


Standard Operating Procedures for Clinical Research at USF Health Morsani CRC			
	RANDOMIZATION AND BLINDING		
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PURPOSE: The purpose of this SOP is to describe procedures that protect the health and welfare of participants in a blinded, randomized clinical trial.

SCOPE: This SOP applies to all randomized, controlled clinical trials conducted at the CRC and all study personnel involved in the development and implementation of the randomization and/or blinding process.

RESPONSIBILITY: The PI and designated study personnel are responsible for following the randomization and blinding procedures described in each clinical trial protocol.

DEFINITIONS:

Blinding: A procedure in which one or more parties involved in the trial are kept unaware of the treatment assignment(s). Single-blinding usually refers to the subject(s) being unaware, and double blinding usually refers to the subject(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s).

Interactive Voice Response System (IVRS): Phone or web-based tool used by sites to register the enrollment of patients and to allocate patients to a particular treatment arm.

Randomization: The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.

Unblinding: Identification of the treatment code of a subject or grouped results in studies where the treatment assignment is unknown to the subject and investigators. Also referred to as “breaking the blind.”

PROCEDURE:

1. The PI and research personnel will receive and review the randomization procedure (e.g., IVRS) and manual, if applicable, prior to participant recruitment.
2. The PI and designated research personnel are responsible for ensuring that the randomization schedule is followed.
3. **Blinding:**
 - 3.1 The PI and study staff will review the protocol to identify any individuals in the trial who should not be blinded to treatment
 - 3.2 Research personnel will verify that the sponsor has taken adequate steps to ensure that the treatments are indistinguishable.
 - 3.3 The master randomization codes should be kept by the pharmacy and/or the trial data manager with appropriate security measures and access control.

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PROCEDURE (cont.):

4. Unblinding:

- 4.1 Circumstances for unblinding must be clearly established before the first patient begins treatment. Randomization procedures, if any, must be followed to ensure the code is broken only in accordance with the protocol.
- 4.2 During study initiation, 24-hour sponsor contact information should be obtained including names, telephone numbers and e-mail addresses of the medical officer, monitor, and other relevant safety personnel. This information should be retained in a readily accessible location, known to all study staff.
- 4.3 The study codes may be stored at the study site or may only be available directly from the sponsor.
- 4.4 If stored at the study site, the study codes may be contained on the Study Drug Label or in individual envelopes depending on direction from the sponsor. The code must be stored in a secure area with access being provided by keys assigned to the Clinical Research Coordinator/Nurse.
- 4.5 If unblinding a participant is allowed during conduct of a clinical trial, the protocol must state procedures for obtaining permission to break the blind.
- 4.6 In general, the code should only be broken in the case of an adverse event where it is necessary for the Principal Investigator to know which treatment the patient is receiving before the participant can be treated. The code may also have to be broken if someone not in the study uses the investigational agent. For example, if a child in the participant's household takes a study medication, the blind may be broken to determine treatment for the child.
- 4.7 When it is necessary to break the blind, the researcher must notify the IRB.
- 4.8 The sponsor should be notified as soon as possible, preferably by fax or telephone and then in writing, regarding the necessity of code breaking.
- 4.9 If the code is broken for a participant, this must be documented on the CRF, together with the reasons for breaking the code. The reason for breaking the code should also be written on the code document.
- 4.10 Premature unblinding must be reported to the Site Monitor immediately.
- 4.11 Justification for premature unblinding of the investigational product should be documented (e.g. accidental unblinding, unblinding due to serious adverse event) in the source document as well as the Regulatory File.

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REFERENCES:	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use: Choice of Control Group and Related Issues in Clinical Trials E10 Guidance for Industry E6 good Clinical Practice: Consolidated Guidance	
RELATED POLICIES:	SOP 204 Adverse Event Reporting	
APPENDICES:	None	
REVISION HISTORY: Keep a running history of all revision dates.		
Approval Date	Effective Date	Review/Revision Date
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