www.mycetoma.edu.sd
info@mycetoma.edu.sd

TABLE OF CONTENT

SOP 01: Preparation of Standard Operating Procedures

1. Purpose

This SOP describes how to prepare, review, approve, share, update, and use SOPs at the Mycetoma Research Center. SOPs help ensure that all studies are conducted in a proper, consistent, and ethical way, following national and international standards.

2. Scope

This SOP applies to all staff involved in clinical research at the Mycetoma Research Center, including doctors, nurses, pharmacists, lab staff, and support staff. It covers all types of studies, whether sponsored by external partners or investigator-led, and includes processes for drafting, revising, and using SOPs at the site.

3. Responsibilities

Person/Role	Responsibility
Site Principal Investigator (PI)	Approves final SOPs and ensures implementation at the site.
Site Coordinator / Clinical Research Coordinator (CRC)	Helps prepare drafts, organises reviews, manages SOP records, and tracks training.
Study Team Members (Doctors, Nurses, Lab, Pharmacy, Admin)	Review SOPs relevant to their duties and provide suggestions when needed. Follow the SOPs during study work.
Ethics/Regulatory Liaison (if applicable)	Helps check SOP compliance with local and international guidelines.

4. Procedure

4.1 Drafting a New SOP

- When a new SOP is needed, a draft will be prepared by the designated team member (CRC, PI, or relevant staff).
- The content should reflect the actual site practice, local context, and applicable regulations (ICH-GCP, national guidelines, sponsor instructions).
- The draft is shared with concerned team members for their feedback.

4.2 Review and Finalisation

- All comments and suggestions are collected and discussed.
- The draft is revised based on team feedback.
- The final version is approved and signed by the PI and kept as the official version.

4.3 SOP Numbering and Version Control

- Each SOP will have:
    - **A unique SOP number**

    - **A version number** (e.g., Version 1.0, 2.0)
    - **Approval date**
- Once a new version is approved, the old version will be marked as "Obsolete" and filed separately.
- Only the current version will be used.

4.4 Distribution and Storage

- Copies of the approved SOP will be distributed to all relevant staff members (PI, CRC, doctors, lab personnel, pharmacy staff, and nurses).
- A master file (signed copy) will be kept in the site's SOP file cabinet.
- A soft copy may be stored on a secure, password-protected computer located on-site.

4.5 Training

- All team members must be trained on the SOPs before starting work on a study.
- All new staff members are required to undergo training upon joining.
- A training log will be maintained, including the participant's name, role, and date of training.

4.6 Review and Revision of SOPs

- SOPs will be reviewed **every 3 years or as needed,** or earlier if:
    - A change in procedure is needed
    - New guidance is received from the sponsor or regulatory body
    - Issues arise during monitoring or audits
- Revisions will follow the same preparation and approval steps as new SOPs.

4.7 Emergency or Interim Changes

- If urgent changes are needed (e.g., for safety or compliance), a temporary update may be issued with PI's approval.
- The full revised SOP should then be prepared and shared with the team.

5. Documentation and Archiving

- All SOP versions (current and obsolete) will be stored and labeled clearly.
- Each SOP will have a **SOP History Log** to track changes and version updates.
- Training records, distribution lists, and review dates will be maintained in the **SOP Control File**.

6. Compliance

- All staff must follow the SOPs related to their duties.
- Failure to follow SOPs may lead to protocol deviations or non-compliance, which the PI will address.

Prepared by:
Name: Dr Eiman Siddig Ahmed
Title: Research Assistant
Signature: *Eiman*
Date: 20/07/2025

Reviewed by:
Name: Dr Samira Mohammed Hussein
Title: Research Assistant
Signature: *Samira*
Date: 21/07/2025

Approved by:
Name: Prof Ahmed Hassan Fahal
The Mycetoma Research Center, Director
Signature: *Fahal*
Date: 24/07/2025

SOP 02: Training of Principal Investigator (PI) and Research Team

1. Purpose

To describe how training will be given to the Principal Investigator (PI) and the study team before starting a clinical study and throughout the study period. This ensures all staff understand how to conduct clinical research properly, safely, and ethically, following international and national guidelines (e.g., ICH-GCP, local ethics requirements, and sponsor instructions).

2. Scope

This SOP applies to all clinical study staff at the Mycetoma Research Center involved in planning, conducting, and supporting research activities. Training will include general guidelines (such as GCP), site-specific SOPs, and study-specific information.

3. Responsibilities

Person	Responsibility
Site Principal Investigator (PI)	Ensures all team members are trained before and during the study. Reviews training needs and records.
Site Coordinator / CRC	Maintains training records, organises training sessions, and tracks attendance.
Ethics Committee (if applicable)	Shares updates or policies related to research ethics and EC SOPs.
Sponsor / Monitor / DNDi (if involved)	Provides study-specific training or supports training sessions.

4. Procedure

4.1 Required Training for Research Team

All team members must be trained in:

1. Good Clinical Practice (GCP)
2. Good Laboratory Practice (GLP)
3. Good Financial Practice (GFP)
4. Applicable national and international guidelines
5. Mycetoma Research Center SOPs
6. Study-specific SOPs and protocol requirements
7. Policies or requirements shared by the Ethics Committee, Regulatory authorities and/or sponsor

4.2 Training for New Staff

- New investigators, nurses, pharmacists, lab staff, or data handlers must receive GCP and site-specific SOP training before commencing work on any study.
- Training can be conducted online or in person, depending on availability and resources.

