Stony Brook University

Good Clinical Practice (GCP) for National Institutes of Health Sponsored Studies

Stony Brook University
Department of Psychiatry and Behavioral Health

Presenter:
Natalka Haubold
Assistant to the Vice Chair for Research | Department of Psychiatry
Lab Manager | Multi-Modal Translational Imaging Lab
Administrator | Long Island Network for Clinical and Translational Science (LINCATS)

FAR BEYOND

Stony Brook University

Presentation Sources:

Stony Brook Research | Office of Research Compliance

About ORC | Compliance Programs | Metrics | myResearch | e-Tools | Forms | Training Chart | Contact Us

Home > Human Subject Research > Standard Operating Procedures

Human Subject Research

SUBMISSION GUIDELINES

TRAINING REQUIREMENTS

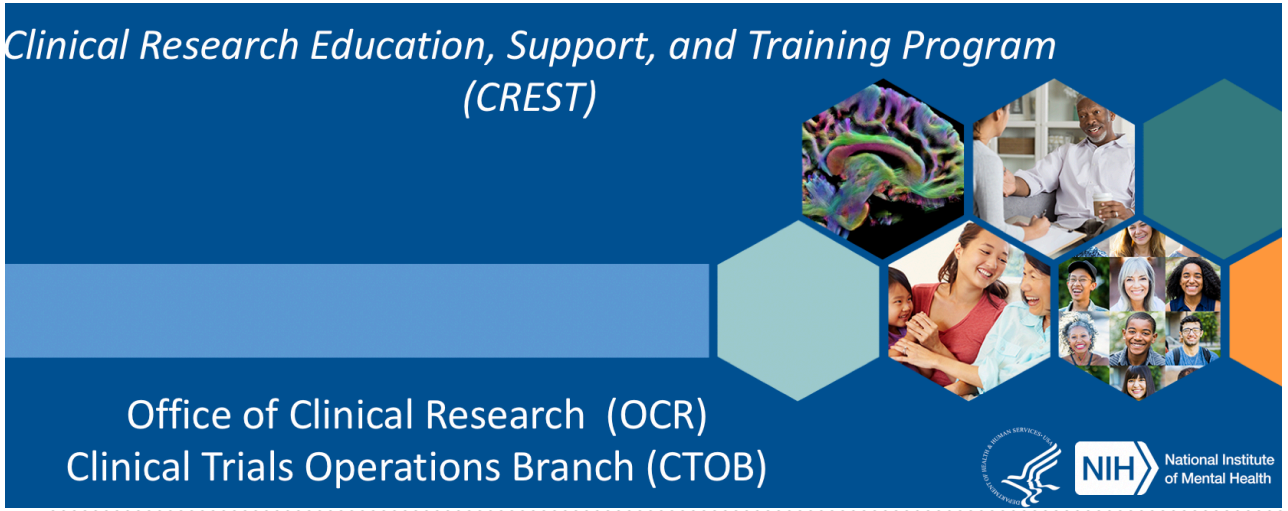
MEETING SCHEDULE AND DEADLINES

STANDARD OPERATING PROCEDURES

Standard Operating Procedures

Learn about existing protection programs, review boards and processes, informed consent, and other governing regulations in order to allow research to be conducted as smoothly as possible.

In order to ensure ethical research performance on human subjects, Stony Brook issues the Human Subjects Standard Operating Procedures Manual and expects researchers to be familiar with its policies.



FAR BEYOND

https://www.nimh.nih.gov/funding/clinical-research/nimh-clinical-research-education-support-and-training-crest-program

https://www.stonybrook.edu/research-compliance/Human-Subjects/sops

Stony Brook University

Objectives and Overview

To define Good Clinical Practice and to describe why it is important in NIMH-funded research

- Regulatory Requirements
- Resources and Staffing
- Delegation of Responsibilities
- Informed Consent
- Documentation and Storage of Data
- Assessment and Reporting
  - Protocol Adherence
  - Adverse Events/ Unanticipated Problems
- Noncompliance

Stony Brook University

Good Clinical Practice (GCP)

WHY IS **GCP** IMPORTANT?

- Sets minimum quality standards for the conduct of clinical research
- Sets standards for a system of mutual accountability among sponsors, regulatory authorities, investigators, and Institutional Review Boards (IRBs)
- Compliance with **GCP** ensures that the rights, safety, and well-being of study participants are protected
- Compliance with **GCP** ensures the study team is protected and the research data is credible (i.e., accurate, verifiable, and reproducible)
- The regulations and guidelines concerning the establishment of **GCP** apply to all studies involving human subjects in NIMH studies

Stony Brook University

Regulatory Requirements

Among other requirements, all NIH studies must comply with:

Code of Federal Regulations (CFR) Title 45

- 45 CFR 46: HHS Regulations for the Protection of Human Subjects
- 45 CFR 50: Subpart F HHS Regulations for Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought
- 45 CFR 160: Health Insurance Portability and Accountability Act (HIPAA)
- 45 CFR 164: Regulations for Standards for Privacy of Individually Identifiable Health Information

https://www.nimh.nih.gov/funding/clinical-research/nimh-clinical-research-education-support-and-training-crest-program
https://www.stonybrook.edu/research-compliance/Human-Subjects/sops

