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PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the process by which reservations for enrollment slots on NACHO research protocols are obtained and managed. This policy applies to all NACHO research protocols with limited enrollment unless a specific reservation policy is posted on the protocol webpage for an individual protocol.

POLICY

A reservation system for enrollment on Phase I or limited enrollment protocols will be utilized to ensure the availability of a treatment slot before obtaining informed consent.

PROCEDURES

- I.
 - A. **Criteria for Obtaining a Reservation**
 - 1. Reservations may only be made if the protocol has local IRB approval and documentation of approval is on file at the NACHO Operations Center. (NACHO OC)
 - 2. The protocol has been activated at the site by the NACHO OC.
 - B. **Process for Making a Reservation**
 - 1. The NACHO Patient Reservation Form (found on the NACHO Website under each research protocol's supporting documents) is to be completed for each patient who is potentially eligible.
 - 2. The completed form is emailed to the NACHO OC Clinical Research Associate.
 - 3. A confirmation email will be returned with the date and time the reservation is made along with the expiration date and time.
 - 4. Reservation slots may be held for seven (7) calendar days.
 - 5. A reservation may be renewed only if an additional reservation slot is open.
 - 6. A waitlist will be established only if no treatment slots are available.
 - C. **Enrollment After a Reservation**
 - 1. The patient can be enrolled only if they meet all eligibility criteria specified in the protocol.
 - 2. Once a treatment slot is secured, an eligible patient must be consented and begin treatment within two (2) weeks of securing the treatment slot on the research protocol.
 - 3. A patient who became ineligible after securing a reservation, and then becomes eligible once again, can hold a new reservation.

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

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



NACHO STANDARD OPERATING PROCEDURES

Protocol Reservations Policy

Effective Date: 12/11/2017

Approved by: NACHO Executive Committee

Revised Date: NA

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VERSION/REVISION HISTORY

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