4.3 Ongoing / Refresher Training

- Team members will be given refresher training if:
  - A new study is starting
  - There are updates to the SOP or protocol
  - Regulatory requirements change
- The PI and site coordinator will ensure this training is done.

4.4 Study-Specific Training

- Before study procedures begin, the sponsor's representative, monitor, or PI will conduct study-specific training for the team.
- This includes reviewing the protocol, safety procedures, and responsibilities of each team member.

4.5 Certificates and Documentation

- After each training session, the trainer and trainee must sign a training log and a certificate of completion for the trained staff member.
- Copies of certificates, training attendance sheets, and logs will be kept in the Training File.

4.6 Maintenance of Training Records

- A Training Log will be updated each time a new training is completed.
- When a staff member leaves the site, their training records will be archived with the site study documents.

5. Documentation Checklist

- Training attendance sheets
- Certificates of completion
- Training logbook (including name, role, date, trainer, type of training)
- Copies of materials used in training sessions (slides, handouts, etc.)

Prepared by:
Name: Dr Eiman Siddig Ahmed
Title: Research Assistant
Signature: *Eiman*
Date: 20/07/2025

Reviewed by:
Name: Dr Samira Mohammed Hussein
Title: Research Assistant
Signature: *Samira*
Date: 21/07/2025

Approved by:
Name: Prof Ahmed Hassan Fahal
The Mycetoma Research Center, Director
Signature: *Fahal*
Date: 24/07/2025

SOP 03: Communication with Ethics Committee and Regulatory Authority

1. Purpose

To outline the steps for communicating with the Ethics Committee and relevant regulatory bodies in Sudan. This includes how to submit documents, seek approvals, and report updates before, during, and after the conduct of a clinical study.

2. Scope

This SOP applies to all clinical research studies conducted at the Mycetoma . It is applicable to the Principal Investigator (PI), co-investigators, study staff, and sponsors (if involved). It includes initial submissions, approvals, amendments, and ongoing communication with the Ethics Committee and regulatory authority.

3. Responsibilities

Person	Responsibility
Principal Investigator (PI)	Responsible for all communication with the Ethics Committee and regulatory authority, including submissions, follow-ups, and clarifications.
Site Coordinator / CRC	Supports in document preparation and tracking submissions, but does not submit documents independently unless authorised.
Sponsor / Collaborator (if any)	May provide templates, technical inputs, or assist with submission packages; however, the PI is the primary person responsible.

4. Procedure

4.1 Initial Communication

- Before starting any study, the PI must submit the **study proposal and required documents** to the Ethics Committee for review and approval.
- Communication is addressed to the **Chairperson or Member Secretary** of the Ethics Committee of the Soba University Hospital IRB, or the relevant regulatory authority (e.g., the National Medicines and Poisons Board).

4.2 Documents to Submit

- The Principal Investigator (PI) must submit all required documents to the Ethics Committee and/or the relevant Regulatory Authority before the study commences.
- The exact list of documents may vary depending on the local requirements of the Ethics Committee (EC) and/or Regulatory Authority (RA). Some documents may be added or removed as needed.

Below is a general list of commonly required essential documents:

- Final version of the study protocol (with version number and date)
- Investigator's Brochure (IB) or product safety information (if applicable)
- Informed Consent Forms (ICF) in English and local language(s)
- Data collection forms or Case Report Forms (CRFs)

- Curriculum Vitae (CV) of the Principal Investigator and co-investigators
- GCP or GLP training certificates of research team members
- Qualifications and professional registration certificates
- Site-specific Standard Operating Procedures (if requested)
- Clinical trial insurance certificate or indemnity letter (if applicable)
- Local regulatory or national submission forms (as per the Sudanese RA)
- Evidence of prior approvals (if any), such as previous EC or RA approvals
- Study-related agreements or collaboration letters (if required)
- The PI should check with the specific Ethics Committee or Regulatory Authority for the most updated submission requirements and follow their guidance accordingly.

4.3 Submission Process

- The PI (or a delegated senior member, in special cases) submits all documents and keeps proof of submission.
- The PI or designee must coordinate with the Ethics Committee/regulatory bodies to determine meeting dates and timelines.
- The PI should be available to **present the protocol** to the committee and respond to questions or required changes if needed.
- No study activity should start until **written approval** is received.

4.4 Review of Approval Letter

- Once approval is received, the PI must:
    - Verify that the approval letter includes the meeting date, the names of members present, the quorum status, and a list of approved documents.
    - Ensure that the approved document versions match the submitted versions.
    - If there is any error or missing information, PI should request a corrected approval letter or clarification in writing.

4.5 Ongoing Submissions

During the course of the study, the PI must submit:

- Protocol amendments (prior to implementation)
- Serious Adverse Events (within 24–48 hours or per protocol or applicable procedure)
- Deviations or violations
- Progress reports (as required)
- Final study closure or termination report

These should be submitted with covering letters, referencing the study and including the version/date of documents.