Stony Brook University

Study Staffing/Training

PRIOR to seeing subjects and/or handling study data, all study staffs members must:

- Have received IRB approval to work on the specific study
- Have all required credentials (e.g., CV, license, CITI training certificates) filed in the study regulatory binder
- Be fully informed about the protocol and study-related tasks
- Be delegated by the PI on the Delegation of Authority (DOA) Log to perform study tasks

Stony Brook University

Monitoring Recommendations Based on Level of Risk:

Safety monitoring for a protocol must be appropriate for the level of risk identified. A combination of factors used in assessing the level of risk drives the intensity of monitoring required for a protocol. The requirements outlined below represent the minimal necessary to ensure subject safety. In some cases, the NIMH OCR or the PO may require more frequent and/or enhanced monitoring along with site initiation visits and regular monitoring visits by the NIMH. Additionally, changes to the research project during the course of a study may necessitate an increased level of monitoring (see NIH Guidance NOT-OD-12-129).

Standard reporting of unanticipated problems and adverse events to the IRB is required regardless of the level of monitoring.

Stony Brook University

Monitoring Recommendations Based on Level of Risk:

Minimal Risk Studies –

- The PI (or approved co-investigator) will monitor the study with prompt reporting of adverse events and other study related information to the IRB, NIMH, and other agencies as appropriate.
- Non-serious adverse events and unrelated serious adverse events will be reported in the annual progress report to the NIMH.
- Serious adverse events that could be related to the study should be reported to the NIMH Program Officer within 7 days of becoming aware of the event.
- All study deaths must be reported to the NIMH Program Officer immediately.
- Team meetings by the PI and his/her staff will be conducted on a routine basis to discuss any new adverse events or changes in the protocol.
- A Data and Safety Monitoring Plan (DSMP) that addresses the potential risks of the study will be reviewed and approved by the NIMH Program Officer and the OCR. This plan will be revised and updated if the benefit-risk analysis changes.

https://www.nimh.nih.gov/funding/clinical-research/nimh-guidance-on-risk-based-monitoring

Stony Brook University

Monitoring Recommendations Based on Level of Risk:

Greater than Minimal Risk Studies / Significantly Greater than Minimal Risk Studies-

- The PI monitors the study on a day-to-day basis with prompt reporting of adverse events and other study related information to the IRB, NIMH, and other agencies as appropriate.
- **Non-serious adverse events** and unrelated serious adverse events will be reported in the annual progress report to the NIMH.
- **Serious adverse events** that could be related to the study should be reported to the NIMH Program Officer within 7 days of becoming aware of the event.
- Team meetings by the PI and their staff will be conducted on a routine basis to discuss protocol issues and review adverse events.
- A Data and Safety Monitoring Plan (DSMP) that addresses the potential risks of the study will be reviewed and approved by the NIMH Program Officer and the OCR. This plan will be revised and updated if the benefit-risk analysis changes.
- For all greater than minimal risk studies, sufficient surveillance and protections must be in place to adequately identify adverse events promptly.
- An Independent Safety Monitor or independent Data and Safety Monitoring Board may also be utilized for the studies/trials that have a higher probability of a moderate-severity event occurring, to review adverse events as they occur and make recommendations as they deem necessary to the study team.

Stony Brook University

Delegation of Authority

Delegation of Authority Log (DOA)

- Show which study staff are delegated by the PI to conduct study-specific tasks
- All staff listed on the DOA should have at minimum in the study regulatory binder:
  - Signed and dated CVs (and licensure if appropriate)
  - Human subject protection and GCP training certificates (CITI Trainings)
- The log should have a column for the PI to sign off on each staff member's delegation individually (not one line at the end of the log)

