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Revision History		
Version No.	Effective Date	Description

## 1 Purpose

- 1.1 This procedure outlines the process to obtain informed consent from subjects, the legally authorized representatives (LAR) of adults unable to consent, or the parents or guardians of children. This SOP aims to ensure that the informed consent process adheres to ethical standards, regulatory requirements, and best practices in clinical research, thereby safeguarding the rights and welfare of research participants.
- 1.2 The informed consent process begins when a potential candidate for a research study is identified and lasts throughout the duration of the subject's participation in the study. If at any time during the initial consent discussion or during the subject's participation in the study, the subject/LAR withdraws their consent to participate, all study procedures in which the subject/LAR no longer wishes to participate must stop.
- 1.3 The informed consent process ends when a subject or the subject's LAR declines to participate in the study or when the subject's participation in the study comes to an end for any reason. (e.g. withdrawal, study completion, etc.).

## 2 Scope

- 2.1 The PI or delegate is required to follow the regulations set forth for obtaining informed consent for the protection of human subjects as found in the Department of Health and Human Services Common Rule (45 CFR §46) and the U.S. Food and Drug Administration (FDA) regulations (21 CFR §50), as applicable. This SOP applies to all clinical research studies not otherwise exempt from obtaining informed consent outlined in 45 CFR §46 and 21 CFR §50 and which do not fall into the consent without signature or opt-out consent models approved by the IRB.
- 2.2 Additionally, clinical trial investigators should adhere to the International Council on Harmonization (ICH) GCP guidelines, which provide assurance that freely given informed consent is obtained from every subject prior to clinical trial participation.

## 3 Responsibilities

- 3.1 This SOP applies to investigators, research staff, and any personnel involved in obtaining informed consent from research subjects who participate in clinical research studies in the Department of Neurosciences.
- 3.2 The PI and study staff involved in the consent process must have proof of completion of Human Subjects Research Protection (BMR) and Good Clinical Practice (GCP) trainings

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which can be obtain via the CITI program. See Training GOP for details on required training to conduct clinical research at UCSD.

## 4 Definitions and Acronyms

**Clinical Research/Investigational Study:** Clinical research includes all research involving human participants. It does not include secondary studies using existing biological specimens or data collected without identifiers or data that are publicly available.

**Clinical Trial:** Clinical trials are clinical research studies involving human participants assigned to an intervention in which the study is designed to evaluate the effect(s) of the intervention on the participant and the effect being evaluated is a health-related biomedical or behavioral outcome.

**Health Insurance Portability and Accountability Act of 1996 (HIPAA):** Federal law that safeguards the confidentiality and security of protected health information (PHI). “Protected health information is any information in the medical record or designated record set that can be used to identify an individual and that was created, used, or disclosed in the course of providing a health care service, teaching, treatment or research activities”. To access, obtain, or add data to a Medical Health Record, subjects enrolled in research studies must provide a signed HIPAA Authorization. Alternatively, the project must have a Waiver of Authorization approved by an Institutional Review Board (IRB). These are the most common identifiers of PHI.

Name	Fax	IP Address
MRN	Account #	Insurance #
Address	Images	License #
Phone	URL Address	Vehicle #
Email	SSN	Device #
Dates	Biometric ID	Other identifier

**Remember: Personal Identifier + Health Information = PHI**

Note: Please refer to the Office of Compliance and Privacy’s (UCSD Pulse Intranet page) policies for more information on obtaining HIPAA authorization.

**Informed Consent:** Informed consent is a fundamental ethical principle in clinical research. It refers to a subject’s (or the subject’s legally authorized representative’s) voluntary agreement to participate in research based on knowledge and understanding of relevant information.

**Investigational Procedure:** A procedure regulated as part of a research study under sections 351 and 354-360F of the Public Service Act (e.g. administration of experimental drug).

**Legally Authorized Representative:** For research purposes, a LAR is an individual or

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judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in a research study. The LAR advocates for the best interests of the prospective subject while considering their autonomy and well-being. A LAR is typically necessary when the prospective subject (research participant) is unable to provide consent themselves due to factors like age, cognitive impairment, or incapacitation to make a conscious and informed decision. There is no requirement to obtain proof of LAR from research participants.

**Individual LAR:** This can be a family member, guardian, or someone designated by the prospective subject (e.g., a parent consenting for a minor child, spouse consenting for a participant).

**Judicial or Other LAR:** In some cases, a court-appointed representative or an institutional body (such as a hospital ethics committee) may act as the LAR.

**Medical Experiment:** The definition of "medical experiment" provided by the California Health and Safety Code encompasses any scientific investigation involving human subjects to test or evaluate medical interventions, including research studies and clinical trials.