4.6 Compliance and Training

- The PI and research team must **attend any training** sessions offered by the Ethics Committee on GCP, ethics, or SOPs.
- The PI must follow all instructions and decisions issued by the Ethics Committee throughout the study.

- Study documents must be made available for **monitoring or audit** by the Ethics Committee upon request.

4.7 Delegation

- Although some tasks can be delegated (e.g., collecting signatures, compiling documents), the PI is ultimately **responsible for the content, accuracy, and timelines** of all submissions.
- In unavoidable situations (e.g., PI on leave), a **qualified team member** may submit on behalf of the PI with proper authorisation.

5. Summary Checklist for PI

- Submit the study for approval before starting.
- Use the latest protocol and consent forms.
- Track all document versions and submission dates.
- Review the approval letter details carefully.
- Report amendments, SAEs, and updates on time.
- Attend EC-required trainings and support site inspections.
- Maintain proper records and archive them securely.

Prepared by:
Name: Dr Eiman Siddig Ahmed
Title: Research Assistant
Signature: *Eiman*
Date: 20/07/2025

Reviewed by:
Name: Dr Samira Mohammed Hussein
Title: Research Assistant
Signature: *Samira*
Date: 21/07/2025

Approved by:
Name: Prof Ahmed Hassan Fahal
The Mycetoma Research Center, Director
Signature: *Fahal*
Date: 24/07/2025

SOP 04: Informed Consent Process

1. Purpose

To describe the process of obtaining, documenting, and managing informed consent from all study participants at the Mycetoma Research Center before beginning any study-related procedure. This SOP ensures that the informed consent process is ethically conducted and properly documented.

2. Scope

This SOP applies to all clinical research studies conducted at the Mycetoma Research Center. It covers obtaining informed consent from adults, minors, vulnerable populations, and the use of legally acceptable representatives (LAR), and includes requirements for re-consent and audiovisual recording where necessary.

3. Responsibilities

- **Principal Investigator (PI):**
  - Ensures informed consent is taken before any study activity.
  - Verifies that the correct and approved consent documents are used.
  - Trains team members on the consent process.
  - Ensures documentation is complete and filed.

- **Designated Study Team Members:**
  - Support in providing study information.
  - Assist with documentation.
  - May conduct consent if authorised and trained.

- **Ethics Committee (EC):**
  - Reviews and approves consent forms and participant information sheets before use.

4. Procedure

4.1 Before Starting Consent

- The PI or authorised team member will explain the study using the approved Informed Consent Form (ICF) and Participant Information Sheet (PIS).
- The participant must be informed in **a language they understand clearly** (Arabic or other preferred local language).
- Ample time should be given to ask questions and consider participation.

4.2 Key Information to Be Shared with Participants

Participants should be informed of the following:

1. Purpose of the study and expected participation.
2. Study procedures (including any tests or treatments).
3. Risks, discomforts, and benefits (if any).
4. Alternatives to participation.

5. Confidentiality of their data and access by EC, monitors, or regulatory bodies.
6. Voluntary participation and right to withdraw at any time.
7. Compensation and treatment in case of injury (if applicable).
8. Contact persons for further information or emergencies.
9. Number of people expected to participate in the study.
10. Duration of participation.
11. Possible reasons for discontinuation from the study.

4.3 Consent for Vulnerable Populations

- **Minors (children):**
  - Parental/legal guardian **written consent** is required.
  - **Assent** (verbal or written) from older children or adolescents should be obtained where appropriate.

- **Participants unable to read/write:**
  - A **neutral and impartial witness must be present throughout** the entire consent process.
  - The witness must also sign the consent form.

- **Participants unable to consent (e.g., unconscious, mentally impaired):**
  - Consent should be taken from a **Legally Acceptable Representative (LAR)**.
  - If LAR is not available and urgent inclusion is needed, follow protocol-approved emergency procedures and notify EC.

4.4 Consent Form Handling

- The **signed and dated original consent form** must be kept in the participant's file.
- A **copy must be provided** to the participant or their LAR.
- Only the most **recent EC-approved version** should be used.
- Each page should be initialed or marked by the participant.

4.5 Re-Consent

- If there are **amendments to the study or consent form**, re-consent must be taken using the newly approved version.
- The re-consent process follows the same steps as the original consent.

4.6 Documentation and Quality Check

- PI or CRC should check that:
  - The correct version of the form is used.
  - All sections are completed and signed.
  - The process is documented in the source notes (date, time, personnel involved, questions asked).
  - Blank versions of each ICF are archived in the study master file.

5. Summary Checklist

- Use the latest EC-approved consent documents.
- Provide information in the local language (Arabic).
- Give time and freedom to decide.
- Use LAR and impartial witness if required.
- File signed original; give a copy to the participant.
- Document the full process in source notes.
- Follow AV recording procedures if applicable.
- Ensure compliance with any EC guidance updates.