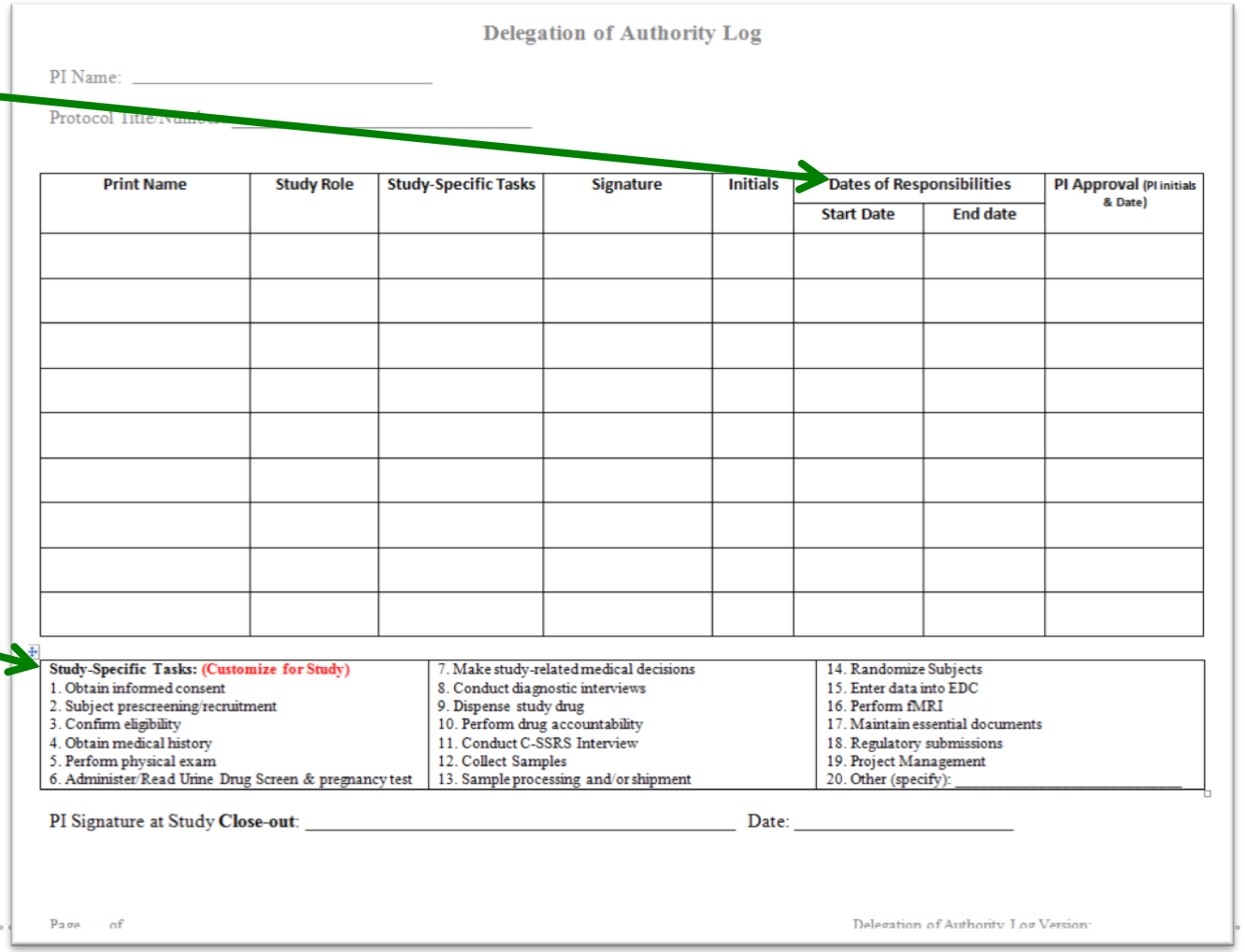
Stony Brook University

Example Delegation of Authority Log

Study start date after all required trainings and IRB approvals have been completed.

Study end date accurate with end date of IRB participation and must be verified by the PI.

Customize the tasks to be specific to the study and to be comprehensive of all types of study tasks



Delegation of Authority Log

PI Name: _____

Protocol Title/Number: _____

Print Name	Study Role	Study-Specific Tasks	Signature	Initials	Dates of Responsibilities		PI Approval (PI initials & Date)
					Start Date	End date	

Study-Specific Tasks: (Customize for Study)	7. Make study-related medical decisions	14. Randomize Subjects
1. Obtain informed consent	8. Conduct diagnostic interviews	15. Enter data into EDC
2. Subject prescreening/recruitment	9. Dispense study drug	16. Perform fMRI
3. Confirm eligibility	10. Perform drug accountability	17. Maintain essential documents
4. Obtain medical history	11. Conduct C-SSRS Interview	18. Regulatory submissions
5. Perform physical exam	12. Collect Samples	19. Project Management
6. Administer/Read Urine Drug Screen & pregnancy test	13. Sample processing and/or shipment	20. Other (specify): _____

PI Signature at Study **Close-out**: _____ Date: _____

Page of Delegation of Authority Log Version:

FAR BEYOND

NIH National Institute of Mental Health

Stony Brook University

Delegation of Authority

- 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 consenting 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.

Stony Brook University

Documentation

Documentation Expectations (ICH E6 GCP 4.9. & 4.10.)

Data must be **ALCOAC**

- **A**ttributable – it should be clear who has documented the data
- **L**egible – readable and signatures identifiable
- **C**ontemporaneous – information should be documented in the correct time frame
- **O**riginal - original or exact copy (photocopy preferred over 2nd original); the first record made by the appropriate person. Originals maintained at satellite locations during the study with copy to PI. Originals filed with PI at conclusion of study for records retention
- **A**ccurate – consistent and real representation of facts
- **C**omplete – study documents should be completed at the time of the study visit, not at a later date

Stony Brook University

Examples of ALCOAC

Attributable: a team member collects UTOX/Upreg results and initials on the source document

Legible: team member clearly makes a correction on a source document with initial and date

Contemporaneous: both the PI and subject sign the ICF on the same date

Original: if there's a mistake on the source, a correction is made instead of throwing the form away and starting over

Accurate: Height of 68 inches is not written 5'6". Payment information of $10.00 is not written $10

Complete: every data field on a form is filled in, including the header and staff signature line

- *How and where the data is recorded is key!*
- *If it's not documented, it doesn't exist!*
- *If it isn't IRB approved, don't do it!*
- *Data on checklists/case report forms must match the source documents*
- *Document, document, document!! Study chart should "read as a story"*

