

DF/HCC Operations for Human Research
Documenting Delegation of Authority

1. BACKGROUND:

The Principal Investigator (PI) at each DF/HCC site must maintain a list of appropriately qualified persons to whom significant trial-related duties have been delegated. RCO-203 requires the use of a standard DF/HCC Delegation of Authority Log.

2. ASSOCIATED DF/HCC POLICIES:

2.1. [RCO-203](#)

3. PROCEDURE:

3.1. **Components for documenting Delegation of Authority (DOA) for all applicable DF/HCC trials:**

Components of Documenting Delegation of Authority at DF/HCC		
Document Title	Purpose	Notes for Use
Delegation of Authority (DOA) Log	<ul style="list-style-type: none"> Lists the name, role, start and end date for all research personnel on a protocol Captures PI approval 	<ul style="list-style-type: none"> Must maintain a separate DOA Log for each protocol Must be updated as personnel are added or removed from a protocol. See below for instructions.
Key: Delegation of Tasks for Clinical Research	<ul style="list-style-type: none"> Defines the standard research tasks delegated to DF/HCC personnel 	<ul style="list-style-type: none"> If an individual has a role that significantly differs from DF/HCC standard roles, this must be defined on the DOA Log for that specific protocol.
Policy and Signature Training Record	<ul style="list-style-type: none"> Documents individual training on applicable DF/HCC research policies Captures the signature and initials of individuals participating in the conduct of DF/HCC trials 	<ul style="list-style-type: none"> Signature and initials must be consistent with how they will appear on other documentation related to human subject research at the DF/HCC Must be completed and maintained for all individuals listed on the protocol-specific DOA Log

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Maintained by: Office of Data Quality (ODQ)

3.2. New Protocols

- 3.2.1. The PI, or designee, will complete a new Delegation of Authority Log (DOA Log) using the [DF/HCC DOA Log template](#) for each individual protocol prior to initiating research. Ensure all research personnel making a significant contribution to the research at their respective site are listed.
- 3.2.1.1. Ensure each individual has a completed [DF/HCC Policy Training and Signature Record](#) on file and has been trained on the protocol before being listed on the DOA Log.
- 3.2.1.2. Assign each individual a role according to the [DF/HCC Key for Delegation of Tasks for Clinical Research](#). Record the current version of the Key on the Delegation of Authority Log where indicated.
- 3.2.1.2.1. It may be helpful to file a copy of the corresponding version of the DF/HCC Key to the DOA Log.
- 3.2.1.2.2. The PI may utilize the “Other tasks” box on the DOA Log for additional research tasks that are not included under a specific role on the Key. For example, an individual could be assigned the role of Study Coordinator as well as one or more additional tasks that are specific to that protocol and not listed on the Key (e.g. administering questionnaires).
- 3.2.1.3. The PI must approve each page of the initially completed DOA Log by signing where indicated. Electronic signature is acceptable.
- 3.2.1.4. Use a line or X to strike through any unused rows on the signed DOA Log. When using the smart form version of the DOA Log template, only add the number of rows necessary for each individual.

3.3. Updates and Changes to an Existing DOA Log

- 3.3.1. To add individuals to the protocol:
- 3.3.1.1. Ensure each individual has a completed [DF/HCC Policy Training and Signature Record](#) on file.
- 3.3.1.2. Capture the new individuals on one or more clean pages of the [DF/HCC DOA Log template](#) per 3.2.1.2..

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3.3.1.3. The PI must approve each page by signing where indicated. Electronic signature is acceptable. Approval is required before the added individuals can participate on the protocol.

3.3.1.4. Use a line or X to strike through any unused rows on the signed DOA Log (n/a when using the smart form version).

3.3.1.5. Attach the new page(s) to the initially completed DOA Log

3.3.2. To change names or roles for an existing individual:

3.3.2.1. Record an end date on the DOA Log. The end date should be the date on which the old name is no longer used or the old role ended for this protocol.

3.3.2.2. For name changes, ensure the individual has an updated the Policy Training and Signature Record on file that reflects their new name, signature, and initials.

3.3.2.3. Re-add the individual with updated information as per 3.3.1. The start date should be the day after the end date entered above.

3.3.3. To remove individuals from the protocol:

3.3.3.1. When delegated staff leave prior to the completion of research activities under the protocol, record the end date next to their name on the DOA Log at the time of their departure.

3.3.3.2. Upon the completion of research activities under the protocol, record the end date for all remaining staff listed on the DOA Log.

3.3.4. To make corrections to the DOA log:

3.3.4.1. All corrections must be made in accordance with [DOC-100](#) (e.g., initialed and dated).

3.3.4.2. Corrections to an individual's role or start date must be initialed and dated by the PI. (For *changes* to an individual's role, see above.)

3.4. Multi-Center Protocols

3.4.1. External sites on multi-center protocols may follow their institutional policies and procedures for documenting delegation of authority.

3.4.2. In cases where an external site does not have a delegation of authority process in place, or does not have a standard template for use at their institution, the coordinating center may provide the [DF/HCC External Site Delegation of Authority Log template](#).