Prepared by:
Name: Dr Eiman Siddig Ahmed
Title: Research Assistant
Signature: *Eiman*
Date: 20/07/2025

Reviewed by:
Name: Dr Samira Mohammed Hussein
Title: Research Assistant
Signature: *Samira*
Date: 21/07/2025

Approved by:
Name: Prof Ahmed Hassan Fahal
The Mycetoma Research Center, Director
Signature: *Fahal*
Date: 24/07/2025

SOP 05: Screening and Enrollment of Research Participants

1. Purpose

To outline the steps for identifying, screening, and enrolling eligible participants into clinical studies at the Mycetoma Research Center. This ensures all participants meet the study protocol requirements and that the screening/enrolment process is ethical, documented, and compliant with local and international standards.

2. Scope

This SOP applies to all clinical research conducted at the Mycetoma Research Center that involves human participants. It includes participant identification, pre-screening, screening, informed consent, and enrollment into the study. It also includes the use of screening/enrollment logs, as well as coordination with study teams.

3. Responsibilities

Role	Responsibility
Principal Investigator (PI)	Overall responsibility for screening and enrolling participants, ensuring protocol compliance.
Medical Team / Sub-Investigators	Assist in identifying eligible participants and performing screening procedures under PI supervision.
Clinical Research Coordinator (CRC)	Maintain logs, provide support documentation, and assist in coordinating participant communication and appointments.

4. Procedure

4.1 Identification of Potential Participants

- Potential participants can be identified through:
    - Patients visiting the clinic/hospital for treatment
    - Hospital medical records and patient databases
    - Community outreach or health camps
    - Referrals from local physicians or partner facilities
    - Public advertisements (only if allowed by the protocol and EC)

Note: All outreach or referral activities must adhere to ethical guidelines and be approved by the Ethics Committee prior to implementation.

4.2 Pre-Screening (Before Study Start)

- Once the study is approved and the site is selected, the PI and study team will:
    - Review the **inclusion/exclusion criteria** in the protocol.
    - Discuss the patient population with internal and external doctors (if applicable).
    - Identify possible participants from available medical records or regular patient flow.
    - Maintain a **pre-screening log** if required by protocol or sponsor.
    - Ensure no procedures are conducted before receiving **Ethics Committee (EC) approval** and **informed consent** from the participant.

4.3 Screening (After Study Initiation)

- After all approvals and site initiation:
    - Pre-identified and walk-in eligible patients are informed about the study.
    - Medical history and prior treatments are reviewed.
    - Informed consent must be obtained before **any study-related procedure**.
    - Provide participants with a copy of the signed consent form.
    - Record all data in a **screening log**.

Only those who meet the protocol-defined criteria can proceed to enrollment. Patients who do not qualify after screening should be documented in the screening log, along with the reasons for non-qualification.

4.4 Randomisation / Enrollment

- Eligible participants are randomly assigned or enrolled as per the protocol.
- Provide each enrolled subject with a **study ID or subject card**.
- Explain:
    - Study schedule and visit dates
    - Medication or procedure compliance
    - Reporting of any side effects or problems (AE/SAE)
    - Emergency contact numbers of the site

Ensure the participant is **not enrolled in another study**, unless permitted by the protocol.

4.5 Special Situations

- **Re-screening** may be done if allowed by the protocol.
- If lab values or investigations are abnormal, the PI decides on the next steps.
- If unplanned visits or external consultations are required, the PI coordinates accordingly.

4.6 Withdrawal of Consent

- If a participant wishes to **withdraw from the study**, they are free to do so at any time.
- The study team should:
    - Explain the importance of continued participation (without coercion)
    - Document the reason for withdrawal (if given)
    - Complete any end-of-study assessments if the participant agrees
    - Record the withdrawal in the participant log and notify the sponsor and EC as applicable

5. Documentation and Logs

The study team should maintain the following:

- **Pre-screening log** (if applicable)
- **Screening log/register** – list of all individuals screened and their eligibility status
- **Enrollment log/register** – list of enrolled participants with date, study ID, and randomisation details
- **Signed Informed Consent Forms**

- **Source documents** related to medical history, lab tests, and inclusion/exclusion assessment

6. Summary Checklist

- Identify potential participants ethically and as per protocol.
- Do not start procedures without EC approval and informed consent.
- Use only the latest approved ICF.
- Follow inclusion/exclusion strictly.
- Document all screening and enrollment steps.
- Inform participants clearly about their role, the associated risks, and their rights.
- Maintain screening and enrollment logs/register.

Prepared by: Name: Dr Eiman Siddig Ahmed Title: Research Assistant Signature: *Eiman* Date: 20/07/2025	Reviewed by: Name: Dr Samira Mohammed Hussein Title: Research Assistant Signature: *Samira* Date: 21/07/2025

Approved by:
Name: Prof Ahmed Hassan Fahal
The Mycetoma Research Center, Director
Signature: *Fahal*
Date: 24/07/2025

SOP 06: Responsibilities of Principal Investigator (PI), Co-Investigator, and Research Staff

1. Purpose

To describe the roles and responsibilities of the Principal Investigator (PI), Co-Investigator(s), and study team members involved in clinical research at the Mycetoma Research Center.
The goal is to ensure that clinical studies are conducted ethically, safely, and in accordance with Good Clinical Practice (GCP) and local regulatory requirements.

