Office of Clinical Research (OCR)

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Responsibility: OCR		Page 1 of 6
Policy 1.3.5		

GUIDELINES FOR THE DELEGATION OF AUTHORITY LOG

Policy This policy is to provide guidelines for the delegation of authority log

Affected Department(s)

The Principal Investigator and any member of the research team to whom related duties are assigned.

Procedure

Electronic Delegation of Authority Log

Electronic delegation of authority logs may be used within the Complion e-Regulatory system. Ongoing studies may be integrated into the e-Regulatory system and switched to an electronic delegation of authority log.

Revisions to the Delegation of Authority/Study Signature Log

When additional individuals need to be added to the Delegation of Authority Log, the name, Title/Position/Role of the new person being added will be listed on the log. Once this information has been entered, the principal investigator (PI) will sign and date to acknowledge the new addition.

Removal of Staff from a Study

If a research staff member listed on a delegation log needs to be removed from the study before study close-out, a memo to file will be created to document the final date of participation in that study. The memo to file will be kept with the delegation of authority log.

Principal Investigator (PI) Change

In the event of a PI change, the Delegation of Authority log, will be updated (corrected) to note the incoming PI. A memo to file will be created to document the PI change. The start date of the new PI will be determined by the date that the revised 1572 is signed and/or the new PI resumes their responsibilities as PI, once the PI change is approved by the IRB.

The PI and study team will ensure the logs are kept current and maintained within the study files. A copy of the logs will be provided to the Sponsor and/or CRO, if requested.

Complion

A study specific Delegation of Authority Log (DOA-L) may be generated within the Complion eRegulatory system. The log will contain the name of the individuals listed on the Form FDA 1572 as well as applicable research staff not listed on the Form FDA 1572 (e.g Research Area Specialists (CRa), Data Coordinators (DC)), PK Technicians, Pharmacy Staff, Regulatory Staff, etc.), involved with the clinical trial at any given time. Service Providers (treatment room nurses, staff performing biopsies at an offsite location, radiology staff, etc.) will not be listed on the Delegation of Authority Log. The Complion system will list out the delegated tasks on a person-by-person basis.

The DOA-Log will be reviewed and signed off by the PI prior to or at the site initiation visit.

If a study team member is added, or a current study team member has a role change or additional tasks delegated throughout the life of the study, the existing study team member delegation will be ended, and a new delegation will be added with the updated information. The PI will review the end and start of these delegations respectively and electronically sign-off of the updated DOA log.

If a study staff member's role ends during the course of the study, an end date will be placed on the DOA log and the PI will electronically sign-off.

Appendicies

I. Site Authority Log Key
II. Site Authority Log
III. Memo to File

Appendix I

Site Authority Log Key

List of Titles/Position/Role
Principal Investigator
Co-PI
Data Coordinator
Honest Broker
Research Assistant
Statistician
Study Coordinator
Study Nurse
Sub-Investigator

List of Tasks
1. Recruitment
2. Assess inclusion and exclusion criteria
3. Obtain informed consent
4. Assist with the consent process
5. Source documentation or case report form completion
6. Perform physical examination
7. Perform physical assessment
8. Obtain medical history or evaluate concomitant medications
9. Prescribe intervention being tested
10. Administer intervention being tested
11. Perform study procedures
12. Adverse event inquiry and reporting
13. Laboratory or other specimen handling
14. Specimen shipping**
15. Investigational product dispensing and accountability
16. Regulatory and essential document, other record keeping or admin function
17. Review private identifiable information
18. Direct REDCap access to identifiable study data (other than data entry)
19. Posting, monitoring, responding to social media recruitment communications
20. Directing the research team members and assessing compliance with study protocol
21. Lead PI – direct the study site PI(s) at other locations
22. Determine significance of subject safety indicators (e.g. AE/SAEs, UADEs, SUSAR, UPs)
23. Determine the significance of protocol deviations or violations
24. Ensure the integrity of the data
25. Sponsor-Investigator monitoring and reporting***
26. REDCap Study Administrator

**Requires IATA training
***Requires GCP for investigator-initiated studies of drugs, biologics or devices

A. Medical license (US)
B. Dental license (US)
C. RN license (US)
D. RPH license
E. Other license (US)
F. Good Clinical Practice training (GCP)

G. Research related certification (e.g. CCRC)
H. Advanced academic degree
I. and J. Other certification
K. Specialized training for the use of a device
L. and M. Other

Additional duties may be added as needed.

Appendix II
SITE AUTHORITY LOG

Name	Title / Position / Role	Signature	Initials	Write Numbers 0-9 corresponding to Inst CT/Inst Form (Handwriting Sample)	Start Date	End Date

Appendix III

Memo to File

Sponsor

Study Name:

RE: Delegation of Authority Log

Please allow this memo to serve as notification that on XX.XX.XXXX the responsibilities of Principal Investigator were changed from <current PI> to <new PI>.
As of this date <new PI> agrees to the tasks delegated to all active personnel listed on the Delegation of Authority Log.

_____

<New PI Name and Title>
<Date>