**Minimal Risk:** The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during routine physical or psychological examinations or tests.

**Short (ICF) Form:** The Short-Informed Consent Form is a condensed version of the standard informed consent document provided to participants before their enrollment in a research study. The short ICF aims to present key details in a concise and accessible format, allowing participants to make informed decisions about their participation while ensuring compliance with ethical and regulatory requirements. Typically, the short ICF may be used in studies with minimal risk or where participants have limited time or literacy levels.

**Voluntary:** Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.

- CFR: Code of Federal Regulations
- FDA: Food and Drug Administration
- GCP: Good Clinical Practice
- ICF: Informed Consent Process
- ICH: International Council on Harmonization
- IRB: Institutional Review Board
- PI: Principal Investigator
- SOG: Standard Operating Guidance

## 5 Procedure Requirements

- 5.1 Consent form(s) must be reviewed and approved by the IRB of record (central or local) prior to consenting study subjects. Any changes made to the consent form(s) after initial

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IRB approval must also be submitted to the IRB and approved prior to use. See IRB Submissions SOG for details.

- 5.2 Document Consent Process according to the determinations of the IRB, which states that informed consent must be documented. *See Informed Consent Documentation Check List GOP for details.*
- 5.3 Only the principal investigator and the staff delegated by the principal investigator - as documented in the Delegation of Duty Log - , who are appropriately trained for the study, and are included as IRB-approved key personnel may obtain consent from subjects or their LAR.
- 5.4 Conduct all discussions in a setting that provides reasonable measures to protect patient privacy.
  - 5.4.1 The consent process needs not be conducted in-person regardless of whether the person consenting is the subject or a(n) LAR/guardian. The consent process may be done via teleconference or other remote means in accordance with prevailing privacy policies and the IRB-approved study consenting process.
  - 5.4.2 Use of Electronic Signatures for consenting subjects Unless the IRB waives the requirement for signed consent, such as through 45 CFR 46.117(c), a written consent must be given to and signed and dated by the subject or the subject's legally authorized representative. An electronic signature on a consent document may be used if the procedures for obtaining electronic signature are approved by the IRB.
  - 5.4.3 In order for the IRB to approve use of electronic signature on a consent form , the IRB will consider such issues as how the electronic signature is created, if the signature can be shown to be legitimate, and if the consent document can be produced in hard copy for review by the potential subject. As noted by OHRP, "If properly obtained, an electronic signature can be considered 'original' for the purposes of recordkeeping." However, UCSD Health Sciences research does not have a GCP 21 CFR Part 11 compliant DocuSign license for obtaining electronic signatures. However, it is possible that individual investigators may have purchased a license thus ensuring their electronic signatures are legitimate.
- 5.5 If the subject/LAR understands more than one language, conduct the consent process in the preferred language of the subject/LAR.
  - 5.5.1 If the short form process will be used, follow the procedures noted below in Section 5.12. If the subject/LAR cannot speak/read English and there is not someone on the study team who is trained to conduct the consent procedures and speaks the subject's/LAR's language, arrange for the services of an interpreter and, when required by regulation, statute, policy, or the IRB (e.g. when using the short form consent form in special circumstances only), an impartial witness fluent in both English and the language understood by the subject/LAR, as determined by the person obtaining consent.
- 5.6 If an interpreter is required, the interpreter may be a professional interpreter provided by the institution, a family member, or friend of the subject/LAR. The interpreter may not be the same person who provided/will provide consent for the subject's participation in the study.
- 5.7 If an impartial witness is required, the impartial witness may not be a person involved in

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the design, conduct, or reporting of the research or the person(s) who provided/will provide consent for the subject's participation.