FAR BEYOND

Stony Brook University

Correcting Study Information

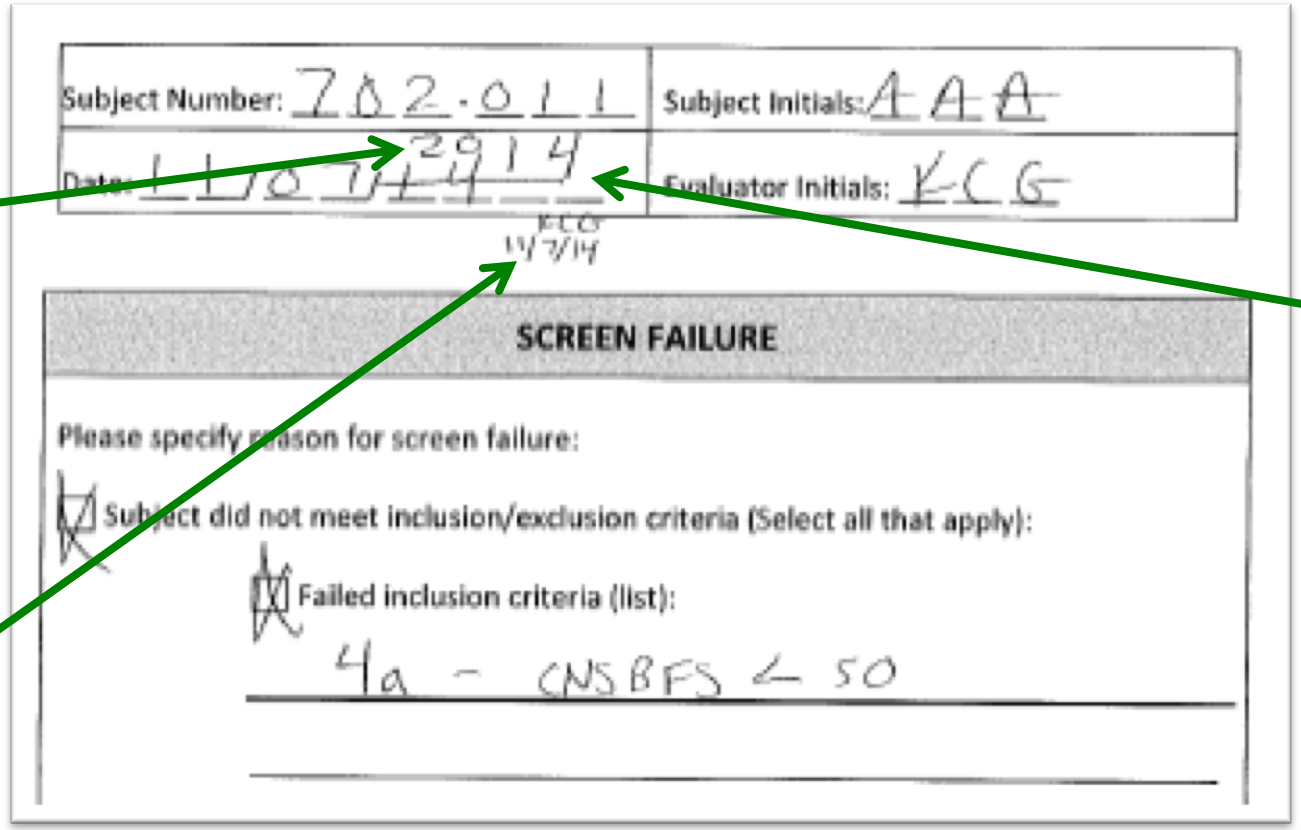
- Corrections are expected!
- Single line through incorrect information, making sure not to obscure the original data
- No white out or writing over data (e.g. turning a 0 into a 9), because it hides the original data
- Enter the correct information
- Initial and date when the corrections were made
- Entries on the study documents and changes to those entries should be made by study team members with the authority to do so as delegated by the PI
- Remember ALCOAC when correcting information, and document everything!

Stony Brook University

Example Documentation Corrections

The correct date was written near the mistake

The same evaluator who made the mistake initialed and dated the correction



A **single** line was drawn through the inaccurate data

FAR BEYOND

NIH National Institute of Mental Health

Stony Brook University

Data Storage

Paper/ Hard Copy Subject File Storage (ICH-E6 GCP 4.9.4. & 4.9.5.)

- All paper study forms for a subject should be located in the subject's study binder, with the exception of unblinding forms and forms with personally identifiable information (PHI) (e.g. informed consent forms, contact sheets with phone numbers)
- Stored in a locked cabinet in a locked office only accessible to study staff (not shared)
- Study data collected for the present study should not be removed from a subject's binder and placed in a binder for a different study
- Study data collected for the present study should be true and accurate to the procedures of study visit and should not be completed retroactively (i.e., participant notes)

Stony Brook University

Informed Consent

The informed consent process (45CFR46 & ICH-E6 GCP 4.8)

- Do not use any potentially coercive measures
- Answer all questions regarding any aspects of the study
- Give participants as much time as needed to make the decision
- Consent should be obtained by a qualified, IRB-approved study staff member listed on the delegation log