2. Scope

This SOP applies to all clinical research studies conducted at The Mycetoma Research Center, It covers the responsibilities of the PI, Co-PI, study coordinators, nurses, pharmacists, lab staff, and other research personnel.

3. Responsibility

- The **PI** holds full responsibility for the overall conduct of the study at the site, even if certain tasks are delegated.
- **Co-Investigators and other study staff** are accountable for performing the tasks assigned to them by the PI.
- All responsibilities must be documented, and all delegated persons must be qualified and trained.

4. Procedure

4.1 PI Qualifications

- The PI must be medically qualified and experienced in clinical research.
- The PI must understand the protocol, investigational product, and applicable GCP and ethical guidelines.

4.2 PI Responsibilities

The PI is responsible for:

1. **Ethical Conduct of Study**
    - Ensure the study is conducted according to the approved protocol and EC guidelines.
    - Obtain EC approval before starting the study or implementing protocol amendments.

2. **Oversight and Supervision**
    - Delegate study-related duties only to qualified and trained staff.
    - Maintain a **Delegation of Responsibilities Log**.
    - Supervise the work of all research team members throughout the study.

3. **Participant Safety**
    - Ensure that medical care is provided in the event of adverse events.
    - Protect the rights and well-being of participants.
    - Be available during emergencies or arrange a qualified substitute.

4. **Informed Consent Process**
    - Ensure informed consent is obtained from all participants using the **EC-approved form**.
    - Provide clear information in a language the participant understands.
    - Document the consent process properly.

5. **Safety Reporting**
    - Report all Serious Adverse Events (SAEs) to the sponsor, EC, and regulatory authorities as per protocol timelines.
    - Submit any follow-up or final reports for SAEs as required.

6. **Compliance with Protocol and GCP**
    - Follow the approved protocol.
    - Report any protocol deviations/violations to the EC and sponsor.
    - Implement urgent changes only to eliminate immediate risks and inform the EC as soon as possible.

7. **Investigational Product (IP) Oversight**
    - Ensure proper storage, use, and accountability of study medication or investigational product.
    - Supervise the pharmacy team or person handling the IP.

8. **Monitoring and Audits**
    - Be present and assist during monitoring visits, audits, or inspections by EC, sponsor, or regulatory bodies.
    - Provide access to all requested study records.

9. **Data Accuracy and Reporting**
    - Ensure all data entered into Case Report Forms (CRFs) is accurate and timely.
    - Maintain source documents to support all data entries.
    - Keep all study-related records and logs up to date.

10. **Study Closure**
    - Notify EC and sponsor of study completion or early termination.
    - Submit final reports as required.
    - Ensure participants are informed if the study ends early.

11. **Communication and Coordination**
    - Serve as the primary point of contact for EC, regulatory authorities, and sponsors.
    - Coordinate internal team communication and task updates.

4.3 Co-Investigator Responsibilities

- Assist the PI in clinical evaluations, patient safety, and the conduct of study procedures.

- Obtain informed consent if delegated and trained.
- Maintain medical records and follow-up assessments.
- Report adverse events to the PI immediately.

4.4 Responsibilities of Research Staff (CRC, Nurses, Pharmacists, Lab Technicians, etc.)
Under PI supervision, research staff may:

- Schedule participant visits and ensure timely follow-up.
- Collect and record clinical data.
- Perform assigned protocol procedures (e.g., vitals, sample collection, dispensing study drug).
- Maintain regulatory files and documentation.
- Support the informed consent process and participant education.
- Monitor drug accountability (pharmacy staff).
- Record and report any issues or adverse events promptly.
- Participate in monitoring or audit preparation.

5. Summary Checklist for PI

- Qualified, trained, and available to oversee the study.
- Maintains updated delegation log.
- Ensures informed consent is taken using approved forms.
- Supervises all study procedures and staff.
- Report SAEs within protocol-defined timelines.
- Keeps data and records complete, accurate, and secure.
- Communicates regularly with EC, sponsor, and regulatory authorities.

6. Records to Maintain

- Delegation of Responsibilities Log
- Training Records of all team members
- Informed Consent Forms (signed)
- SAE reports and related correspondence
- Participant source documents and CRFs
- Investigational Product Accountability Logs
- Monitoring/Audit Reports and Responses

Prepared by:
Name: Dr Eiman Siddig Ahmed
Title: Research Assistant
Signature: *Eiman*
Date: 20/07/2025

Reviewed by:
Name: Dr Samira Mohammed Hussein
Title: Research Assistant

Signature: *Samira*
Date: 21/07/2025

Approved by:
Name: Prof Ahmed Hassan Fahal
The Mycetoma Research Center, Director
Signature: *Fahal*
Date: 24/07/2025

SOP 07: Responsibilities of Clinical Research Coordinator and Other Research Staff

1. Purpose

To describe the roles and duties of the Clinical Research Coordinator (CRC) and other study staff, ensuring participant safety, protocol compliance, data integrity, and overall quality at the Mycetoma Research Center.

2. Scope

Applies to all CRCs and research staff involved in any clinical study at the Mycetoma Research Center.

3. Responsibilities

- **CRC & Research Staff** must be qualified by education, training, and experience to carry out assigned tasks.
- They support study start-up, participant recruitment, data collection, regulatory compliance, and study close-out under PI supervision.