- 5.7.1 When required, the impartial witness attests that the information required by the IRB to be presented as a part of the informed consent process has been accurately explained to the subject/LAR, that the subject/LAR apparently understood the information, and that the subject/LAR freely gave consent to participate in the study.
- 5.8 If both an impartial witness and an interpreter are required for the consent process, the witness and the interpreter may be the same person, provided they meet requirements in 5.6 and 5.7 above.
- 5.9 If the subject/LAR cannot read:
  - 5.9.1 If the subject/LAR cannot read due to visual impairment, assess whether the visual impairment can be overcome via technological means (e.g., screen reader, magnifying glasses, braille reader, etc.). If the visual impairment cannot be overcome, arrange for an impartial witness to be present during the entire consent discussion to attest that the information in the consent form and any other information provided was accurately explained to, and apparently understood by, the subject/LAR, and that consent was freely given.
  - 5.9.2 If the subject/LAR cannot read due to illiteracy, arrange for an impartial witness to be present during the entire consent discussion to attest that the information in the consent form and any other information provided was accurately explained to, and apparently understood by, the subject/LAR, and that consent was freely given. The IRB must have specifically approved the protocol to allow the use of surrogate consent.
  - 5.9.3 While interactions and/or interventions with the subject are ongoing, if the subject regains capacity to consent to research procedures, they must either consent to continue in the study or decline further participation in the study.
- 5.10 Specific considerations for participants with neurocognitive disorders.
  - 5.10.1 There are provisions for subject's who become incapacitated with progression of motor symptoms after the initial consent which may prevent them from signing the consent themselves. Health and Human Services/OPHS Regulations separate the content requirements of consent (45 CFR 46.116) and the documentation of consent, i.e., the actual signing of consent (46.117). Section 46.117 says that "informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative." The emphasized language provides two options for participants with mobility issues.
    - 5.10.1.1 First, some of the participants in this group may be able to type with a simple finger motion on a key board, but not to hold a pen and sign. They could sign the consent form electronically even with simple initials (note that anything allowable as a signature by the law of the jurisdiction where the research takes place is permissible under the Common Rule). If participant is able to hold a pen, then a simple X or any other symbol or letter may be allowable.

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5.10.1.2 The other option is for the LAR to sign the consent form for them. Even if not required by the regulations but for clarity, adding a line explaining that participants consented verbally, but the LAR is signing because of mobility issues is suggested. The line can be added to the same signature page and should be initial and date by the study coordinator or PI.

5.10.2 There are provisions for participants with cognitive impairment: Some neurological conditions may lead to cognitive impairment, affecting patients' ability to understand and retain information about the research study, its risks, and benefits. Cognitive deficits may hinder the subject's capacity to provide informed consent independently. In this circumstance, the study staff should determine whether the prospective participant retains Decision-Making Capacity to provide voluntary and informed consent. The principal investigator and study staff must carefully evaluate a patients' decision-making capacity on a case-by-case basis and consider involving the use of the Decision-Making-Capacity questionnaire to determine if the subject is capable of consenting or if legally authorized representation is necessary. *See Decision-Making-Capacity SOG for details.*

5.11 If the subject is a child:

5.11.1 The IRB must have specifically approved the protocol to allow the enrollment of children.

5.11.2 Consent is obtained from both parents unless:

5.11.2.1 One parent is deceased, unknown, incompetent, or reasonably available;

5.11.2.1.1 "Not reasonably available" does not apply to situations when a parent is at work, traveling, caring for other children or living in another state or country and is not intended to mean that a parent is temporarily unavailable, unless there are specific circumstances where time is of the essence.<sup>1</sup>

5.11.2.1.2 A parent who is "not reasonably available" is one whose whereabouts are unknown or there is no way to reach them by phone, mail, email, fax, or any type of videoconferencing to arrange for consent or who has not responded to multiple contact attempts.

5.11.2.2 Only one parent has legal responsibility for the care and custody of the child; or

5.11.2.3 The IRB has specifically approved the protocol to allow the consent of one parent regardless of the status of a second parent.

5.11.3 In the absence of a parent, consent may be obtained from an individual authorized to consent to general medical care on behalf of a child under applicable law.

5.11.4 The IRB must have specifically approved the protocol to require assent from none, some, or all of the children.

5.11 Re-consenting study participants may be necessary if new information that is relevant to the subject's continued participation in the study becomes available during the study.



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- 5.11.1 information must be submitted to the IRB in accordance with *UCSD - Reconsenting Process and IRB submission SOGs*.
- 5.11.2 The principal investigator must indicate in their submission whether, when, and how re- consent will occur.
- 5.11.3 The IRB or designated reviewer may approve a re-consent process, as necessary, in accordance with prevailing regulations and guidance, taking into consideration the information to be communicated, the status of any enrolled subjects, and the status of the study.
- 5.12 If the short form consent is used to enroll a non-English speaking subject/LAR into a study that is greater than minimal risk and/or a study that has multiple study visits/interactions, the long form consent form must be translated into the language spoken by the subject/LAR and the subject/LAR reconsented with the translated long form consent form.
  - 5.12.1 The IRB recommends that reconsent with the long form consent must occur within 30 days of initial consent.