Stony Brook University

Informed Consent Continued 1

The Informed Consent Form (ICF) (45CFR46 & ICH-E6 GCP 4.8)

- No study procedures should occur prior to the subject providing written informed consent
- Only the **current** IRB-approved ICF should be signed by the subject
- All subjects should receive a copy of the signed and dated informed consent form, prior to their participation in a study

Stony Brook University

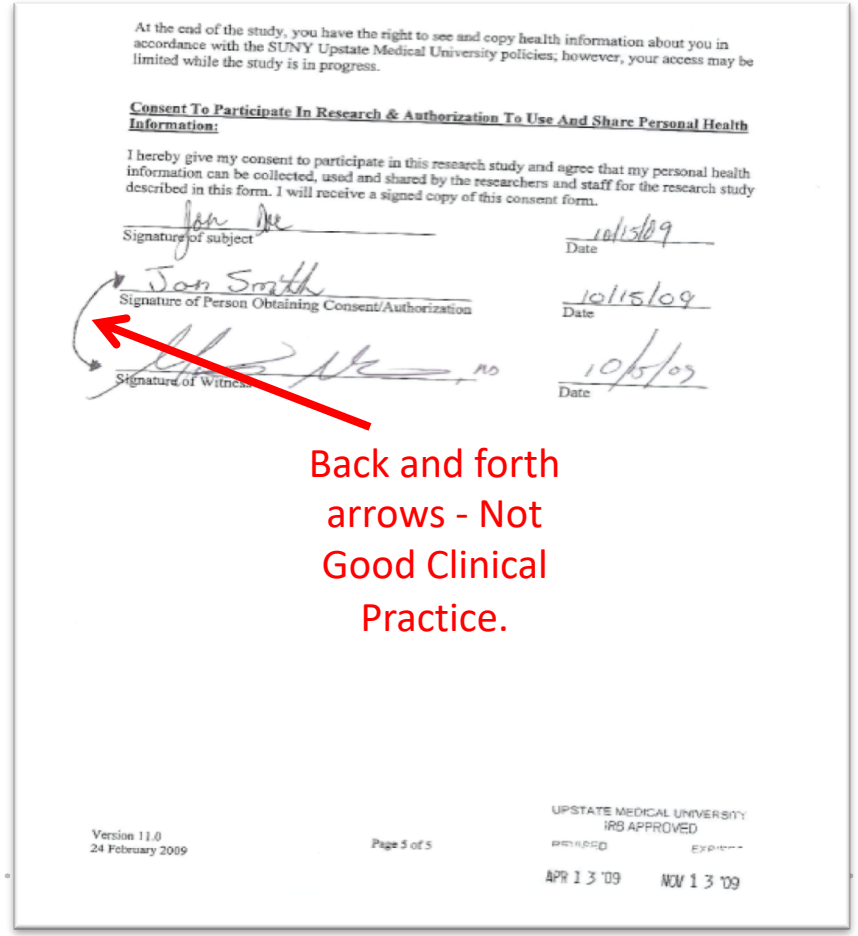
Informed Consent Continued 2

Informed Consent Documentation (45CFR46 & ICH-E6 GCP 4.8)

- Best practice is to complete a Documentation of Informed Consent source document after each subject is consented. This may be included on a pre- structured Case Report Form (CRF), but includes at minimum:
  - Name of person conducting the consent process
  - Date & time of consent
  - Statement that the subject was provided an opportunity to ask questions
  - Statement that the subject was provided a copy of their signed ICF
- This document should not contain identifying information and should be placed in the subject's study binder

Example ICF Documentation Errors

ICFs should be reviewed for completeness, accuracy, and legibility before commencing study procedures



At the end of the study, you have the right to see and copy health information about you in accordance with the SUNY Upstate Medical University policies; however, your access may be limited while the study is in progress.

Consent To Participate In Research & Authorization To Use And Share Personal Health Information:

I hereby give my consent to participate in this research study and agree that my personal health information can be collected, used and shared by the researchers and staff for the research study described in this form. I will receive a signed copy of this consent form.

