or will be collected solely for non-research purposes
- Category 9: Collection of images, video or audio recordings solely for research
- Category 10: Psychosocial interventions, including benign behavioral intervention which may or may not involving deception.

*Category 5 has specific criteria which must be met to qualify under this category such as limits on amount of blood collected depending upon the subject population to be included.

3.0 IRB Approval Periods

Registration projects reviewed and determined to qualify for FLEX review as defined by this policy will not be required to submit a continuous progress report for the life of the project unless the project is modified in such a way that it no longer qualifies for FLEX review. The approval period will be determined by the date of completion stated in the protocol application.

4.0 Consent

Registration projects may involve a variety of activities, and the research team should consider several factors regarding consent, including:

- If there will be direct contact or interaction with subjects;
- The nature of the research activities.

4.1 No Consent Required

For projects which do not have direct contact with subjects such as those that propose to review records or access biospecimens not created for the research project, teams may indicate “no direct contact” in the protocol submission form.

4.2 Informational Letter or Consent Scripts

Projects looking solely at the following activities:

- Evaluating education curriculum, instructional techniques;
- Distributing surveys, or questionnaires;
- Conducting interviews and focus groups.

These activities may involve varied levels of contact with subjects and may qualify to use an information letter or consent script to explain the research to subjects, participation being voluntary, the risk of research activities, benefits, and who to contact if they have any questions.

4.3 Minimal Risk Consent Form

For projects which may include activities such as blood draws, MR scans, imaging, non-invasive collection of biospecimens, audio/visual recording, or psychosocial interventions, the IRB recommends the use of either the Biomedical Minimal Risk Consent which also has HIPAA authorization language/Personal Identifying Information (PII) authorization language incorporated into the document or the Social/Behavioral Minimal Risk Consent Form which has Personal Identifying Information (PII) authorization language incorporated into the document.

Purpose:	Campbell University’s Human Research Protection Program (HRPP) is a comprehensive system to ensure the protection of the rights and welfare of participants in Human

	Research. This policy establishes flexibility in review, administration, and oversight of human subjects research which meets the qualifications specified in this policy.
Procedure:	**1.0 Protocol Submission** **1.1** Investigators must complete and submit an "IRB New Protocol Submission Form" in accordance with *IRB SOP: New IRB Protocol Submission*. Exceptions will be granted to certain classroom research projects. Please contact the IRB for details. **1.2** Projects which may qualify for FLEX review will follow the same process of undergoing departmental and applicable ancillary/safety committee reviews prior to being received by the IRB Office. Investigators must secure all the applicable department/institutional approvals prior to their project being reviewed by the IRB. **1.3** The IRB Office will review the project, confirm that the project qualifies for FLEX review, if applicable, and identify the applicable Registration categories. **1.4** During the review, an IRB Coordinator may request changes in the project to ensure the following criteria have been met: **1.4.1** The project meets the following ethical requirements: **1.4.1.1** The research holds out no more than minimal risk to subjects; • The selection of subjects is equitable; • If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data; **1.4.1.2** If the project involves interaction with subjects, a **consent process and form (if applicable)** has been reviewed and discloses the following information: • That the activity involves research. • A description of the procedures. • That participation is voluntary. • Name and contact information for the researcher. • There are adequate provisions to maintain the privacy interests of subjects. **1.5** After the review is complete, and any requested changes have been completed, the IRB Office will issue a determination letter in accordance with *IRB SOP: Post-Review Activities*. **2.0 Additional Investigator Responsibilities** **2.1 Modifications/Amendments to a Registration Project** It is the responsibility of the Principal Investigator (PI) to secure IRB approval prior to the implementation of changes to a Registration project. Examples of changes requiring approval include but are not limited to: • PI change • Addition of federal or for-profit funding • Addition of new activities or project phases • Changes that trigger FDA jurisdiction (e.g. you are now planning to report research results to a drug/device manufacturer for the purpose of FDA application) • Addition of completely new project population

