BCM Office of Clinical Research: OCR-R-25-01

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:

Approval Date	Version	Owner	Approver	Revision Summary
10/13/21	1	OCR	Catherine Simmons (CS), Jose Rodriguez (JR)	