4. Duties and Procedures

4.1 Study Start-Up

- Participate in feasibility assessment and site selection.
- Review the study protocol, timelines, inclusion/exclusion criteria, and confidentiality requirements.
- Collect and submit required start-up documents (e.g., site CVs, delegation logs).

4.2 Training and Documentation

- Record all study-specific and GCP training in the **Training Log**, with dates and trainer signatures.
- Attend Sponsor/Monitor meetings (e.g., Investigator Meeting, Site Initiation Visit).
- Ensure ongoing SOP and protocol training.

4.3 Informed Consent Support

- Assist in or conduct informed consent discussions under the PI's delegation.
- Ensure that the correct, EC-approved consent forms are used and signed.
- File originals and provide participants with a copy.

4.4 Screening and Enrollment

- Use the **Eligibility Checklist** to screen participants per protocol.
- Maintain the **Screening Log** to document who was screened and the outcome of their eligibility.
- Schedule and register participants for study visits and procedures.

4.5 Data Collection and CRFs

- Complete Case Report Forms accurately and on time.
- Maintain source documents and narrative notes as needed.
- Track and resolve data queries with the PI and data management team.

4.6 Investigational Product (IP) and Supplies

- Monitor inventory of study supplies (e.g., lab kits, questionnaires).
- If handling IP, follow the sponsor's accountability procedures. Only delegated pharmacists or staff (as per the Delegation Log) may access the IP store.

4.7 Communication and Coordination

- Maintain clear and timely communication with the PI, sponsor, monitor, Ethics Committee, and participants.
- Report monitoring and audit findings to the PI and department head promptly.

4.8 Adverse Events and Deviations

- Assist the PI in documenting and reporting protocol deviations and adverse events to the Ethics Committee and sponsor.
- File all correspondence and follow-up actions.

4.9 Study Close-Out

- Help prepare and submit final close-out documents to the sponsor, EC, and regulatory authorities as needed.
- Archive study files according to sponsor and local requirements.

5. Study Handover

When a CRC or staff member leaves or takes extended leave, they must:

1. **Notify** the PI in advance.
2. **Train** the designated replacement on protocol, procedures, and pending tasks.
3. **Transfer** all study files, logs, and outstanding queries.
4. **Update** the Delegation Log and inform the sponsor and Ethics Committee of team changes.
5. **Document** the handover in a brief note, signed by both outgoing and incoming staff.

Upon return, the original staff member and PI review the handover note and update any outstanding items.

6. Applicable Staff

- Clinical Research Coordinator
- Study Nurses
- Pharmacists (for IP handling)
- Lab Technicians
- Data Entry Personnel
- Any other staff listed in the site's Delegation Log

The PI ensures all staff are aware of and comply with this SOP, and receives training on any updates.

Prepared by:
Name: Dr Eiman Siddig Ahmed
Title: Research Assistant
Signature: *Eiman*
Date: 20/07/2025

Reviewed by:
Name: Dr Samira Mohammed Hussein
Title: Research Assistant
Signature: *Samira*
Date: 21/07/2025

Approved by:
Name: Prof Ahmed Hassan Fahal
The Mycetoma Research Center, Director
Signature: *Fahal*
Date: 24/07/2025

SOP 08: Use of Instruments, Equipment, and Devices in Studies

1. Purpose

To describe the standard procedures for using various instruments, equipment, and devices during clinical trials at the Mycetoma Research Center, ensuring accurate and safe use in compliance with study protocols.

2. Scope

This SOP applies to all clinical research staff at Mycetoma Research Center who are involved in handling and using equipment/devices for patient assessments or procedures.

3. Responsibilities

- Principal Investigator (PI)
- Co-Principal Investigator (Co-PI)
- Clinical Research Coordinator (CRC)
- Research Nurses and Laboratory Staff
- Any staff delegated to operate instruments/devices (as per the delegation log)

4. Procedure

4.1. Weight Measurement

- Use a calibrated digital scale placed on a hard, level surface.
- Ensure the subject wears light clothing and no shoes.
- Wait for the scale to reset to zero.
- Ask the subject to stand still, with arms at their sides, looking straight ahead.
- Record weight in kg to one decimal point.

4.2. Height Measurement

- Use a stadiometer on a flat surface.
- The subject should stand barefoot, with heels and back against the stadiometer.
- Align head straight (horizontal plane).
- Lower the headpiece gently to the top of your head.
- Record height in cm to the nearest mm.

4.3. Blood Pressure Measurement

- Ensure 5 minutes of rest before taking the measurement.
- Use a properly sized cuff.
- Seat subject comfortably with arm supported at heart level.
- Record BP using either a digital monitor or a sphygmomanometer.
- Take two readings, one minute apart; average if the difference is greater than 5 mmHg.
- Classify readings as per hypertension stages.
- Refer to a cardiologist if high readings are noted.

4.4. ECG Acquisition

- Position the subject in the supine position; ensure they are calm and still.
- Attach electrode patches and leads at the correct anatomical sites.
- Check for noise/artifacts before recording.
- Print and file the ECG in the participant file.
- Repeat if the lead placement was incorrect.

