

**1. PURPOSE:**

To describe the responsibilities and strategies for the follow-up and assessments of research subjects for clinical research protocols.

**2. SCOPE:**

This procedure applies to all clinical research protocols managed by the Office of Surgical Research (OSR)

**3. PROCEDURES:**

During a clinical study, all assessments and procedures outlined in the protocol must be carried out in a way that guarantees the gathering of relevant and dependable data, as well as the welfare of the subjects. Visits should be scheduled and organized, and the outcomes of procedures and interactions promptly and accurately recorded. Subjects need to be vigilantly observed for adverse effects, alterations in health status, and adherence to the protocol. If the investigator determines that a subject's participation in the study could jeopardize their well-being or the integrity of the data, the investigator has the authority to terminate that subject's involvement in the study.

**4. PROCESS OVERVIEW:****4.1. Preparing for and Conducting Study Visits:****4.1.1. Review of Protocol Requirements:**

- Before the scheduled visit, thoroughly review protocol requirements for the upcoming visit.

**4.1.2. Medication Review:**

- Review the list of all allowed and disallowed medications for the study, if applicable.

**4.1.3. Research Binder Checklist:**

- Print and partially complete the Research Binder Checklist.

**4.1.4. Subject-Specific Worksheets:**

- If applicable, create a worksheet for each subject to align with the specific requirements for the upcoming visit.

**4.1.5. Supplies Inventory:**

- Review and inventory supplies, including those for laboratory tests, procedures, diaries, and other materials for subject use.

**4.1.6. Investigational Product Check:**

- Check investigational product inventory and expiration dates, if applicable.

**4.1.7. Forms and Appointments Preparation:**

- Prepare requisition forms and prescriptions, if applicable.
- Confirm appointments with other departments.

**4.1.8. Medical Records and Source Documents:**

- Requisition medical records if needed or confirm access to required medical records.
- Check source documents from the previous visit, ensuring completeness of Case Report Forms (CRFs) to date.

**4.1.9. Recording Outstanding Issues:**

- On the Research Binder Checklist, note any outstanding issues that need attention.
- Appointment Confirmation:
- Confirm the date and time of appointments for subjects.

**4.1.10. Subject Advocates and Interpreters:**

- Notify subject advocates and interpreters if needed.

**4.1.11. Subject Payments Material:**

- Obtain the necessary material for subject payments, if applicable.

**4.1.12. Material Assembly:**

- Assemble all the required materials, documents, and supplies for each subject.

**4.1.13. Exam Room Availability:**

- Double-check the availability of exam rooms. If necessary, reserve rooms for visits and procedures.

**4.1.14. Confirmation with Staff:**

- Confirm the schedule with phlebotomists, lab personnel, and any other staff involved in the visit, as applicable.

#### **4.1.15. Follow-Up Period:**

- If there is a follow-up period, schedule the next visit or discuss methods of follow-up, providing instructions to the subject.
- If applicable, discuss options available to the subject regarding access to the investigational product, return to current therapy, etc.
- Send a message in EPIC to the subject with the next research study appointment.

#### **4.1.16. End of Study Visit**

- Complete the Research Binder Checklist
- Add notes, if necessary
- Make sure the completed Research Binder Checklist is signed dated and stored in the Subject Binder.

### **4.2. Communication with the clinical team:**

#### **4.2.1. Responsibilities:**

##### **4.2.1.1. Research Coordinator (RC):**

- Initiate the scheduling process by coordinating with the research participants to identify suitable dates and times for follow-up visits.
- Communicate participant availability and preferences to the clinical team in a timely manner.
- Maintain an organized record of scheduled follow-up visits, including participant contact information and preferred appointment times.

##### **4.2.1.2. Clinical Team (CT):**

- Responsively review the information provided by the Research Coordinator regarding participant availability.
- Collaborate with the Research Coordinator to finalize and confirm follow-up visit schedules.
- Notify other relevant departments (e.g., laboratory, pharmacy) of scheduled follow-up visits to ensure preparedness.

