SOP: Training and Coverage Requirements for Investigators Conducting Clinical Trials and Clinical Investigations				
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1 PURPOSE

1.1 This policy establishes the requirements for investigators who conduct clinical trials and clinical investigations.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Principal Investigators must ensure that all research personnel have completed the following training prior to conducting any research activities:

- 3.1.1 For research involving only minimal risk:
  - 3.1.1.1 NIH Program Protecting Human Research Participants;
  - 3.1.1.2 CITI online Basic Human Research Protections Training for Biomedical Researcher; or
  - 3.1.1.3 CITI online Basic Human Research Protections Social Behavioral Researchers and staff.
- 3.1.2 For social behavioral clinical trials:
  - 3.1.2.1 GCP – Social and Behavioral Research Best Practices for Clinical Research.
- 3.1.3 For clinical investigations subject to FDA jurisdiction:
  - 3.1.3.1 GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus); or
  - 3.1.3.2 GCP for Clinical Trials with Investigational Medical Devices.

3.2 For biomedical trials involving greater than minimal risk, Principal Investigators must ensure that a responsible person is available to provide medical care to research participants whenever the principal investigator is unavailable to provide said care. This responsible person must:

- 3.2.1 Be included on the Research Personnel List on the Electronic Initial Review Application or on FORM HRP 215 Research Personnel List Template if there is no electronic application.
- 3.2.2 Have sufficient medical training to oversee the medical care of participants; and
- 3.2.3 Have sufficient training on the protocol requirements to avoid deviations from the protocol requirements unless the deviation is necessary to prevent imminent harm to participants.

3.3 When a Principal Investigator leaves his/her position at UC Davis, s/he must perform one of the following actions with respect to all clinical trials and clinical investigations for which s/he is the Principal Investigator:

- 3.3.1 Close the study;
- 3.3.2 Transfer close the study to a qualified Principal Investigator at UC Davis as outlined in the UC Davis Investigator Manual; or
- 3.3.3 Work with IRB Administration to develop an alternative plan for supervision of the research.

4 MATERIALS

4.1 None

5 REFERENCES

5.1 None