4.5. Temperature Monitoring for Refrigerators/Coolers

- Use calibrated min/max thermometers with a valid certificate.
- Record daily fridge temperature (2°C to 8°C).
- Maintain monthly logs.
- Investigate and document any deviation or alarm.
- Report deviations to the responsible pharmacist or PI.

4.6. Infusion Pump Usage

- Insert the fluid line correctly; set the appropriate infusion rate and volume.
- Press RUN to start infusion; monitor progress.
- Ensure patient safety throughout.
- Clamp IV line before removal.

4.7. Centrifuge Use

- Use proper PPE and read SDS for hazardous materials.
- Balance tubes before centrifugation.
- Avoid overfilling.
- Clean and maintain the machine regularly.
- Avoid aerosol generation with infectious materials.

4.8. Body Temperature Measurement (Axillary)

- Use a digital thermometer with a beep signal.
- Place the mometer in the centre of the armpit, holding the arm close to the body.
- Wait for the beep; record the reading directly on the CRF.
- Disinfect the probe tip after each use.
- Repeat measurement if below 36.0°C.

5. Quality Assurance

- Perform calibration of devices at defined intervals.
- Maintain calibration and maintenance records.
- Conduct periodic training and competency assessments.
- Ensure backups and alternative options for each instrument in the event of a malfunction.

6. Record Keeping

- All equipment logs, maintenance logs, and calibration records must be retained in the site documentation file.

- Any deviations in usage or malfunction must be reported to the PI and documented.

7. Safety Precautions

- Always follow manufacturer guidelines.
- Handle biological and chemical samples with care.
- Use gloves, masks, and other PPE as required.

8. References

- Equipment User Manuals
- Study Protocols
- GCP Guidelines
- Local Institutional Safety Procedures

Prepared by:
Name: Dr Eiman Siddig Ahmed
Title: Research Assistant
Signature: *Eiman*
Date: 20/07/2025

Reviewed by:
Name: Dr Samira Mohammed Hussein
Title: Research Assistant
Signature: *Samira*
Date: 21/07/2025

Approved by:
Name: Prof Ahmed Hassan Fahal
The Mycetoma Research Center, Director
Signature: *Fahal*
Date: 24/07/2025

SOP 9: Procedure for Source Documentation

1. Purpose

To describe the importance of source data and standardise the process of maintaining source documents during the conduct of a clinical study.

2. Scope

This SOP applies to all source documents generated or used in clinical studies conducted at the Mycetoma Research Center. It outlines how source data should be recorded, verified, and maintained in compliance with ICH-GCP, GLP, and applicable regulatory guidelines.

3. Responsibilities

- Principal Investigator (PI)
- Co-Investigator / Sub-Investigator
- Clinical Research Coordinator (CRC)
- Designated Research Staff

These team members are responsible for the accurate collection, recording, verification, and maintenance of source documents.

4. Procedure

4.1. Source Data Collection

- The PI or their designee will take a complete medical history (as required by protocol) verbally and from available documents.
- This information will be documented in the participant's hospital or source notes.

4.2. Identification of Source Documents

- Original or certified copies of reports, prescriptions, diagnostic tests, and medical history form the source documents.
- Photocopies (with participant's personal identifiers masked) may be collected, verified against the original, signed, dated, and certified by the PI or designee.
- These certified copies are filed in the participant's study file.

4.3. Corrections in Source Data

- Corrections must not obscure the original entry (no erasing, overwriting, or using correction fluids).
- Draw a single line through the incorrect entry, write the correction nearby, and include the date and initials of the person making the change.
- If making a new entry or clarification, note the reason and date of the addition.

4.4. Review and Certification

- The PI must review and initial all laboratory and diagnostic reports.
- If abnormal findings are reported, the PI will determine clinical significance and take appropriate action.

4.5. Types of Source Documents These may include (but are not limited to):

- Past hospital/clinic visit records (OPD and IPD)
- Laboratory reports, ECG, X-rays, and other imaging
- Medical prescriptions and consultation notes
- Any medical referrals or discharge summaries

4.6. Storage and Archival

- All source documents should be securely filed and stored.
- Records must be retained as per sponsor requirements and local regulatory guidelines.
- Documents must be readily available for monitoring, audit, or inspection purposes.

5. Quality Assurance

- Regular checks by PI or designee to ensure completeness and accuracy of source documents.
- Any discrepancies should be resolved and documented.

6. References

- ICH-GCP E6(R2)
- Sponsor's Clinical Study Protocol
- Local Regulatory and Ethical Guidelines
- Site SOPs.

Prepared by:
Name: Dr Eiman Siddig Ahmed
Title: Research Assistant
Signature: *Eiman*
Date: 20/07/2025

Reviewed by:
Name: Dr Samira Mohammed Hussein
Title: Research Assistant
Signature: *Samira*
Date: 21/07/2025

Approved by:
Name: Prof Ahmed Hassan Fahal
The Mycetoma Research Center, Director
Signature: *Fahal*
Date: 24/07/2025

SOP 10: Procedure for Reporting Adverse Events (AE) and Serious Adverse Events (SAE).