##### **4.2.1.3. Investigator:**

- Stay informed about the scheduled follow-up visits for participants under their supervision.
- Provide necessary input to the Clinical Team regarding any specific requirements or considerations for follow-up visits.

#### **4.2.2. Communication Channels:**

##### **4.2.2.1. Regular Meetings:**

- Conduct regular team meetings to discuss and plan follow-up visits collectively.
- Address any scheduling challenges or conflicts during these meetings to find prompt resolutions.

##### **4.2.2.2. Electronic Communication:**

- Utilize BCM email or Tiger Connect for quick and efficient communication regarding follow-up visit scheduling.
- Ensure that all relevant team members are included in communication threads to maintain transparency.

#### **4.3. Documentation:**

- Maintain a centralized and up-to-date scheduling log or system accessible to the entire clinical team.
- Document any changes, cancellations, or rescheduling of follow-up visits promptly utilizing the OSR Subject Communication Log Template

#### **4.4. Emergency Situations:**

In the case of unexpected circumstances or emergencies, establish a designated point of contact and a clear communication protocol to address immediate scheduling adjustments.

#### **4.5. Review and Updates:**

- Regularly review the effectiveness of the communication protocol and make necessary updates to enhance efficiency and accuracy in scheduling follow-up visits.
- Solicit feedback from the clinical team to identify areas for improvement.

#### **4.6. Specimen Collection and Handling**

##### **4.6.1. Collecting Specimens:**

- Follow appropriate precautions based on OSHA guidelines, infection control manual, and/or institutional procedure manual for handling bodily fluids.
- Collect the specified specimens outlined in the study protocol.
- Label study-specific test tubes or containers with subject identifiers and dates.
- If the protocol requires; include the time collected and additional information for

storage or shipment preparation.

- Use a Sharpie or other water-resistant pen for labeling.
- Process the specimen as per protocol specifics (e.g., centrifuge speed, duration, temperature).
- Spin, separate, and transfer the specimen to the designated transport tube(s).
- Complete the laboratory requisition slip, including one copy with the specimens for shipment, and retain one copy for filing with other study-related subject records.
- On the subject's medical record and/or Case Report Form (CRF), document the collection date and time, along with relevant information about the subject's status during the procedure.

#### 4.7. Preparation and Packaging for Shipment:

- Prepare and package the specimens following the shipping instructions outlined in the study protocol and/or central laboratory procedure manual.
- Retain a copy of the shipping receipt and file it with other study-related subject records.
- Follow-up, Completion, and Early Termination from the Study

##### 4.7.1. Completion Visit:

- Conduct the completion visit for each subject as directed by the protocol upon study completion.
- If there is a follow-up period, schedule the next visit or discuss follow-up methods, providing instructions to the subject.
  - If applicable, discuss options available to the subject regarding access to the investigational product, return to current therapy, etc.

##### 4.7.2. Early Termination:

- If a subject's participation is being terminated, accurately record the reason for termination (e.g., withdrawal due to an adverse event), ensuring documentation aligns with the source document.
- Document details related to adverse events, results of assessments, tests, procedures, observations, and reports from medical providers.
- Obtain comprehensive information from study subjects who drop out, focusing on adverse events, concomitant medication status, return of study drug/device, last day of dosing or test article use compliance, and contact information for follow-

up.

- Collect and account for used and unused investigational products.
- Provide payment to the subject as outlined in the informed consent form, if applicable

## **5. APPLICABLE REGULATIONS AND GUIDELINES:**

### **5.1 FDA**

- 21 CFR 50.20
- 21 CFR 56.109
- 21 CFR 312.60
- 21 CFR 312.62

### **5.2 ICH**

- E6- Harmonized Tripartite Guideline for GCP 47 - Informed consent of trial subject.

## **6. MATERIALS AND REFERENCES:**

- OSR Subject Communication log template
- Research Binder Checklist

## **7. VERSION/REVISION HISTORY:**

<b>Approval Date</b>	<b>Version</b>	<b>Owner</b>	<b>Approver</b>	<b>Revision Summary</b>
2024.01.30	1.0	OSR	L. Eberlin	