

TABLE OF CONTENTS

- Purpose
- Policy
- Procedures
- Maintenance Responsibility
- Authorization
- Version/Revision History

PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the responsibilities of the NACHO Operations Center in verifying subject eligibility for enrollment on NACHO research protocols.

POLICY

Every NACHO research protocol must include inclusion and exclusion criteria to determine patient eligibility for enrollment. The criteria will differ from protocol to protocol. These criteria make certain that subjects at risk for harm by participating in the protocol are excluded, and therefore, not exposed to the risk. In this sense, eligibility criteria are set for participant protection, as well as to identify the population being investigated. Participants who fail to meet all eligibility criteria listed in the associated protocol will not be enrolled on a NACHO trial.


PROCEDURES

- I. The Institutional PI is responsible for ensuring the participant meets all eligibility criteria prior to enrollment.
 - A. The informed consent form (ICF) cannot be signed until the institutional PI or his/her designee has documented that the participant has met all inclusion and exclusion criteria specified in the protocol.
 - B. Eligibility criteria may not be waived nor modified for any reason.
 - C. An eligibility checklist for each protocol is available on the NACHO website under the specific research protocol, or the site may use a NACHO Operations Center (NACHO OC) approved checklist.
 1. The Institutional CRA may complete the appropriate protocol eligibility checklist
 2. The Institutional PI or sub-investigator will review, sign and date the completed checklist.
 3. A copy of the completed checklist will be emailed to the NACHO OC.
 - D. At the protocol specified time point, during a routine study audit, the NACHO Study Monitor will confirm eligibility by comparing the information on the eligibility checklist with the source documentation from the participant's medical record.
 - E. The participant may remain on protocol until eligibility is finalized, unless precluded by safety issues. A participant must come off protocol if they are determined to be ineligible.
 - F. If there is disagreement concerning eligibility of a participant, the research protocol Study Chair will have final authority to designate the participant as eligible or ineligible. (Refer to "Protocol Study Chair Instructions" SOP).

MAINTENANCE RESPONSIBILITY

The NACHO SOP Ad Hoc Committee is responsible for the annual review of this SOP. Suggested changes must be proposed to and approved by the NACHO Executive Committee.

AUTHORIZATION

	NACHO STANDARD OPERATING PROCEDURES	
	Verification of Eligibility of Research Subjects	
	Effective Date: 12/11/2017	Approved by: NACHO Executive Committee
	Revised Date: NA	Page: 2 of 2

This SOP was developed by the SOP Ad Hoc Committee and reviewed and approved by the NACHO Executive Committee.

VERSION/REVISION HISTORY

Approval Date	Version	Version/Revision Summary
12/11/2017	V 1.0	Original documentation/publication.