	• Addition of site that requires execution of a reliance agreement with our IRB • Addition of international sites See *IRB SOP: Amendments to IRB Approved Protocols*, for more information regarding Amendments. Submitted changes may alter a project's qualification for FLEX review. If changes disqualify a project from FLEX review, the project will be assigned to an IRB Committee for review and reclassified under DHHS and/or FDA regulations. **2.2 Reclassification of Projects which qualify under FLEX review** • Investigators with currently approved minimal risk projects classified as Expedited or Exempt under DHHS or FDA regulations may have their projects reclassified as Registration projects. This may occur during the review of an amendment. • The IRB will confirm if the project qualifies for FLEX review. • Investigators will be notified of this reclassification via an IRB determination or approval letter. **2.3 Reporting to Federal Entities** Research projects that are not federally funded or federally regulated are not subject to the same federal reporting requirements as federally funded projects which must notify the appropriate federal agency. Projects reviewed under the FLEX policy do not have an obligation to report to a federal agency but must adhere to IRB reporting policies. **2.4 Closing Registration Projects** The Principal Investigator is responsible for notifying the IRB when a Registration project is complete. To close a Registration protocol, project teams should submit an "IRB Closure Form." Registration projects can close during data analysis/manuscript preparation activities as long as the data has all Protected Health Information or Personal Identifying Information removed. As with all projects, once a Registration project is closed, it cannot be re-opened. Therefore, data collection, participant enrollment, etc. must be complete prior to closure.

Scope:	Campbell University applies the federal regulations for the protection of human subjects to all human subject research. In an effort to reduce the regulatory burdens, Campbell University has chosen to not apply all federal regulations to certain minimal risk research that is NOT federally funded or federally regulated research. These research projects will nonetheless be afforded equivalent protections under The Belmont Report and will afford protections commensurate with risk as determined by the IRB. Should a project approved under the FLEX Policy obtain federal funding or should the risk level change, it is the responsibility of the Principal Investigator (PI) to notify the Institutional Review Board (IRB). ***Under no circumstances will federally funded or Federal Drug Administration (FDA) regulated research be reviewed under this policy.*** The IRB may make exceptions to this policy for funded research that is not federally funded. At no point is a project guaranteed to qualify under this flex review. The IRB chair or their designee holds final decision on what projects can be reviewed under this policy. Projects reviewed under this policy remain subject to IRB policies and review.

Exclusions:	Research Projects that do not meet the federal definition of Human Subjects Research or meet the federal criteria of Not Human Subjects Research.
Enforcement:	In order to monitor and ensure compliance, internal or external auditors who have expertise in federal and state statutes, regulations and institutional requirements may conduct periodic audits. Audits will focus on areas of concern that have been identified by any entity, i.e., federal, state, local or institutional. Random audits may also be conducted. The Institutional Official and/or the IRB may place limitations or conditions on an investigator's or research staff's privilege to conduct Human Research whenever in the opinion of the Institutional Official such actions are required to maintain the HRPP.
Publication:	On Campbell University's IRB webpage located at https://assets.campbell.edu/wp-content/uploads/2018/09/HSR-030-HRPP-Policy-Registration-Projects-and-FLEX-Review.pdf.
Duration:	Until regulatory requirements change.
Review Period:	This HRPP Policy is to be approved by the Institutional Official or his/her designee. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The Institutional Official or designee has the responsibility to review this plan to assess whether it is providing the desired results and may amend this plan as deemed necessary.
Definitions:	Minimal Risk: means that the probability and magnitude of harm or discomfort anticipated in the research are not great in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests and any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

SACSCOC:	Not applicate
Accreditation:	Not applicable
Related Forms, Policies, or Tools:	The Belmont Report IRB SOP: Post-Review Activities IRB SOP:IRB Initial/New Protocol Submission IRB SOP: Amendments to IRB Approved Protocols IRB SOP: Closure of IRB Approved Protocols

To determine approval level, please consult your respective Vice President.

Reviewed By:	Miranda van Tilburg, PhD	**Title:**	IRB Chair	**Date:**	11/04/2020
Approved By:	Mark Hammond, PhD	**Title:**	Institutional Official, Vice President for Academic Affairs and Provost	**Date:**	12/04/2020
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