

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

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
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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 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