	IRB SOP: Reliance Agreements for Multi-Site Projects		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-710	Miranda van Tilburg, PhD IRB Chair, IRB Office Campbell University	

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

Purpose

To describe the mechanism available for multi-site projects or collaborative research when research is conducted by Campbell University personnel is subject to oversight by the IRB(s) of other institutions or when institutions and/or personnel of other institutions rely on the Campbell IRB.

Background

Local investigators must follow the established procedures in order to assure the effectiveness of this system and to comply with federal regulations regarding the conduct of human subjects research.

In accordance with the Human Research Protection Plan, the IRB Office reviews and determines if it is appropriate to execute an Institutional Authorization Agreement (IAA) or an Individual Investigator Agreement (IIA) for either:


1. The Campbell University IRB to serve as the SingleIRB (sIRB) or IRB of Record for a Multi-Site Project, Collaborative Project, or an individual investigator, in alignment with the requirements outlined in *IRB SOP: Conducting Multi-Site (sIRB) Research*.
2. The Campbell University IRB to cede IRB review to (i.e. rely on) an external IRB from another institution/organization, in alignment with requirements outlined in *IRB SOP: Conducting Multi-Site (sIRB) Research*.

Definitions

Engaged in Research: An institution becomes "engaged" in human subjects research when its employees or agents (all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility):

1. intervene or interact with living individuals for research purposes;
2. obtain individually identifiable private information for research purposes;
3. obtain informed consent from human subjects; or
4. receive Health and Human Service (HHS) funds even when all activities are carried out at another institution or by employees of another institution. Determinations on Campbell University's engagement in human subjects research are made by the Campbell IRB Office.

Federalwide Assurance (FWA): The only type of assurance currently accepted and approved by the Office of Human Research Projection (OHRP). Through the FWA, an institution commits to HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46.

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Individual Investigator Agreement (IIA): An institution holding an OHRP-approved FWA may extend the applicability to cover two types of collaborating individual investigators when the project is federally supported:

- 1) collaborating independent investigator who is not otherwise an employee or agent of Campbell University, is conducting collaborative research activities outside of Campbell University, and is not acting as an employee of any institution when conducting the research;
- 2) collaborating institutional investigator who is not otherwise an employee or agent of Campbell University, is conducting collaborative research activities outside of Campbell University, and is acting as an employee or agent of an institution that does not hold an FWA.

This extension is documented using the Individual Investigator Agreement (IIA). The Campbell IRB Office will make the final decision regarding whether an IIA is appropriate for a specific case.

Local Principal Investigator (PI): the Campbell University investigator serving as the PI at the local site.


Campbell University IRB Oversight Jurisdiction: Campbell University defines the scope of oversight jurisdiction of the Campbell IRB to include:

- Human subject research activities conducted at Campbell University.
- Human subject research activities conducted or initiated by Campbell University employees or agents at any other site.
- Human subject research activities that make use of any Campbell University resources other than faculty or employee time commitment. All research projects meeting these criteria must be submitted to the Campbell University IRB for review and approval. If an investigator wishes the Campbell University IRB to rely upon a non-Campbell University IRB for review and approval of a project, the procedures outlined in the sections below must be followed.

Multi-Site Project: A human subjects research project that will be initiated at more than one location other than or in addition to Campbell University. For examples of multi-site projects, see *IRB SOP: Multi-Site Projects and Investigator Responsibilities*.

Reliance Agreement/IRB Authorization Agreement/ Memorandum of Understanding: An Agreement executed between two or more institutions which transfers IRB oversight to another IRB in order to facilitate a single IRB review for a specified project or a group of projects. The Agreement is between institutions and IRBs, not between collaborating investigators.

Reliance System: A system developed by an IRB Office which allows the institution to cede IRB oversight to another IRB or provide IRB review for a non-Campbell University institution. The system involves the use of policies, procedures, and forms that were developed to simplify

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IRB review for a multi-site project where at least one non-Campbell University site is relying upon the Campbell University IRB or where Campbell University IRB is deferring IRB oversight to a non-Campbell University site.

Rely: Also known as “defer or cede”. An institution agrees to transfer oversight of a project under its jurisdiction to another IRB. Campbell University requires a signed Agreement to be in place prior to final IRB approval of the project.

Relying Site: The institution or agency that is relying upon the Campbell University IRB for review.


Reviewing IRB/ IRB of Record: The IRB responsible for review of research involving a participating site.

Procedures

1. All IRB reliance requests must be initiated with the proper Campbell University IRB Reliance Request Form and any required documentation.
2. All reliance requests are reviewed by the Campbell IRB Office in the order in which they are received.
3. PIs should be aware that there may be cases where a reliance request is denied. Therefore, the IRB encourages PIs to contact the Campbell IRB Office as soon as they can, to avoid possible delays in IRB review.

