POLICY 2: PRINCIPAL INVESTIGATOR ASSIGNMENT & RESPONSIBILITIES

RESEARCH COMPLIANCE COMMITTEE

Southern Wesleyan University

ASSIGNMENT OF PRINCIPAL INVESTIGATOR

The duties that are delegated through the assignments of an individual as the "Principal Investigator" (PI) require that the individual placed within that role has appropriate, formal and legal institutional authority to supervise, direct or otherwise control all decisions necessary for successful project performance.

Therefore, the University and Research Compliance Committee (RCC) have designated the following categories of personnel as eligible to serve as Principal Investigator on research projects:

- All full-time faculty, regardless of academic rank;
- Visiting faculty during the time they are employed by the University
- Full-time staff
- Other University employees as designated by the approval of the Vice President for Academics/ Provost using the variance form (Request to Serve as Principal Investigator)

A suitable level of institutional oversight toward responsible and accountable project conduct must be legally sustainable within the University's policies and procedures. In recognition of this, as well as the legal responsibilities and various internal federal compliance requirements, any other person not formally employed on a full-time basis by the University, is ineligible to assume the position of PI unless formally designated through the variance form.

RESPONSIBILITIES OF PRINCIPAL INVESTIGATOR

The Principal Investigator bears direct responsibility for the implementation of the research and for ensuring the protection of human or animal participants in research. The PI must be knowledgeable about federal regulations and institutional policies and procedures related to the conduct of research. The following lists the major responsibilities of the PI.

The PI must ensure that:

- All members of the research team are appropriately trained.
- All members of the research team comply with the findings, determinations, and requirements of the RCC.
- All members of the research team are provided with appropriate supervision.
- Continuing review and approval of the research has been accomplished within the time frame stipulated by the RCC.
- Any changes in research activity, including changes to the protocol, and/or consent form(s), completion or termination of the study, are promptly reported to the RCC. No change in approved research may be initiated without the RCC's approval except under conditions where it is necessary to eliminate apparent immediate hazards to research participants.
- No research is continued beyond the designated approval period.
- Any unanticipated problems involving risk to subjects and others, and any adverse events are reported immediately to the RCC
- Any non-compliance with applicable regulatory requirements or determinations is reported immediately to the RCC.
- The protocol number and title of the research are cited in all correspondence to the RCC.

- Any significant new information that may affect the risk/benefit ratio is submitted promptly to the RCC.
- For every expedited, designated, or full review protocol, all signed consent forms (if applicable) are maintained for at least three (3) years after completion of the study and are available for RCC to review.
- Only consent/assent/parental permission forms including the current approval and expiration dates may be presented to the research participants.
- Requests for information from the RCC are responded to in a timely fashion.