

Tool Summary Sheet

Tool: Delegation of Authority Log

Purpose: To record all study staff members' significant study-related duties

Audience/User: Principal investigators (PIs), study coordinators, other site staff, clinical monitor

Details: This log should provide a comprehensive list of study staff members and the duties that have been delegated to them by the PI. It is required for both observational and interventional clinical research studies.

- Best Practice Recommendations:**
- List the names of study staff members and record the responsibilities that have been assigned to them using the boxes under the responsibilities header.
 - Revise the Responsibilities Header as needed to reflect study-specific needs, such as signing CRFs and reviewing/signing laboratory reports.
 - Each study staff member listed should initial and sign to indicate understanding of the responsibilities assigned.
 - The site PI should initial and date each line of the form as entries are recorded. The PI's signature at the bottom of each form is required at the conclusion of the study.
 - Update the log as needed following any change in site study personnel.
 - Number each page and maintain this log in the Essential Documents Binder, behind the Delegation of Authority Log tab. (Synonyms for this binder include Investigator Binder, Regulatory Binder, Investigator Site File [ISF], and Study File.)
 - Store pages in reverse chronological order, with the newest pages of the log placed at the front of the section.
 - At the conclusion of the study, identify the final page of the log by checking the box in the footer.
 - Remove this Tool Summary Sheet before use of the log.

Tool Revision History:

Version		
Number	Date	Summary of Revisions Made:
1.0	20Apr2012	First approved version
2.0	24Apr2013	Added Tool Summary Sheet

Delegation of Authority Log

STUDY NAME

Site Number: _____

The purpose of this form is to: a) serve as the Delegation of Authority Log and b) ensure that the individuals performing study-related tasks/procedures are appropriately trained and authorized by the investigator to perform the tasks/procedures. This form should be completed prior to the initiation of any study-related tasks/procedures. The original form should be maintained at your site in the study regulatory/study binder. This form should be updated during the course of the study as needed.

Please Print	Obtain Informed Consent	Source Document Completion	Case Report Form (CRF) Completion	Assess Inclusion and Exclusion Criteria	Physical Examination	Medical History	Medication History / Concomitant Medication	Collect Vital Signs	Review Vital Signs and Labs for Clinical Significance	Laboratory Specimen Collection/Shipping	AE Inquiry and Reporting	AE/SAE interpretation (severity/relationship to IP)	Administration of Investigational Product (IP)	IP Accountability	Regulatory Document Maintenance	Administrative	
NAME:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	OTHER (specify):
STUDY ROLE:	SIGNATURE:														INITIALS:	DATES OF STUDY INVOLVEMENT:	
NAME:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	OTHER (specify):
STUDY ROLE:	SIGNATURE:														INITIALS:	DATES OF STUDY INVOLVEMENT:	
NAME:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	OTHER (specify):
STUDY ROLE:	SIGNATURE:														INITIALS:	DATES OF STUDY INVOLVEMENT:	
NAME:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	OTHER (specify):
STUDY ROLE:	SIGNATURE:														INITIALS:	DATES OF STUDY INVOLVEMENT:	

I certify that the above individuals are appropriately trained, have read the Protocol and pertinent sections of 21CFR 50 and 56 and ICH GCPs, and are authorized to perform the above study-related tasks/procedures. Although I have delegated significant trial-related duties, as the principal investigator, I still maintain full responsibility for this trial.

Investigator Signature: _____

Date: _____