Signature of subject — Date 10/15/09

Signature of Person Obtaining Consent/Authorization — Date 10/15/09

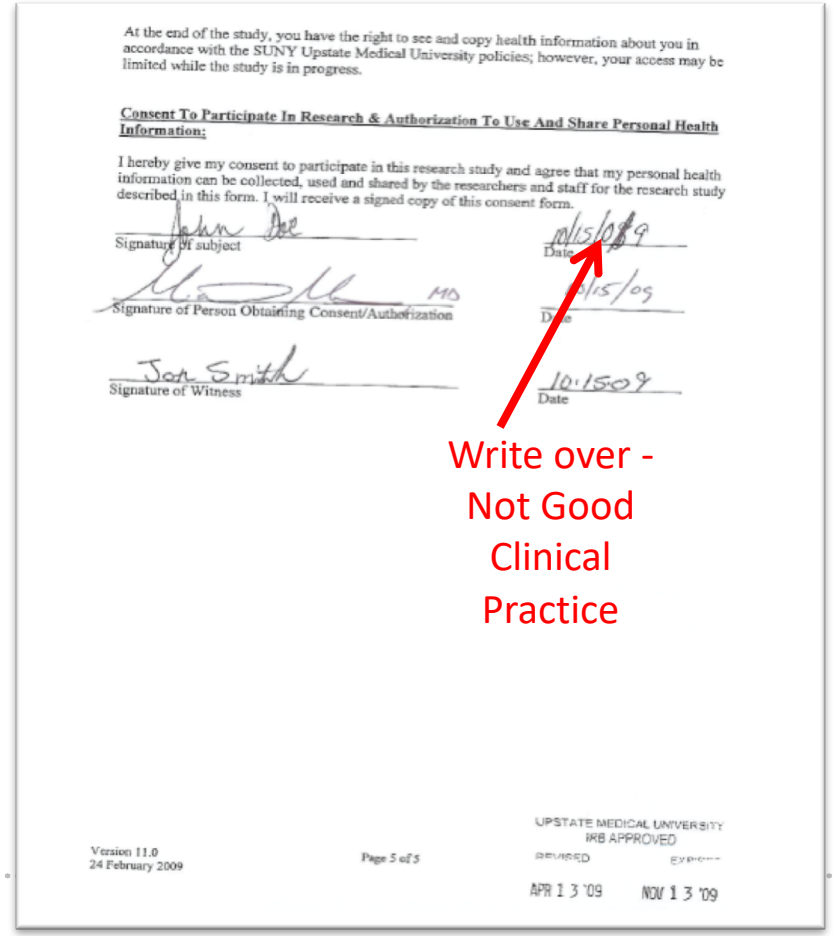
Signature of Witness, MD — Date 10/15/09

Version 11.0
24 February 2009

Page 5 of 5

UPSTATE MEDICAL UNIVERSITY
IRB APPROVED
REVISED EXPIRES
APR 13 '09 NOV 13 '09

Back and forth arrows - Not Good Clinical Practice.



At the end of the study, you have the right to see and copy health information about you in accordance with the SUNY Upstate Medical University policies; however, your access may be limited while the study is in progress.

Consent To Participate In Research & Authorization To Use And Share Personal Health Information:

I hereby give my consent to participate in this research study and agree that my personal health information can be collected, used and shared by the researchers and staff for the research study described in this form. I will receive a signed copy of this consent form.

Signature of subject — Date 10/15/09

Signature of Person Obtaining Consent/Authorization, MD — Date 10/15/09

Signature of Witness — Date 10:15:09

Version 11.0
24 February 2009

Page 5 of 5

UPSTATE MEDICAL UNIVERSITY
IRB APPROVED
REVISED EXPIRES
APR 13 '09 NOV 13 '09

Write over - Not Good Clinical Practice

FAR BEYOND

NIH National Institute of Mental Health

Stony Brook University

Use of Previously-Collected Data

- Some studies plan to reuse diagnostic interviews conducted within the past 6 months or 1 year (e.g., SCID)
- While the best practice would be to obtain all new data for the present study, the use of previous data may be acceptable if:
  - Described in the NIH grant application, IRB protocol, Data Safety Monitoring Board (DSMB) protocol (if applicable) and ICF
  - There is an acceptable process detailed in the protocol or MoP by which a qualified study clinician reconfirms the diagnosis
  - The diagnostic interviews are only reused within a reasonable timeframe
- Remember to document in a participant note!

Stony Brook University

Use of Previously-Collected Data Continued

- If the study plans on reusing documents from other studies, a copy of the original source documents should be filed within the subject study files for the current, accompanied by a participant report.

- **Definition of Certified Copy** (ICH-E6 GCP 1.63): A copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original

Stony Brook University

Protocol Adherence

Protocol Deviation (ICH-E6 GCP 4.5.)

- Noncompliance with the research protocol that does not increase risk or decrease benefit and/or affect the integrity of the data
- Protocol deviations may result from the action of the subject, researcher, or research staff
- Examples of a protocol deviation include:
  - A rescheduled study visit beyond protocol-specified time frame
  - Failure to collect a self-report questionnaire
  - Subject's refusal to complete scheduled research activities
- Deviations are expected to happen in human subjects research
- Remember, correct documentation protects the integrity of the research study as well as the study team

Stony Brook University

Protocol Adherence Continued

Protocol Violation (ICH-E6 GCP 4.5.)

- Noncompliance with the IRB-approved protocol without prior sponsor and IRB approval
- Violations generally increase risk or decrease benefit, affect the subject's rights, safety, or wellbeing, or impact the integrity of the data
- Examples of protocol violations:
  - Failure to obtain valid informed consent (i.e., an expired IRB approval date, illegible IRB stamp)
  - Loss of laptop computer or source document that contained PHI
  - Incorrect study medication or dose administered
  - Not following inclusion/exclusion criteria

Stony Brook University

Protocol Adherence Continued

Protocol Exceptions (HSSOP SBU 9.2.)

- **Protocol exceptions**: Circumstances in which the specific procedures called for in a protocol are not in the best interests of a specific subject (e.g. subject is allergic to one of the medications provided as supportive care).
- **Exceptions are planned, and the investigator gets approval from the sponsor and the IRB ahead of time.** These should be submitted in the electronic management system. Depending on the nature of the exception, an expedited review is possible. In order to be approved by the IRB, exceptions must not increase risk or decrease benefit, affect the subject's rights, safety, welfare, or affect the integrity of the resulting data.
- **The only time a protocol exception would not require prior sponsor and IRB approval** is when it is done to avoid an immediate hazard to the subject. It is then the PI's responsibility to report the incident for IRB review as soon as possible.

