

Proper Documentation in Research Involving Human Subjects

1. Applicability:

This guidance applies to all SBU research involving human subjects (i.e. that qualified for exempt, expedited, or full review), with the exception of pharmaceutical funded/initiated studies. Such studies through the pharmaceutical industry have very specific documentation requirements promulgated by the sponsor and the FDA which must be followed to the letter to ensure the compliant conduct of the clinical trial.

2. Introduction:

Detailed documentation is critical for ensuring, and proving, your compliance with federal regulations and SBU policies for the conduct of any and all research involving human subjects. This guidance provides details for proper documentation in research involving human subjects. When ORC staff conduct audit/monitoring visits, it will be expected that appropriate documentation processes are being followed.

3. There should be 2 types of ‘stories’ that must be clearly documented for each study.

a. **The Regulatory Binder:** The Regulatory History of the Study

Note: Some, but not all, of the documents below may already be available in the IRB electronic system. If the PI decides not to place those documents in the regulatory binder for the study, the PI is responsible for ensuring that all study personnel know how to access them in the electronic system.

The following documents should be in this binder, in sequential order, with most current documents on top:

- i. **IRB approval, acknowledgement letters**
- ii. **All IRB approved/acknowledged study documents** (e.g., protocol, protocol amendments, stamped consent/permission/assent documents, diary forms, translations, advertisements/brochures for recruitment, surveys), package inserts, Investigator brochures, Certificate of Confidentiality, etc.)
- iii. **Protocol deviations/exceptions** with report to the IRB (and sponsor as applicable), and resulting determinations and IRB-approved corrective action plans, if required.
- iv. **Unanticipated problems involving risk to subjects or others (UP’s):** with report to IRB, and their determination
- v. **Data collection form (sometimes called Case Report Form) templates.** A case report form is a data collection tool used to help investigators capture all research-required information for each subject. It is an excellent tool to ensure that the protocol is followed as approved by the IRB. For investigator initiated studies, a case report form/source document collection form can be created by going through the protocol and outlining, step by step, what research procedures will occur, and what data was collected at each study visit. The web has many sites to aid in the construction of case report forms or data collection forms. (see for example, <https://dcc2.bumc.bu.edu/ocr/ClinicalResearchNewsletter/article.aspx?article=188>)
- vi. **Inclusion/Exclusion Checklist template,** with acceptable ranges (i.e., Lab values), and a line for the subject’s value, where applicable. PI should review and sign the completed check list for each subject, prior to any research procedures being conducted on the subject (including screening, randomization etc.). *Although this requirement is currently in place only for more than minimal*

risk studies, it is strongly suggested that all studies adopt the practice to ensure that only IRB approved, eligible subjects are enrolled in the study.

- vii. **Delegation of Authority Form:** With this document, the Principal Investigator formally delegates authority to specific team members to do specific research-related tasks. The delegation must be consistent with the individuals' expertise and licensure where applicable (e.g., Ms. S. Coordinator: consent process; Dr. C. Investigator, conducts the neuropsych exams; Mr. G. Student: data input/analysis etc.). This document should also show team members signatures and initials (for audit purposes).
- viii. **Proof of licensure for team members,** based on their delegation of authority from the PI, as above.
- ix. **Subject ID code list location**
- x. **Subject screen log/Subject enrollment log:** this allows you to document the chronological enrollment of subjects
- xi. Monitoring visit reports from within or outside SBU, self-audit reports
- xii. **Relevant communications:** e-mails, telephone call notes relating to the conduct of the study, or subject queries or complaint etc.

And, as applicable:

- xiii. Drug/device dispensing log
- xiv. Reports required by sponsors, if any, and resulting correspondence
- xv. Decoding procedures (for blinded trials)
- xvi. Certificate of Confidentiality
- xvii. FDA Forms (e.g., 1571), reports to FDA, FDA communications, DSMB reports (if the PI is the sponsor of an IND/IDE)
- xviii. Location of stored/archived research records
- xix. Membership of the Data Safety Monitoring Board

b. **The Subject Record:** The Complete "Story" for every Subject

There should be a record of all activities that have occurred on the study for each subject. The record should be coded, and the key to the code should be retained in a separate locked location in order to protect subject confidentiality.

- i. **Description of method of recruitment** for the subject in question (e.g., "Ms. Patient was encountered in the clinic when she came for a medication check for her thyroid", or Mr. Grad Student responded to an advertisement in Psych B. etc.)
- ii. **Completed inclusion/exclusion checklist** with specific values/data entered for the subject. *Although this requirement is currently in place only for just more than minimal risk studies, it is strongly suggested that all studies adopt the practice to ensure that only IRB approved, eligible subjects are enrolled in the study.*
- iii. **Details of the consent process** with the subject. A form can be used to facilitate this documentation, an example of such, is provided in Appendix I following this SOP.
- iv. **Signed informed consent/permission/assent documents** (including any consent addenda signed by the subject during the course of the study)

- v. **Source documents:** A source document contains data that is initially collected on the subject. It can be a case report form/data collection form or may simply be lab values, etc. The source documentation details the specific values/data entered for the subject, i.e., inclusion/exclusion data, screening, research procedures conducted/data collected throughout the course of the study. Such information must match what the informed consent documents describe will be conducted/collected. Examples: hard copies of completed surveys, questionnaires, lab/radiology reports, x-rays.

Note: If information is taken from the medical record, a copy of the applicable page (or screen shot from the electronic medical record) will suffice as source documentation.

- vi. **Completed case report forms/data collection forms for each visit.** These should also provide a section where the investigator can put ‘visit notes’ (e.g., subject reported no problems etc.)
- vii. **A log of all adverse events (AE’s) that the subject experienced** (if it does not constitute an unanticipated problem involving risks to subjects or others, which must be reported to the IRB immediately, these AE’s are reported at the time of continuing review).

Appendix I Documentation of Consent/Permission/Assent Process
(To be completed by the Study Team Member who is Obtaining Consent)

Study PI: _____

Study Identifier/IRBNet #: _____

Date: _____

Subject Name: _____

Parent Name(s), if subject is a minor _____

Circle answer:

1. Have you been delegated authority by the Principal Investigator to conduct consent processes for this study? Y N N/A (You are the PI)

2. Did you first verify that the consent document being used is the most current IRB approved/stamped version, obtained either from the electronic system, or the study regulatory binder? Y N

3. Did you discuss with the subject/parent:
 - a. The purpose of the study Y N
 - b. Possible risks and benefits Y N
 - c. All research procedures Y N
 - d. Alternatives to being in study Y N
 - e. Participation is voluntary Y N
 - f. Subject can withdraw at any time Y N

4. Did the subject/parent exhibit an appreciation of:
 - a. The purpose of the study Y N
 - b. Possible risks and benefits Y N
 - c. All research procedures Y N
 - d. Alternatives to being in study Y N
 - e. Participation is voluntary Y N
 - f. Subject can withdraw at any time Y N

5. Was the subject/parent given an opportunity throughout the process to ask questions? Y N
6. After consent process, was the subject/parent given time to review the consent form? Y N
7. Was the subject given a copy of the IRB approved/stamped, signed consent form? Y N

Your signature below confirms the accuracy of the information provided above, and certifies that no study procedures were performed prior to the subject signing the consent document.

Printed Name

Signature

Date