Clinical Research Study Self-Monitoring Tool for Non-Drug Studies

Study Information

Study Title/Protocol #: _____ IRB #: _____

PI: _____ Study Coordinator: _____

Self – Monitor Date: _____ Subject Reviewed: _____

Assent, Consent & HIPAA Process

1) Obtained for subject/legal guardian prior to performing any research-specific screening procedures.	Assent	☐ Yes	☐ No	☐ N/A
	Consent	☐ Yes	☐ No	
	HIPAA	☐ Yes	☐ No	
2) Valid IRB-approved form (most up-to-date version) was used to consent subject/legal guardian.	Assent	☐ Yes	☐ No	☐ N/A
	Consent	☐ Yes	☐ No	
	HIPAA	☐ Yes	☐ No	
3) The subject/legal guardian signed/dated each form for him/herself.	Assent	☐ Yes	☐ No	☐ N/A
	Consent	☐ Yes	☐ No	
	HIPAA	☐ Yes	☐ No	
4) An IRB-approved investigator/study coordinator who consented the subject signed and dated the consent form him/herself.	Consent	☐ Yes	☐ No	
5) Dates are consistent between the subject/legal guardian and the investigator/study coordinator on all forms (i.e. consent, assent, HIPAA).	Assent	☐ Yes	☐ No	☐ N/A
	Consent	☐ Yes	☐ No	
	HIPAA	☐ Yes	☐ No	
6) All yes/no, checkboxes, or similar options on the forms are completed and/or initialed.	Assent	☐ Yes	☐ No	☐ N/A
	Consent	☐ Yes	☐ No	☐ N/A
	HIPAA	☐ Yes	☐ No	☐ N/A
7) All pages of the forms are on file for subject.	Assent	☐ Yes	☐ No	☐ N/A
	Consent	☐ Yes	☐ No	
	HIPAA	☐ Yes	☐ No	
8) Original signed forms are retained in the subject binder/folder and a copy of each form was given to each subject/legal guardian.	Assent	☐ Yes	☐ No	☐ N/A
	Consent	☐ Yes	☐ No	
	HIPAA	☐ Yes	☐ No	
9) The consent discussion is documented in a progress note, visit note, etc.	☐ Yes	☐ No		
10) A non-English speaking subject was consented in accordance with HRPP policies and procedures.	☐ Yes	☐ No	☐ N/A	
11) Subject was consented with revised consent forms in a timely manner and there's documentation of the consent process in a progress note, visit note, etc.	☐ Yes	☐ No	☐ N/A	

Notes:

Subject Eligibility

12) All inclusion and exclusion criteria were met, documented and source information is present to support it.	☐ Yes ☐ No
13) Documentation indicating that the PI reviewed and verified that subject meets all inclusion/exclusion criteria.	☐ Yes ☐ No
Notes:	

Study Procedures

14) Documentation for all subjects who were screened and/or enrolled in the study including date(s), name, DOB and subject identification code (e.g. Subject Screening & Enrollment Log).	☐ Yes ☐ No
15) All procedures and assessments are completed per protocol (e.g. specified visit or timeframe) and results are clearly documented including dates of procedures/assessments and staff who performed procedures; or documentation of missing procedures/assessments includes reason, resolution and preventive measures for future occurrences.	☐ Yes ☐ No
16) Corrections made on any data collection forms are dated and initialed by the corrector (including the subject for self-assessment forms) at the time of correction.	☐ Yes ☐ No
17) Research staff performing study procedures has been approved by the IRB (e.g., consenting).	☐ Yes ☐ No
18) Protocol deviations are documented and have been submitted to the IRB.	☐ Yes ☐ No
19) If subject was withdrawn from the study early, documentation indicates the reason why.	☐ Yes ☐ No
Notes:	

Subject Compensation

20) Subject payments are tracked (e.g., Subject Compensation Log) and subject signed and dated receipt of payment (e.g., Subject Compensation Receipts.)	☐ Yes ☐ No ☐ Not applicable
Notes:	

Data Privacy & Security

21) Study information including subject specific binders/folders and regulatory documents are stored in a locked cabinet with access limited to IRB-approved research staff.	☐ Yes ☐ No
22) Databases used to collect study information are password protected and are located on a secure drive (e.g. hospital network drive, REDCAP, etc.)	☐ Yes ☐ No
23) Study information that is shared outside Connecticut Children's is congruent with the terms of a Data Use Agreement or other Research Agreement.	☐ Yes ☐ No ☐ Not applicable
24) The process for transporting biological materials such as tissue and blood samples outside of Connecticut Children's is congruent with the terms of a Material Transfer Agreement and documentation of the transferred materials is in compliance with Connecticut's Children's policy and education on "Transporting Biological Specimens for Research Studies."	☐ Yes ☐ No ☐ Not applicable
25) Equipment used to collect or store data or specimens such as refrigerator, freezer, thermometers in refrigerators or freezers, centrifuge, weight scale, EKG machine, BP monitoring is calibrated and documented.	☐ Yes ☐ No ☐ Not applicable
Notes:	

Research Staff Training

26) Initial research staff training on the study is documented including date of training, method of training (e.g. meeting, observation of PI), study information discussed and research staff present at training.	
27) Subsequent research staff training regarding protocol changes, study progress or other updates is documented.	
Notes:	

Regulatory Binder

28) All IRB correspondence including IRB approval letters, all versions of assents/consents/HIPAA forms, protocol and protocol amendments and any other study documents is filed in chronological order with newest on top.	☐ Yes ☐ No
29) Documentation of research staff protocol training (#26) and CV's of research staff are filed.	☐ Yes ☐ No
Notes:	