Stony Brook University

Documenting Protocol Deviations and Violations

- Subject Specific Protocol Deviation Log A detailed description of each deviation/violation should be available in each subject's study file
- Study-Wide Protocol Deviation Log There should be a cumulative deviation/violation log in the regulatory binder to facilitate compliance monitoring and reporting to regulatory authorities
- The total number of protocol deviations is typically reported to the IRB at the time of continuing review
- Protocol Violations should be reported to regulatory authorities and NIMH per protocol/policy

Stony Brook University

Adverse Event (AE)

AE= Any change from baseline, even if anticipated, or unfavorable medical occurrence in a human subject.

- This includes any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research

See link below for additional information:

http://www.hhs.gov/ohrp/policy/advevntguid.html#AA

Stony Brook University

Serious Adverse Events (SAE)

SAE = Any untoward medical occurrence that:

- Results in death
- Is life-threatening
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect
- Any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition

See link below for additional information:

http://www.hhs.gov/ohrp/policy/advevntguid.html#AA

Stony Brook University

Recording AEs and SAEs

Each subject should be asked about the presence/absence of AEs at **every study visit**, including those conducted via telephone or electronically

- Protocol should specify the timeframe for collecting AEs (e.g., starting at consent or baseline visit? Ending at last study visit or 30 days after?)

- Protocol and/or MoP should have AE severity grading scale
  Include rules for classifying AEs that are characteristic of the study condition
  Helps ensure Co-Is are classifying AEs consistently

If a Co-I is unblinded they should not make any determinations of AE relationship to study treatment

AE Documentation

AEs should be clearly documented in each subject's file

- Subject AE Log

Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol

There should be a log in the regulatory binder (or a note-to-file stating its electronic location) to summarize all AEs across subjects

- Facilitates safety monitoring and helps identify AE trends across subjects
- Facilitates overall AE reporting to IRB and DSMB
- Study-wide AE Log

Stony Brook University

Example Subject-Specific AE Log

Study/Protocol ID:_____ Site Name/Number:_____ Subject ID:_____

Subject-Specific Adverse Event Log

This log is cumulative and captures adverse events (including serious adverse events) of a single participant throughout the study. Each subject should be asked about the presence/absence of AEs at every study visit.

Severity	Study Intervention Relationship	Action Taken Regarding Study Participation	Outcome of AE	Expected	Serious Adverse Event (SAE)
1 = Mild 2 = Moderate 3 = Severe	1= Not related 2 = Unlikely related 3 = Possibly related 4 = Probably related 5 = Definitely related	1 = None 2 = Study intervention modification 3 = Study intervention discontinued 4 = Concomitant medication administered 5 = Subject withdrawn from study 6 = Hospitalization 7 = Other	1 = Resolved 2 = Recovered with sequelae 3 = Ongoing/Continuing treatment 4 = Condition worsening 5 = Death 6 = Unknown	1 = Yes 2 = No (AE is not listed as side effect in Investigator's Brochure, package insert, or as a characteristic of the study condition)	1 = Yes (complete SAE Form) 2 = No

At end of study only, check here if no AEs occurred: ☐ No AEs

Adverse Event	Start Date	Stop Date	Severity	Relationship	Action Taken	Outcome	Expected	SAE	Investigator Initials & Date

Page ___ of ___ Subject-Specific AE Log Version:

FAR BEYOND

NIH National Institute of Mental Health

Stony Brook University

SAE Documentation and Reporting

All SAEs should be reported immediately to the sponsor except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports. The immediate and follow-up reports should identify subjects by unique code numbers assigned to the trial subjects rather than by the subjects' names, personal identification numbers, and/or addresses. The investigator should also comply with the applicable regulatory requirement(s) related to the reporting of unexpected serious adverse drug reactions to the regulatory authority(ies) and the IRB/IEC (ICH-E6 GCP 4.11.)

For reported deaths, the investigator should supply the sponsor and the IRB/IEC with any additional requested information (e.g., autopsy reports and terminal medical reports)

SAE Report Form:

- Captures the details of the SAE and is typically sent to IRB, DSMB, Independent Safety Monitor, Medical Monitor, NIH, or other regulatory bodies as applicable
- For IND/IDE studies, also report SAEs to FDA using FDA Form 3500A

Stony Brook University

NIMH Reportable Events Policy

Reportable Event	When is Event Reported to the NIMH	Reported By
IRB/ISM/DSMB/OHRP/FDA Suspensions or Terminations	Any suspension or termination of approval must include a statement of the reason(s) for the action and must be reported promptly to the NIMH PO within 3 business days of receipt.	Regulatory or Monitoring Entity and Investigator
Deaths related to study participation	Deaths must be reported immediately (no later than within 5 business days) of the principal investigator first learning of the death.	Investigator
Unexpected Serious Adverse Events related to study participation	Reported to the NIMH PO within 10 business days of the study team becoming aware of the SAE.	Investigator
Unanticipated Problems Involving Risks to Subjects or Others	Reported to the NIMH PO within 10 business days of the investigator learning of the event.	Investigator
Serious or Continuing Noncompliance	Reported to the NIMH PO within 10 business days of IRB determination	Institution
Adverse Event	For all AEs and SAEs that are deemed expected and/or unrelated to the study, a summary should be submitted to the NIMH PO with the annual progress report.	Investigator
Protocol Violations	With the annual progress report.	Investigator

