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PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the procedure for transferring participants enrolled in North American Consortium for HIstiocytosis (NACHO) research studies between member institutions.

POLICY

During a research study it may be necessary or desirable for research participants at one NACHO site to transfer to a different NACHO site. This may be due to the participant relocating, the site discontinuing its research program, or for other reasons. A seamless transfer ensures that the participant's safety is protected, his or her participation in the study continues, and data completeness and integrity are preserved.

PROCEDURES

I. Responsibilities of the Transferring Site Principal Investigator (Transferring Site PI):

A. Contact the study manager to obtain information on whether the receiving site is participating in the research protocol.
B. Notify the receiving site Study Principal Investigator (Receiving Site PI) of a potential patient transfer on a NACHO research protocol.
C. If required per local policy, notify the IRB of the potential transfer of the research participant.
D. Obtain authorization from the patient/LAR to release information to the receiving site.
E. Resolve all database queries conducted at the transferring site.
F. Fill out the Transferring Institution Information section on the NACHO Patient Transfer Form (found on the NACHO website), sign, date, and send to the Receiving Institution.
G. Coordinate transfer activities and handover responsibilities to the receiving site.
H. Send a copy of the completed, signed Transfer Form to the Study Manager.
I. The original completed Transfer Form should be filed in the institution's Study Binder.
J. All necessary patient files pertaining to the study need to be transferred along with any required documentation needed by the receiving site.

II. Responsibilities of the Receiving Site PI:

A. The Site PI must complete the Receiving Institution Information on the NACHO Patient Transfer form, including signature and date if accepting the patient.
B. The form should then be sent back to the Transferring institution's PI.
C. The following Documents must be requested and received from the Transferring Site:
   1. Patient's contact information
   2. Copies of all patient source documents
   3. Copy of the patient's Study Informed Consent
   4. Copies of the patient's CRFs
   5. A copy of the completed signed, dated NACHO Patient Transfer Form.
D. The Site PI must document acceptance to enroll the patient at the receiving site
E. The Transfer Form must be filed in the Study Binder.
F. Send a copy of the completed, signed Transfer Form to the Study Manager.

G. Receiving site must re-consent patient and obtain authorization to use protected health information prior to commencement of any protocol specific procedures.

III. Study Manager Responsibilities

A. Ensure the receiving site is able to receive the participant and assume all protocol required responsibilities
B. Ensure the participant's data is current and complete at transferring site
C. Upon receipt of completed form from both the transferring and receiving sites, transfer the patient in the database
D. Contact both sites of the date of the completed transfer
E. File the NACHO Patient Transfer form in the study binder

IV. Transfer of Research Site Responsibilities

A. Upon completion of the patient transfer, the protocol and data reporting responsibilities shift from the Transferring Site to the Receiving Site.
B. Subsequent patient visits post-transfer and all protocol requirements become the responsibility of the Receiving Site.

MAINTENANCE RESPONSIBILITY

The NACHO SOP Ad Hoc Committee is responsible for the 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.

VERSION/REVISION HISTORY

Approval Date	Version	Version/Revision Summary
5/25/2022	V 1.0	Original documentation/publication.

ATTACHMENT A

NACHO PATIENT TRANSFER FORM

This form must be completed in order to authorize the transfer of a patient from one NACHO member institution to another. IRB approval for the protocol(s) at the recipient institution must be on file. This form must be signed by the institutional Principal Investigator at the institution where the patient was originally registered to study and by the Principal Investigator at the recipient institution. Send copy to: NACHO.OperationsCenter@stjude.org

Transferring Institution Information					
NACHO Protocol Name				Course or Stratum #	
Patient registration ID		**Patient Initials**		**Case Status**	☐ **Active Therapy** ☐ **F/U only**
All required data has been submitted	☐ **Yes** ☐ **No** **Date:**				
All queries have been resolved		☐ **Yes** ☐ **No** **Date:**			
Date of pending transfer					
Transferring Institution Name		Study IRB Expiration Date			
Transferring Principal Investigator	Name				
Contact information for the transferring PI	Phone #				
	Fax #				
	E-mail Address				
Transferring PI Signature			Date		
Recipient Institution Information					
Recipient Institution Name		Study IRB Expiration Date			
Recipient Principal Investigator	Name				
Contact information for the transferring PI	Phone #				
	Fax #				
	E-mail Address				
Recipient PI Signature			Date		