## 6 Procedure

- 6.1 If the consent process will be documented in writing with the long form consent form:
  - 6.1.1 Obtain the current IRB approved long form consent form and a copy of the experimental participant’s bill of rights (required for medical experiments, optional for non-medical experiments), and which may be incorporated into the long form consent form.
    - 6.1.1.1 By California law, a Bill of Rights is not required for studies that are no medical experimentation. The California Health and Safety Code states that a “medical experiment” includes one or more of the following procedures:
      - \* The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject.
      - \*The investigational use of a drug or device as provided in Sections 111590 and 111595 of the CA Health and Safety Code.
      - \*Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject.
  - 6.1.2 Obtain the University approved HIPAA form and apply the study specific information to it before obtaining the participant’s signatures.
  - 6.1.3 Confirm the informed consent form is the most current IRB-approved version of the study specific long consent form and ensure the consent form is in language understandable to the subject/LAR. For non-English speakers, the long form consent form should be an IRB-approved translated version in their preferred

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language. Be aware that Informed Consents from Central IRBs may be provided in word format and the stamp with the date may differ from what is used at UCSD and may be editable. You should always save a copy of these ICFs in PDF format to prevent accidental modifications. Check with the regulatory coordinator to ensure you have the most up to date document.

- 6.1.4 Provide copies of the long form consent form to the subject/LAR. Whenever possible provide the consent form to the subject/LAR in advance of the consent discussion to ensure they have ample time to read, review and ask questions.
- 6.1.5 Copies of the informed consent may be provided to the subject/LAR ahead of the initial screening study visit via email, USPS, or in person during a standard of care visit at the clinic. See Documentation of Informed Consent SOG for more details.
- 6.1.6 Using the long form consent form as a guide, go over the details of the study (using an interpreter as necessary) with the subject/LAR, explaining the details in such a way that the subject/LAR understands what it would be like to take part in the research study. When necessary, provide a different or simpler explanation to make the information understandable.
- 6.2 If the consent process will be documented in writing with the short form consent form:
  - 6.2.1 Obtain the current IRB-approved short form consent form and the summary (which may be the IRB-approved English long form consent form), and a copy of the experimental participant's bill of rights (medical experiments only), which may be incorporated into the short form consent form and a copy of the HIPAA form.
  - 6.2.2 Confirm the ICF form is the most current IRB-approved version of the study specific long form consent form if this is the document used as the summary.
  - 6.2.3 Provide copies of the consent forms to the subject/LAR. Whenever possible provide the short form consent form and summary to the subject/LAR in advance of the consent discussion.
  - 6.2.4 Provide copies of the Bill of Rights if not part of the completely signed/dated ICF and HIPAA forms.
  - 6.2.5 Arrange for an impartial witness, who is fluent in English (and, when consenting a non- English speaking subject/LAR, the language spoken by the subject/LAR) to be present during the entire consent discussion to attest that the information in the short form consent form, summary, and any other information provided was accurately explained to, and apparently understood by, the subject/LAR, and that consent was freely given.
  - 6.2.6 When using this procedure for a non-English speaking subject/LAR, ask the interpreter to translate the summary (the English long form consent form) to the subject/LAR.
  - 6.2.7 Explain the details in such a way that the subject/LAR understands what it would be like to take part in the research study. When necessary, provide a different or simpler explanation to make the information understandable. When using this procedure for a



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non-English speaking subject/LAR, this conversation will be conducted through the interpreter.

- 6.2.8 Ask the subject/LAR to read the short form consent form, or if the subject cannot read the form themselves, read, or if applicable ask the interpreter to read the short form consent form to the subject/LAR.
- 6.3 If the requirement for use of written informed consent process has been waived by the IRB:
  - 6.3.1 Obtain the current IRB-approved script or information sheet.
  - 6.3.2 Confirm the form is the most current IRB-approved version of the study specific script or information sheet.
  - 6.3.2 Confirm that the script or information sheet language is understandable to the subject/LAR.
    - 6.3.2.1 For non-English speakers who will be specifically targeted by the study or are expected to present for recruitment regularly (e.g., Spanish), the script or information sheet should be an IRB-approved translated version.
    - 6.3.2.2 For non-English speakers who are not specifically targeted by the study and are not expected to present for recruitment regularly, use an interpreter to conduct the consent discussion and, when an information sheet is required, use an impartial witness and provide the subject/LAR with the short form consent form in the language they understand.
  - 6.3.3 When an information sheet is used, provide a copy of the information sheet to the subject/LAR. When possible, provide a copy of the information sheet to the subject/LAR in advance of the consent discussion. You may provide the information sheet ahead of the visit to allow participant ample time to read, review and ask questions.
  - 6.3.4 Read the script or information sheet, using an interpreter as necessary, with the subject/LAR. Explain the details in such a way that the subject/LAR understands what it would be like to take part in the research study.
- 6.4 Invite and answer the subject's/LAR's questions. Complete the *written documentation of informed consent form (check list) GOP*
- 6.5 Give the subject/LAR time to read any written information further. Invite and encourage the subject/LAR to take any written information home to discuss taking part in the research study with family members, friends and other care providers as appropriate before deciding.
- 6.6 In conducting the informed consent process with the subject/LAR, the person obtaining consent should be able to affirm that:
  - 6.6.1 The subject/LAR understands the information provided.
  - 6.6.2 The subject/LAR does not feel pressured by time or other factors to decide.
  - 6.6.3 The subject/LAR understands that there is a voluntary choice to make.
  - 6.6.4 The subject/LAR is capable of making and communicating an informed choice.
  - 6.6.5 The subject/LAR had ample time to review the consent form and ask questions.
- 6.7 If the study is an FDA-regulated clinical investigation and the person obtaining consent above is not a physician or another physician extender (NP, PA). The person obtaining consent should consider, and the IRB may require, that a physician or physician extender