FAR BEYOND

NIH National Institute of Mental Health

Stony Brook University

Unanticipated Problems (UP)

UP= any incident, experience, or outcome that meets **all** of the following criteria:

Unexpected (in terms of nature, severity, or frequency) given

(a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; **and**

(b) the characteristics of the subject population being studied

Related or possibly related to participation in the research; and suggests that the research places subjects or others at a **greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized

See link below for additional information:

http://www.hhs.gov/ohrp/policy/advevntguid.html

Stony Brook University

Noncompliance

Noncompliance:

Defined as a failure to follow the regulations, applicable law, institutional policy, and deliberations of the IRB

Serious Noncompliance:

Defined as noncompliance that jeopardizes the safety, rights, and welfare of participants

Continuing Noncompliance:

Defined as a repeated pattern of noncompliance

Noncompliance Continued

Why does noncompliance occur?

- Lack of education
- Lack of appreciation
- Error in judgment
- Not usually direct intent to inflict harm

Stony Brook University

Noncompliance Continued

Non-Compliance (HSSOP SBU 10.4.)

Investigators and their study staff are required to report instances of possible non-compliance.

- The PI is responsible for reporting any possible non-compliance by study personnel to the IRB.
- Any individual or employee may report observed or apparent instances of noncompliance to the IRB. In such cases, the reporting party is responsible for making these reports in good faith, maintaining confidentiality and cooperating with any institutional review of these reports.
- If an individual, whether investigator, study staff or other, is uncertain whether there is cause to report noncompliance, they may contact the IRB staff to discuss the situation informally.

Stony Brook University

Protocol Adherence Continued

Examples of Non-Compliance

- When determining eligibility for an in-person screening via phone screening, **only** the IRB-approved phone screen questions should be asked.
- If a subject DQ's on the phone survey, they should **not** be brought in for any research procedures without an IRB exception. Similarly, if a subject DQ's during the in-person visit, they should **not** be brought in again without an IRB exception.
- Post-it notes are **not** approved source documents.
- Document margins are **not** approved note spaces.
    - If additional information needs to be added to a subject chart, put it in a participant note.
    - If a document needs to be updated to allow for additional information, it must have a version # or IRB approval
- Inclusion/exclusion documentation must be completed **at the time** of the screening visit.
    - If it is a two-part visit to determine eligibility, the inclusion/exclusion checklist should reflect those dates.

Stony Brook University

Applying GCP to Your Study

- Understanding is key to protecting subject safety and integrity of data
- Monitoring and quality management help ensure compliance
- Ultimately, compliance with GCP is the PI's responsibility

Stony Brook University

Additional Resources

Topic	Reference
Protection of human subjects	45 CFR 46
Staff qualifications/training	ICH-E6 GCP 4.1, ICH-E6 GCP 4.2.
Research resources	ICH-E6 GCP 4.2.
Protocol adherence	ICH E6, Sec 4.5
Record keeping	ICH E6, Sec 4.4.1, Sec 4.9, Sec 8
FAQs OHRP Investigator Responsibilities	http://answers.hhs.gov/ohrp/categories/1567
NIMH Reporting	NIMH Reportable Events Policy

FAR BEYOND

NIH National Institute of Mental Health

Stony Brook University

Additional Resources Continued

ICH GCP: http://www.ich.org/products/guidelines.html

FDA Regulations: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm#FDARegulations

NIMH Clinical Research Policies: http://www.nimh.nih.gov/funding/clinical-research/index.shtml

Office for Human Research Protections (OHRP): http://www.hhs.gov/ohrp/humansubjects/index.html

GCP training course: http://gcplearningcenter.niaid.nih.gov/ or https://gcp.nidatraining.org/

NIMH Clinical Research Toolbox:
https://www.nimh.nih.gov/funding/clinical-research/clinical-research-toolbox/nimh-clinical-research-toolbox.shtml

ICH Clinical Safety Data Management: Definitions and Standards for Expedited Reporting Guideline:
https://www.fda.gov/media/71188/download

Stony Brook University

Additional Resources Continued

Stony Brook Human Subjects Standard Operating Procedures Manual : https://www.stonybrook.edu/research-compliance/Human-Subjects/sops

SBU BOX: Coordinator Docs > Guides

- 15 Golden Rules
- Guidance on the Conduct of Clinical Research
- MyResearch IRB Quick Reference
- Phone Survey First Guide
- Regulatory Binder Contents
- SBU IRB Documentation Regulatory Compliance

Your lab manager is always available to answer questions and offer recommendations!

Stony Brook University

Questions?

Email: natalka.fallon@stonybrookmedicine.edu
Phone: 631-638-2363
Office: HSC, T10-087G

FAR BEYOND