

## CTO – SOP 4.3



## SUBJECT MANAGEMENT WHILE ON STUDY

### INTRODUCTION AND PURPOSE

The safety and well-being of subjects is of paramount concern to the research team. This standard operating procedure (SOP) describes the steps for fulfilling the regulatory and clinical requirements to ensure adherence to study procedures for the evaluation of a subject's response to the investigational article. Through close monitoring and careful assessment of subjects, adverse events can be detected early and treated appropriately. By following these procedures, close attention is paid to subject well-being and to integrity of the data.

### SCOPE

This SOP applies to the activities involved in managing subjects on clinical studies conducted at UNM CRTC subject to investigational new drug (IND) regulations for drugs and biologics or investigational device evaluation (IDE) regulations for devices during all phases of development.

### APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50.20	General requirements for informed consent
21 CFR 56.109	HRRC review of research
21 CFR 312.60	General responsibilities of investigators

21 CFR 312.62

Investigator record keeping and record retention

May 1997

International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline

## RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in ensuring the appropriate clinical management of all clinical trial activity. This includes the following:

- Principal investigator
- Sub-investigator
- Research coordinator
- Research technician
- Pharmacist
- Information specialists
- Regulatory coordinators
- Research technicians
- Data managers
- Patient services assistants
- Quality assurance auditors

## PROCEDURES

### Enrollment assessments and management

• PI	Determine that patient has consented (SOP 12)
• Research coordinator	Elicit and document the subject's medical history Perform a complete or directed physical examination Establish the subject's baseline signs and symptoms. Review with the subject the use of any current medication Inform the subject about the required study procedures and visits. Collect specimens as directed by the protocol Order tests/procedures as directed by the protocol. Treat patient according to protocol

	<p>Provide contact information to the subject.</p> <p>Schedule the follow-up visit.</p> <p>Complete enrollment process in Evelos database.</p>
<ul style="list-style-type: none"> <li>• Data Coordinator</li> <li>• Research coordinator</li> </ul>	<p>Register the subject.</p>
<ul style="list-style-type: none"> <li>• PI</li> <li>• Study pharmacist</li> <li>• Research coordinator</li> </ul>	<p>Randomize and dispense the test article.</p> <p>Review with the subject the use of any study aids, such as a diary.</p>

### Treatment Activation and Management

<ul style="list-style-type: none"> <li>• Study pharmacist</li> </ul>	<p>Verify patient enrollment in Evelos.</p> <p>Change patient to active status in Evelos after medication is dispensed.</p>
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### Follow-up, completion and early termination from the study

<ul style="list-style-type: none"> <li>• PI or sub-investigator</li> <li>• Research coordinator</li> <li>• Data Manager</li> </ul>	<p>Perform a complete or directed physical examination.</p> <p>Assess the subject for signs and symptoms of any intercurrent illness and document adverse events appropriately</p> <p>Collect specimens as directed by the protocol.</p> <p>Order diagnostic tests and procedures.</p> <p>Institute appropriate therapy if required by the subject's condition.</p> <p>Review any use of concomitant medication.</p> <p>Schedule follow-up visits per protocol.</p>
<ul style="list-style-type: none"> <li>• PI or sub-investigator</li> <li>• Research coordinator</li> <li>• Study pharmacist</li> <li>• Research coordinator</li> </ul>	<p>Assess the subject's compliance with the test article.</p> <p>Collect unused test article, if appropriate.</p> <p>Dispense additional test article, as appropriate.</p>
<ul style="list-style-type: none"> <li>• PI</li> <li>• Sub-investigator</li> </ul>	<p>Diagnose and document any intercurrent illness and endpoints.</p> <p>Review the subject's laboratory and other test results.</p>

### **Communication with primary or referring medical providers**

- Research coordinator
- Data Manager

Place the original signed consent form in the patient's UNM-CRTC medical record.

The UNM-CRTC dictation will inform the subject's primary care provider about the subject's progress while on study, as appropriate.

### **Management of ineligible subjects**

- PI or sub-investigator
- Data Coordinator

Document the reason for ineligibility. Retain any supporting data available.

Discuss treatment alternatives with the subject.

Approved: \_\_\_\_\_  
CTO/NMCCA Medical Director

Date: \_\_\_\_\_