# Delegation of Authority

## Introduction

This procedure describes the process for delegation of study-related duties to study personnel by Principal Investigator (PI). This process applies to all clinical research studies that are non-exempt as approved by the IRB, see 45 CFR 46.101 for more information.

## PI duties

The Principal Investigator (PI) is responsible for ensuring that only individuals qualified by means of education, training, and experience are delegated the authority to perform research-related duties as listed on the study Delegation of Authority (DoA) Log. Appropriately trained and qualified individuals to whom the PI has delegated significant trial-related duties are documented as indicated in applicable regulatory guidelines.

For individuals who provide ancillary services related to the study as part of their normal job duties, the staff/provider is not added to the training or DoA logs. If the duty can be done by a contracted service or done by individuals not specifically designated by the investigator to perform significant trial-related duties, then they do not need delegated authority.

## DoA log contents

The DoA Log should list the following, at a minimum:

- IRB of Record Protocol # and/or BCM IRB Protocol H#
- Principal Investigator name
- Site name/Number
- Sponsor
- For each study team member:
  - Name
  - Role (sub-investigators, study coordinators, etc.)
  - Study responsibilities (consent, dispense study drug, ship samples, etc.)
  - Start date and end date of involvement with the study
  - PI signature initials and date

## DoA log requirements

Each person listed on DoA Log signs and/or initials and dates in the provided space indicating acknowledgement and acceptance of the delegated duty(ies).

- The DoA Log is updated each time delegated duties to a study team member are modified, new personnel are added to study team, or a study team member is no longer involved with the study.

- The PI or designee is responsible for maintaining and filing the DoA log in the regulatory binder.

- Credentials and training documentation for individuals listed on the DoA are maintained in the regulatory binder.
**VERSION/REVISION HISTORY:**

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<td>OCR</td>
<td>Catherine Simmons (CS), Jose Rodriguez (JR)</td>
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