Requests to rely on an outside IRB

1. The *IRB Institutional Authorization Agreement Request Form* should be used when a Campbell University investigator plans to participate in a multi-site project and would like to request that Campbell University IRB rely upon a non-Campbell University IRB. The form must be fully completed and submitted via the instructions on the form. All required associated documentation must be included with the initial email submission or the submission will be considered incomplete and will not be reviewed.
2. When the Campbell University IRB Office receives a request to rely on another IRB, IRB staff will log the request, review the information, contact the PI for any additional information needed, and contact the appropriate HRPP/IRB Office or Point of Contact (POC) regarding the proposed reliance request or have the Campbell University PI contact the appropriate project PI for further instructions. Teams should allow 2 weeks for initial intake and review.
3. If the outside IRB has agreed to provide IRB review for the project, the local investigator must provide a signed *Investigator Attestation Form* for deferred Studies to the Campbell University IRB Office. This form is required before the Campbell University IRB will finalize a deferral of IRB oversight to any outside IRB.
4. The local Principal Investigator must provide the IRB approval letter for involvement of this site when received.


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Requests to rely upon the CU IRB

1. The *IRB Institutional Authorization Agreement Request* should be completed and sent to the Campbell IRB Office along with a copy of the protocol or narrative and proposed consent form, if applicable. These documents must be provided to the Campbell IRB Office before the request will be considered.
2. a. If an investigator wishes the Campbell University IRB to serve as the single IRB for multiple sites and the sites do not fall under an existing Reliance Agreement, the Campbell University IRB Office will be consulted in order to make a final determination regarding this request. When the Campbell IRB Office is notified of a request to serve as the reviewing IRB, IRB staff will review the information, contact the PI for any additional information needed, and determine if the request is appropriate. If there is a decision to move ahead with the request, IRB staff will contact the relying IRB directly.
3. If the Campbell IRB agrees to provide IRB review for an outside institution, additional information in the *New Protocol Submission Form* and in the *Research, Plan* must be provided as described in the *IRB SOP: Conducting Multi-site Projects and Investigator Responsibilities*.
4. In addition to the above, the local investigator must provide the following information in the *Research Plan* and in the research protocol regarding local context for each site that is relying upon the CU IRB:
 - a. The CV for each relying site's lead investigator must be uploaded in the electronic submission form application.
 - b. Specific research activities to be conducted at that site.
 - c. Available resources for each relying site's lead investigator must be described in the protocol or addendum to the protocol.
 - d. Whether the relying site's research team will review records to determine eligibility for study participation.
 - e. Recruitment procedures to be conducted.
 - f. Consenting procedures to be conducted.
 - g. Confidentiality measures.
 - h. If project involves a drug, device, or biologic, where these will be stored, who will dispense them, and who will manage them
 - i. For more than minimal risk projects, plan at the relying site for evaluating and responding to subject complaints and reporting UPIRSOs to the Campbell University IRB.
 - j. Age of majority in the relevant state (if minors will be recruited).
 - k. Explanation of any state or local laws governing the conduct of research.
 - l. Any cultural concerns in the local community.

Requests to initiate an Individual Investigator Agreement (IIA)


1. An *IRB Individual Investigator Agreement Request Form-Campbell IRB of Record* can be requested of the Campbell University IRB when all of the following are met:

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- a. The Campbell University IRB is the reviewing IRB;
- b. The project is federally supported, non-federally funded or non-funded and will be conducted under the direction and supervision of a local investigator;
- c. The collaborative investigator will be engaged in research activities outside of Campbell University;
- d. Non-Campbell University research staff are employed by an institution that does not have an FWA, OR are not acting as an employee of any institution with respect to his or her involvement in the research; and
- e. The collaborating investigator is not affiliated with Campbell University.
2. This mechanism does not apply if the collaborating investigator's institution is the primary awardee of federally-funded human subject research.
 - a. The Campbell University investigator should contact the Campbell IRB Office in this case to discuss how to proceed.
3. In order to initiate a request for an Individual Investigator Agreement, the Campbell investigator must complete the form *IRB Individual Investigator Agreement Request Form-Campbell IRB of Record* and submit to the Campbell IRB Office along with:
 - a. the protocol or the Campbell IRB submission number;
 - b. evidence of the collaborating investigator's completion of human subject research protection (HSRP) training; and
 - c. a letter of support from the collaborating investigator's institution if the collaborating investigator is an employee or agent of that institution. This letter of support must state that the institution is aware and supports the research activity taking place at their site. The letter of support is not required if a letter of support has already been provided with the grant proposal.

