


Standard Operating Procedures for Clinical Research at USF Health Morsani CRC			
	SCREENING AND ENROLLMENT		
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PURPOSE: This SOP describes the process to be followed for screening and enrolling participants in clinical trials at the CRC.

SCOPE: This SOP applies to investigators and research staff at this study site who perform screening and enrollment procedures for a clinical research study.

RESPONSIBILITY: The investigator has ultimate responsibility for ensuring that all applicable study staff members follow this SOP, and for ensuring that only participants who meet the protocol-specific eligibility criteria are enrolled in the study.

It is the responsibility of each study staff member who takes part in the screening and enrollment process to fully understand the study eligibility criteria and to only enroll eligible participants.

DEFINITIONS:

Clinical Trial/Study: Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

Eligibility Criteria: Summary criteria for participant selection; includes inclusion and exclusion criteria

Enrollment: Number of subjects in a clinical trial

Informed Consent: A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.

Legally Authorized Representative (LAR): An individual or judicial or other body authorized under applicable law to consent on behalf of a potential subject to the subject's participation in the procedure(s) involved in the research

Screening: Procedures performed to determine whether a potential participant is eligible to take part in a particular clinical trial.

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PROCEDURE:

1. Pre-Screening Activities:

- 1.1. After initial IRB approval, the study/ regulatory coordinator will develop a Subject Eligibility Checklist (Appendix BB) that includes all inclusion/exclusion criteria listed in the protocol if one is not provided by the sponsor or CRO for the trial.
- 1.2. He/she will prepare a Screening and Enrollment Log (Appendix AA), if not provided by the sponsor or CRO, for use at the study site.

2. Screening Activities:

- 2.1. The research team will count Day Zero as the day on which the prospective participant or legally authorized representative signs the informed consent document. The screening period for a clinical study may take several days
- 2.2. During the screening period, the research designee will assess the prospective participant's eligibility for participation in the study per the inclusion and exclusion criteria detailed in the study protocol.
- 2.3. Every individual considered as a potential candidate for the study should be entered on the screening and enrollment log.
- 2.4. The designee will review the Screening Criteria Checklist developed or provided by the sponsor to determine if the participant meets criteria for screening.
- 2.5. If the potential study participant meets screening criteria, they must be consented and sign the informed consent form **before** any screening procedures are initiated. Please refer to the *SOP #402: Informed Consent Process* for a description of the procedure.
 - If the participant agrees to be screened, a participant number will be assigned and the participant's information will be entered into the Master Log.
 - Screening evaluations and procedures will be followed according to the study protocol.
 - Review the Screening Visit Checklist if provided by the sponsor to ensure all screening procedures have been completed.
 - If a prospective study participant is found to be ineligible, the screening evaluations will be stopped. The patient or legally authorized representative will be informed that he/she is not eligible to join the study and the final case report form (CRF) will be completed.

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PROCEDURE (cont.):

3. Eligibility Determination:

- 3.1. The Investigator, study coordinator or designee is responsible for reviewing all information pertinent to the prospective participant's eligibility status (all chart notes, checklists, laboratory results and information obtained via medical examinations and interview) after all screening evaluations and test results have been completed and received. He/ she will then record on the chart note the prospective participant's current eligibility status.
- 3.2. The research designee will review all documents as stated above, as well as the screening evaluation documentation to determine if the prospective participant is eligible for the study.
- 3.3. If the prospective participant is found to be ineligible, the patient or LAR will be informed that he/she is not eligible to join the study and the final CRF will be completed.
- 3.4. If the research designee finds the prospective participant to be eligible, then the prospective participant or LAR will be informed of his/her status. If they are still interested in becoming a study participant, the study staff may begin the process of enrolling the participant into the study.

4. Enrollment Procedures:

- 4.1. Designated research staff will provide informed consent if the participant agrees to participate in the study. This procedure will be performed in accordance with *SOP #402: Informed Consent Process*
- 4.2. After informed consent is signed by the participant or LAR, he/ she will be randomized to a study drug treatment, if applicable, or begin study treatment as described in the protocol.
- 4.3. Research staff will complete on the Inclusion Criteria and Exclusion Criteria case report forms. .
- 4.4. The remaining participant information will be entered into the Master Log.
- 4.5. Research staff will complete the appropriate case report forms (CRFs).

5. Subject Numbering

- 5.1. Each Investigator participating in a study must have procedures for assigning a unique participant numbering system that includes a site number and sequential subject number. Subject numbering procedures may be developed by the sponsor or CRO.

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PROCEDURE (cont.):

- 5.2. Once a participant's eligibility to participate in the clinical study has been confirmed, the participant will be assigned the unique subject number according to the predetermined numbering system.
- 5.3. All study records that are maintained on each participant will use the unique subject number where possible to protect the participant's confidentiality.

REFERENCES:	21 CFR 50.20 General Requirements of Informed Consent 21 CFR 56.109 IRB Review of Research 21 CFR 312.60 General Responsibilities of Investigators 21 CFR 312.62 Investigator recordkeeping and record retention FDA Information Sheets, October 1988 Screening Tests Prior to Study Enrollment and Recruiting Study Subjects ICH GCP Consolidated Guideline, May 1997
RELATED POLICIES:	SOP #201: Regulatory Documentation SOP #401: Subject Recruitment SOP #402: Informed Consent Process
APPENDICES:	Appendix AA: Screening and Enrollment Log Appendix BB: Subject Eligibility Checklist
REVISION HISTORY: Keep a running history of all revision dates.	

Approval Date	Effective Date	Review/Revision Date
01/01/2015	01/01/2015	06/01/2016