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complete the following steps:

- 6.7.1 Invite and answer the subject's/LAR's questions.
- 6.7.2 Confirm that the following are true, in the person obtaining consent's judgment, or repeat the above steps:
  - 6.7.2.1 The subject/LAR understands the information provided.
  - 6.7.2.2 The subject/LAR does not feel pressured by time or other factors to decide.
  - 6.7.2.3 The subject/LAR understands that there is a voluntary choice to make.
  - 6.7.2.4 The subject/LAR is capable of making and communicating an informed choice.
  - 6.7.2.5 The subject/LAR had ample time to review the consent form and ask questions.
- 6.7.3 This step in this procedure, when completed, is to be documented in the research record.
- 6.8 Once a subject/LAR indicates that they do not want to take part in the research study, this procedure stops.
- 6.9 If the subject/LAR agrees to take part in the research study:
  - 5.9.1 If the subject is a child:
    - 5.9.1.1 Whenever possible explain the research to the extent compatible with the child's understanding.
    - 5.9.1.2 Request the assent (affirmative agreement) of the child unless:
      - 5.9.1.2.1 The capability of the child is so limited that the child cannot reasonably be consulted.
      - 5.9.1.2.2 The IRB determined that assent was not a requirement.
    - 5.9.1.3 Once a child indicates that they do not want to take part in the research study, this procedure stops.
  - 5.9.2 If the subject is an adult unable to consent:
    - 5.9.2.1 Whenever possible explain the research to the extent compatible with the adult's understanding.
    - 5.9.2.2 Request the assent (affirmative agreement) of the adult unless:
      - 5.9.2.2.1 The capability of the adult is so limited that the adult cannot reasonably be consulted.
      - 5.9.2.2.2 The IRB determined that assent was not required.
    - 5.9.2.3 Once an adult unable to consent indicates that they do not want to take part in the research study, which might be done verbally or behaviorally, this procedure stops.
  - 5.9.3 Obtain written documentation of the consent process according to UCSD XX SOG: Documentation of Informed Consent Process, unless waived by the IRB.

## 7 MATERIALS

- 7.1 Long form consent form documentation:
  - 7.1.1 Long form consent form
  - 7.1.2 Experimental participant's bill of rights (when the study is a medical experiment, may be

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- incorporated into the long form consent form)
- 7.1.3 Study specific HIPAA form
- 7.2 Short form consent form documentation:
  - 7.2.1 Short form consent form
  - 7.2.2 Summary (the English long form consent form used for long form of consent documentation)
  - 7.2.3 Experimental participant's bill of rights (when the study is a medical experiment, may also be incorporated into the short form consent form)
- 7.3 Requirement for written documentation of the consent process has been waived by the IRB:
  - 7.3.1 Consent script (may be same as long form consent form used for long form of consent documentation except that signature block is optional)
  - 7.3.2 Documentation of Informed Consent Process form (check list)

## 8 References

- 8.1 [California Health and Safety Code 24174](#)
- 8.2 [21 CFR 50.20](#)
- 8.3 [21 CFR 50.25](#)
- 8.4 [21 CFR 50.27\(b\)\(2\)](#)
- 8.5 [45 CFR 46.116](#)
- 8.6 [45 CFR 46.117\(b\)\(2\)](#)
- 8.7 [FDA Information Sheet: A Guide to Informed Consent](#)
- 8.8 [Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers](#)
- 8.8 The regulations separate the content requirements of consent (45 CFR 46.116) and the documentation of consent, i.e., the actual signing of consent (46.117).
- 8.9 California Health and Safety Code Section 24174 short form

## 9 Document Approval

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

Approved By:

Date:

\_\_\_\_\_

Insert Name and Title