Consent forms for multi-site projects when a Reliance Agreement is involved

1. In all cases, the proposed consent form (if applicable) will need to be provided to the Campbell University IRB Office.
2. **When the Campbell IRB is the reviewing IRB**, the appropriate Campbell multi-site consent form template must be used. Changes in the following sections may be allowed to accommodate local standards and requirements: compensation for injury, who to contact with questions about the project, and who to contact regarding rights and welfare of subjects. Template change requests may be required for these changes.
 - a. The local investigator must provide the consent form for a non-Campbell University site for review and approval prior to use.
The Campbell IRB will review, approve and stamp the consent form to be used at the non-Campbell University site. This consent form must be used by the non-Campbell University site to enroll subjects.
3. When the Campbell University IRB has deferred oversight to another IRB, the Campbell IRB Office will work with the reviewing IRB to assure that the consent form used at this site includes language reflecting local standards and requirements.


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- a. The Campbell IRB's expectation is that the consent form to be used locally includes select language on costs, compensation for injury, who to answer questions, and HIPAA (if applicable).

Principal Investigator Responsibilities

Local PIs must follow *IRB SOP: Responsibilities for Principal Investigators Conducting Human Subjects Research* and *IRB SOP: Multi-site Projects and Investigator Responsibilities*. In addition to the responsibilities outlined in these policies, local PIs using the reliance system must also comply with the responsibilities listed below.

1. Principal Investigator Responsibilities when a non-Campbell IRB is the Reviewing IRB:
 - a. Ensure that human subject research activities do not begin until IRB approval is obtained in writing from the reviewing IRB.
 - b. Ensure that all Campbell University institutional policies and requirements are met before initiating human subjects research at that site.
 - c. Ensure that all budgetary and contractual issues relevant to the conduct of the project are resolved before starting the research, if applicable.
 - d. Ensure required agreements for data or specimen transfer (e.g. data use agreements, material transfer agreements, etc.) are in place prior to receiving or transferring data or specimens.
 - e. Adhere to the decisions and determinations of the reviewing IRB. Including using only those project documents approved by the reviewing IRB.
 - f. Ensure that all project personnel at Campbell University complete and maintain human research subject protection training as required by Campbell University.
 - g. Obtain and follow the most current IRB approved protocol. No changes may be made without approval from the reviewing IRB.
 - h. Unless the IRB determines that a waiver of informed consent process or waiver of documentation of informed consent is appropriate, obtain and document consent using only the current IRB approved consent forms. Ensure that informed consent is obtained prior to initiating project procedures.
 - i. Report adverse events, unanticipated problems involving risks to subjects or others, and deviations from the protocol that occur at Campbell University per the reviewing IRB policies.
 - j. Notify the Campbell University IRB Office of serious or continuing noncompliance or unanticipated problems involving risks to subjects or others that occur at this site.
 - k. Report subject complaints that occur at this site to the Campbell University IRB Office as well as the overseeing IRB.
 - l. Upon request, provide access to records for audit by the Campbell University IRB or the reviewing IRB and notify the Campbell University IRB Office of any non-Campbell University audit.

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- m. Provide IRB approval (initial, modification, continuing review), closure, and suspension or termination letters to the Campbell University IRB Office when received.
 - n. Notify the Campbell University IRB Office when the project closes at this site per the *Closure Submission Form*.
2. Investigator Responsibilities when the Campbell IRB is the Reviewing IRB:
 - a. Ensure that human subjects research activities do not begin at any relying site until IRB approval is obtained in writing from the Campbell IRB.
 - b. Submit an amendment to the IRB when adding a site to a project that has already been approved by the CU IRB. The amendment should revise the *Research Plan*:
 - Addition of the site;
 - Explanation of research activities to be conducted at that site, and
 - Research activities to be conducted by employees of the site and where they will be conducted.
 - c. Include key personnel from the relying site on the *Research Personnel Form*. If there are changes to key personnel during the course of the project, these changes should be reported to the Campbell IRB.
 - d. Ensure that investigators at the relying site receive a copy of the IRB approval letter, approved protocol document, consent form, and other documents (if applicable).
 - e. Notify investigators at relying sites of all Campbell IRB determinations and communications, including those for initial/new review, continuing review, amendments and reportable events.
 - f. Upon request, provide access to records for audit by the Campbell IRB.
 - g. The Campbell PI is responsible for gathering progress information from relying sites, collecting information, and providing a status report for each relying site in the *Continuing Review Submission Form* to the Campbell IRB. If the Campbell PI is the Principal Investigator for the entire project, the continuing review must also include the status of the overall project.

References

The Belmont Report

45 CFR 46

IRB SOP: Responsibilities for Principal Investigators Conducting Human Subjects Research

IRB SOP: Conducting Multi-site Projects and Investigator Responsibilities

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