Title: Obtaining Informed Consent	Version Number: <#>	Effective Date: <Date>	Page **1** of **5**

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Purpose:

The purpose of this (SOP) is to provide detailed instructions and guidelines for documenting the Informed Consent Process effectively. This SOP aims to ensure consistency, accuracy, and compliance with regulatory standards in documenting participant consent within the clinical research setting.

Scope and Responsibilities:

This Standard Operating Procedure (SOP) establishes the protocol for documenting informed consent in clinical research conducted within the Department of Neurosciences at UCSD.

This SOP applies to investigators, research staff, and any personnel involved in obtaining informed consent from research subjects who participate in clinical studies in the Department of Neurosciences.

Definitions and Acronyms

EMR:	Electronic Medical Record
HIM	Health Information Management
HIPAA	Health Insurance Portability and Accountability Act
HR:MM	Hours: Minutes
ICF	Informed Consent Form
ICP	Informed Consent Process
MRN:	Medical Record Number
SOC	Standard of Care

Procedures

1. Documentation of ICF Process Form (Appendix A): This document serves as an official record of the Informed Consent Form (ICF) process, as mandated by study monitors. It must be securely filed within the subject's research chart, alongside the signed ICF, HIPAA, and California Bill of Rights documents.

Informed Consent Process Template Re

2. Instructions for Completion of Informed Consent Process Form:
   - Enter the study title, protocol# and participant ID.
   - Ensure the most up-to-date and approved IRB approved informed consent form that was used to consent the participant. Document the version and date of the UCSD ICFs used during the consent process.
   - Enter the date the consent was first given to the participant under the space allocated under the first bullet of the Informed Consent Process Form. This date may be the date when the participant first received the ICF at the clinic during a SOC visit or via email. This is to document the participant was given sufficient time to review the ICF.
   - Corroborate that the date on the informed consent was obtained prior to carrying out any research activities.
   - Confirm that all signatures, printed names and dates (DD/MM/YYYY) on all consents (participant or participant's legally authorized representative; study partner/caregiver, person consenting participant) are legible and accurate. Note that the date of consent should be the day the participant started screening procedures.
   - Obtain the participant's and/or participant's legal representative and study partner signatures on the HIPAA (Health Insurance Portability and Accountability Act) form. If there are any amendments to the HIPAA authorization requirements during the trial or if there are changes to the Protocol that may affect the ICF such as additional assessments; disclosure of new adverse events; change of PI; etc., the participants may need to re-sign the HIPAA form to indicate their continued consent to those terms. This ensures ongoing compliance with privacy regulations and ethical standards.
   - Staff completing ICF process must sign and date the bottom of the Informed Consent Process form on the space provided.
   - Document the date and time (HR:MM) of the actual Informed Consent at the bottom of the Informed Consent Process form. Note that many ICFs do not

include a line to document time of consent; however, many monitors and auditors will require the time when the ICF process took place to verify that no assessments took place before the signing of the ICF.

- File the informed consent process form in the participant's study binder on top of the original signed ICF, HIPAA, and CA Bill of Rights.

3. Verification Process
   - The ICF process must be verified by a member of the study team other than the staff who completed the actual informed consent. The "verify by" signature should be completed by a coordinator at the CRC-A level or higher.

4. Scanning and Filling
   - Subject must have an MRN to participate in therapeutic or device clinical research involving drugs or devices.
   - Scan Informed Consent Form, HIPAA Authorization and CA Bill of Rights, to the Health Information Management (HIM) System.
   - Check off the box at the bottom of the Informed Consent Process Form confirming upload of documents to the subject's MRN in the Electronic Medical Record (EMR) via HIM. In the context of UCSD Health, HIM works closely with the EPIC system, the electronic medical record (EMR) platform used across the entity. HIM ensures that documents such as Informed Consent Forms and other medical records are uploaded and managed within EPIC, where clinicians and researchers can access them as needed. EPIC provides the digital infrastructure, while HIM ensures compliance, accuracy, and privacy of the data. This is particularly important experiences a AEs/SAEs and requires treatment at a UC facility.
   - File "Informed Consent Process Form "along with any other supporting documentation (e.g. signed/dated ICF, HIPAA, CA Bill of Rights) in the participant's research chart.

Appendices

APPENDIX A

UC San Diego
SCHOOL OF MEDICINE
DEPARTMENT OF NEUROSCIENCES

INFORMED CONSENT PROCESS DOCUMENTATION

STUDY TITLE: _____
_____

PROTOCOL#: _____

SUBJECT#: _____

Participant ICF UCSD Version/Date: _____
Study Partner/Caregiver ICF UCSD Version/Date (if not applicable write N/A): _____

Investigator/Designee:

- I provided the subject with a copy of the Informed Consent form with ample time for review. The subject received a copy of the ICF initially on ___/____/_____. DD/MM/YYYY
- I gave the subject ample time to review and ask questions before completing any assessments.
- I explained and discussed the nature, purpose, requirements, duration, and risk of the study.
- I discussed alternative therapies/treatments.
- I provided the subject with contact details for study staff and emergency care.
- All questions were answered to the subject's satisfaction.
- The Investigator was available during the ICF process and answered the participant's questions.
- The subject was reminded that participation is completely voluntary and he/she has the right to withdraw without penalty.
- The Informed Consent was obtained in a language understandable to the subject prior to any study procedures.
- I provided to the subject a signed copy of the Inform Consent Form and the HIPAA (Health Insurance Portability and Accountability Authorization) form and a copy of the California Bill of Rights.

_____ _____
Name: Date and Time of Consent (HR:MM)
Research Coordinator
Division of Neuroscience

ICF Verified By _____ _____
Date

☐ Informed Consent forms scanned to Health Information Management (HIM) System

Department of Neuroscience
9452 Medical Center Drive, La Jolla, CA 92093 TEL: (858) 999-9999 Fax (858) 999-9999

SAMPLE

5 References

5.1 California Health and Safety Code 24174
5.4 21 CFR 50.27(b)(2)
340-1 UCSDHP

Document Approval

- Name and Title of Approver
- Date in the format (MM/DD/YYYY)
- Insert Name and Title below Signature

Approved By: Date:

_____ _____
Insert Name and Title

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