halfpint Study Document Management Recommendations

All *HALF-PINT* study documents must be maintained in a secure location with limited access. A well-organized system for managing study documents is critical for effective project management and regulatory compliance; it is also required per federal regulations and Good Clinical Practice (GCP) guidelines.

These recommendations are intended to assist sites in managing their study documents. Be sure to follow any existing institutional requirements.

Category	Document	Note	Recommended Storage Location
Original Informed Consent File	Request for Approval to Approach Patient/Family Form (Pregnancy Assertion Form)	The attending physician or delegate must sign this form attesting to the fact that a female patient is not pregnant and allowing study staff to approach the family of an eligible patient for consent.	Keep in a **separate and confidential** location from other study documents (e.g., a separate binder for all original signed ICFs/HIPAA authorizations/assent forms).
	Original signed informed consent and HIPAA Authorization form (a separate document for some sites)	Check with your local IRB/IRB of record to see if a copy of the signed consent and HIPAA authorization form should be kept in the subject's medical record.	
	Original signed assent form	Follow the recommendations of your local IRB/IRB of record for the age of assent. Assent can be obtained up until hospital discharge or Study Day 28 for subjects who are cognitively capable (PCPC 1-3 and not on sedatives for past 72 hours).	
Study Tracking Documents (continued on page 2)	Daily Screening Form Log	Maintain on a daily basis, recording each patient in the appropriate age range who has been newly diagnosed with study-defined cardiovascular and/or respiratory failure. Information for the *current* week (Monday – Sunday) must be entered into the InForm database by the following Monday at 5:00 p.m. (your local time).	1. The log for the *current week* may be maintained on the unit so that it is accessible to staff for the purposes of screening. While on the unit, the log should be kept in a secure location accessible only by study staff. 2. The *completed* Daily Screening Form Log must be filed securely with the other completed logs, preferably in the research office.
	Patient Study ID Log	Maintain on a daily basis, as patients are screened, consented, and randomized.	Keep in a secure location, preferably in the research office.

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Study Tracking Documents (continued from page 1)	Consent Log	Record all consented subjects on this log.	Keep in a secure location, preferably in the research office. Special care should be taken as this log contains protected health information (PHI).
	Consented Subject Tracking Sheet (one per consented subject)	Maintain on a daily basis. Blood glucose (BG) levels are expected to be tracked multiple times per day.	1. This tracking sheet may be maintained on the unit for *current subjects* so that it is accessible to staff to complete every morning summarizing the previous study day's events from 00:00 to 23:59. 2. The *completed* subject's tracking sheet must be filed securely in the subject's research file in a secure location, preferably in the research office.
Other Miscellaneous Documents	Original Contact and Demographic Information Form	Prior to ICU discharge, site personnel should complete the Contact and Demographic Information Form via an interview with the parents/guardians. Do not fax this form to SC-CUMC until prompted by the DCC.	Keep in a secure location, preferably in the research office. Special care should be taken as this log contains protected health information (PHI).
	Delegation Log	Record your research personnel, their study responsibilities, and time worked in the study. This log should include the Site Director, research study nurses, study coordinator, and data entry personnel. Obtain signatures and initials of personnel.	Keep in a secure location, preferably in the research office.
	Original Child Behavior Checklist (CBCL)	While their child is in the ICU, parents/ guardians should fill out the caregiver baseline CBCL questionnaire. Forms should be faxed to the secure CCC fax line.	Keep in a secure location, preferably in the research office.
	Original Pediatric Quality of Life Inventory (PedsQL)	While their child is in the ICU, parents/ guardians should fill out the caregiver baseline PedsQL questionnaire. Forms should be faxed to the secure CCC fax line.	Keep in a secure location, preferably in the research office.