# POLICY 1: HUMAN SUBJECTS RESEARCH WITH NO AFFILIATION TO SOUTHERN WESLEYAN UNIVERSITY

RESEARCH COMPLIANCE COMMITTEE

#### Southern Wesleyan University

Southern Wesleyan University has certain requirements regarding collaboration with researchers not affiliated with SWU. These requirements vary depending on the role of the individual not affiliated with Southern Wesleyan University in the research, the institution(s) involved and the level of review needed for the particular protocol.

The following terms will be used throughout this document:

- **Primary Investigator**: Person who bears direct responsibility for the implementation of the research and for ensuring the protection of human participants in research.
- **Co-Investigator**: Person who shares research responsibilities with the PI.
- **Research Team Member**: Person who participates in research under the direction of the Primary Investigator.

#### PRIMARY INVESTIGATOR AFFILIATED WITH ANOTHER INSTITUTION THAT HAS ITS OWN IRB:

At times, primary investigators request access to faculty, staff, or students or Southern Wesleyan University for research purposes. The RCC requires submission of the following documents to the RCC Chair (rcc@swu.edu), for consideration of these requests:

- Approved IRB application from primary investigator's institution.
- Approval letter from primary investigator's institutional IRB

The Southern Wesleyan University RCC will review these documents. Any questions or concerns from the initial review will be presented to the primary investigator for clarification. Approval will be granted for access to SWU faculty, staff, or students if the SWU RCC reaches consensus agreement.

There will be an initial review and 1 attempt for clarification in these cases. If consensus is not reached after these 2 steps, the SWU RCC will decline the invitation for participation of our faculty, staff, or students.

#### PRIMARY INVESTIGATOR NOT AFFILIATED WITH ANY INSTITUTION OR AFFILIATED WITH AN INSTITUTION THAT DOES NOT HAVE ITS OWN IRB:

The Southern Wesleyan University RCC requires completion of a SWU IRB application and completion of human subject protection training. The non-affiliated Primary Investigator should access the CITI training by declaring an affiliation with Southern Wesleyan University during the CITI registration process.

### CO-Investigators or Research Team Members affiliated with another institution that has its own IRB:

To conduct human subjects research in collaboration with researchers from another institution having its own IRB, researchers should obtain IRB approval from both Southern Wesleyan University and the other institution. A copy of the other institution's IRB approval letter should be submitted with the IRB application. If the SWU RCC defers to another institution's IRB decision, the other institution's IRB approval letter and IRB application are required to be submitted to the RCC Chair. Researchers not affiliated with Southern Wesleyan University will not be required

to take Southern Wesleyan University's human subjects protections training, but instead should meet any training requirements set by their own institution's IRB.

## <u>CO-Investigators or Research Team Members not affiliated with any institution, or affiliated with an institution that does not have its own IRB:</u>

The Southern Wesleyan University RCC requires completion of human subject protections training for these individuals. The non-affiliated team members are welcome to access CITI training by declaring an affiliation with Southern Wesleyan University during the CITI registration process.