

# STANDARD OPERATING PROCEDURE

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Title:	Oversight of Medical Students Conducting Research		

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## 1. PURPOSE

The purpose of this document is to define oversight responsibilities of Principal Investigators when delegating tasks to medical students conducting research.

## 2. DEFINITIONS

**Principal Investigator** – The FDA defines this as an individual who conducts a clinical investigation, under whose immediate direction the drug is administered or dispensed to a subject.

The Principal Investigator is ultimately responsible for the overall conduct of a clinical investigation or research study, including, but not limited to, investigations and/or research that involve or may involve: the collection of information from medical records or directly from human subjects; interactions and interventions with human subjects; or administering or dispensing investigational products to human subjects.

**Medical student**- A student enrolled at any medical school, who is training to become a medical doctor

## 3. RESPONSIBILITY

### 3.1 Principal Investigator

- The Principal Investigator is ultimately responsible for the overall conduct of a clinical investigation or research study, including, but not limited to, investigations and/or research that involve or may involve: the collection of information from medical records or directly from human subjects; interactions and interventions with human subjects; or administering or dispensing investigational products to human subjects.
- Delegates research-related tasks to medical students
- Trains medical students to perform delegated tasks and documents such training
- Performs and documents proficiency and competency assessments of the medical students
- Supervises medical students
- Ensures effort commitments for externally sponsored clinical investigations or research studies are met in accordance with the terms and conditions of the award and that reductions in effort due to delegations described in this Standard Operating Procedure or for other reasons are submitted to the Office of Research Administration when prior approval by the sponsor is required.

### 3.2 Medical Student

- Attends and completes assigned training
- Demonstrates proficiency via competency assessment
- Does not perform any tasks which require a license or certification

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### 4. PROCEDURE

#### 4.1 Delegation of Tasks

- 4.1.1 Prior to conducting any research activities, medical students must be delegated specific tasks that they will perform during the conduct of a research study.
- 4.1.2 Any tasks which require a license or certification cannot be delegated to a medical student unless that license or certification is obtained.
- 4.1.2 The Principal Investigator must document the delegated tasks for each medical student, on a Delegation of Authority Log, which includes the following:
  - Protocol number and title
  - Name of medical student
  - Tasks assigned
  - Date that medical student was assigned tasks

#### 4.2 Training and Documentation

- 4.2.1 Prior to conducting any research activities, the Principal Investigator must train the delegated medical student on the following:
  - Study protocol
  - Specific tasks assigned to medical student
- 4.2.2 The above training must be documented with the following information:
  - Date of training
  - Name of Principal Investigator who conducted the training
  - Topics discussed
  - Names of medical students who attended training
  - Principal Investigator signature or initials
  - Signature or initials of medical students

#### 4.3 Competency Assessment and Documentation

- 4.3.1 Medical students will have to demonstrate proficiency in performing their delegated tasks.
  - 4.3.1.1 For specific tasks involving a patient/subject exam, the Principal Investigator must establish a tutorial that determines the competency to perform the patient/subject exam along with a test that validates the medical student's ability to perform the evaluation.

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4.3.2 Investigators will assess the medical student's proficiency and document this by recording the following:

- Date of proficiency or competency assessment
- Names of medical students assessed
- List of tasks for which proficiency was demonstrated
- Principal Investigator signature or initials

4.3.3 Document any tasks for which additional training is required.

### 4.4 Supervising Students Conducting Research

4.4.1 During the conduct of research studies, the Principal Investigator must supervise medical students at all times. This means the Principal Investigator must be available and in close proximity.

4.4.2 Principal Investigators must have regularly scheduled meetings with the medical students to discuss the research study and the status of their assigned tasks and responsibilities. These meetings must be documented.

## 5. REVISION HISTORY

N/A – New document

## 6. SIGNATURES

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