1. Purpose

To define a clear procedure for reporting Adverse Events (AEs) and Serious Adverse Events (SAEs) during clinical trials conducted at the Mycetoma Research Center. This SOP outlines reporting timelines, responsibilities, documentation requirements, and regulatory compliance as per international and local guidelines.

2. Scope

This SOP applies to all clinical trials conducted at the Mycetoma Research Center, and covers the entire study duration from participant enrollment to study closeout.

3. Responsibilities

- Principal Investigator (PI)
- Co-Investigator/Sub-Investigator
- Clinical Research Coordinator (CRC)
- Research Nurse and other delegated study team members

These individuals are responsible for identifying, documenting, assessing, and reporting all AEs/SAEs per regulatory and sponsor timelines.

4. Definitions

4.1. Adverse Event (AE): Any untoward medical occurrence in a trial participant during a clinical study, regardless of its relationship to the investigational product.

4.2. Adverse Drug Reaction (ADR): A harmful or unintended reaction to an investigational product at normal doses.

4.3. Unexpected ADR: An adverse drug reaction not consistent with existing product information (e.g., Investigator's Brochure).

4.4. Serious Adverse Event (SAE): An AE that results in death, life-threatening condition, hospitalisation/prolongation of hospitalisation, disability, or congenital anomaly.

5. Procedure

5.1. Participant Instructions:

- All participants must be instructed at enrollment to inform the site immediately if they experience any illness, are prescribed medications, or seek medical consultation during the study.
- Participants should be advised to retain any prescriptions, reports, or medication packaging.

5.2. Data Collection & Follow-Up:

- If the participant was treated without a formal consultation, collect details of symptoms and medications taken.
- Record start and end dates (or best approximation) in source documents.
- Follow up until resolution or stabilisation of the event.

5.3. PI Responsibilities:

- Provide or arrange medical care as needed.
- Assess and document all AEs/SAEs in the participant file.
- Determine the clinical significance of abnormal laboratory values.
- Classify events appropriately as AE or SAE.

5.4. Reporting Timelines:

- **Initial SAE Report:** Within 24 hours to Sponsor and SUH-IRB.
- **Final SAE Report with causality analysis:** Within 14 calendar days.
- Continue follow-up until resolution and provide follow-up reports as required.

5.5. Documentation:

- All AE/SAE details must be recorded in source documents.
- SAE forms must be completed from source notes only and signed/dated by the delegated person.
- Supporting medical records, prescriptions, lab reports, and other documentation must be certified, filed in the original source, and shared with the sponsor when requested.

5.6. Safety Review:

- The PI will review all AEs, ADRs, and SAEs to assess causality and determine further action.
- PI must assess the relationship to the investigational product (definite, probable, possible, unlikely, unrelated).

5.7. Global Safety Reports (Multinational Trials):

- PI and site staff must review external safety reports such as SUSARs and CIOMS forms.
- These must be submitted to the SUH-IRB and archived in the Investigator Site File (ISF).

6. References

- ICH-GCP Guidelines
- National Ethics and Regulatory Guidelines
- Study Protocol and Investigator's Brochure
- Sponsor-specific reporting formats and procedures/Safety Management Plan

Prepared by:
Name: Dr Eiman Siddig Ahmed
Title: Research Assistant
Signature: *Eiman*
Date: 20/07/2025

Reviewed by:
Name: Dr Samira Mohammed Hussein
Title: Research Assistant

Signature: *Samira*
Date: 21/07/2025

Approved by:
Name: Prof Ahmed Hassan Fahal
The Mycetoma Research Center, Director
Signature: *Fahal*
Date: 24/07/2025

SOP 11: Archival of Study Documents

1. Purpose

To describe the procedures for secure archival and long-term storage of clinical trial documents at the Mycetoma Research Center following study completion, in compliance with regulatory and sponsor requirements.

2. Scope

This SOP applies to the Principal Investigator (PI) and all research staff responsible for document storage and management after study closure at the Mycetoma Research Center.

3. Responsibilities

- The Principal Investigator (PI) is responsible for arranging secure storage space and ensuring proper archival.
- Designated staff must support the labeling, filing, and secure storage of essential study records.

4. Procedure

4.1. Archival Preparation

- Upon completion of the study or receipt of formal site closure notification from the sponsor, the PI shall organise and prepare all essential study documents for archival.
- Essential documents include, but are not limited to: Investigator Site File (ISF), source documents, CRFs, laboratory reports, consent forms, monitoring visit logs, and correspondence.

4.2. Secure Storage Requirements

- Documents should be stored in sealed cupboards or archival boxes in a clean, dry, and secure location with limited access.
- The storage location should be protected from fire, water, insects, and other forms of damage.
- Documents must remain legible and retrievable throughout the retention period.

4.3. Labeling of Archived Files Each subject file or box must be labeled clearly with:

- DO NOT DESTROY
- Principal Investigator's contact details
- Sponsor's contact details
- Protocol number
- Subject number/initials
- Hospital registration number

4.4. Duration of Archival

- Study documents should be archived for a minimum of the duration defined by national regulatory guidelines and sponsor policies, whichever is longer.

4.5. Third Party Storage (if applicable)

- If archival is outsourced to a vendor, the name and contact of the storage vendor must be recorded and shared with the sponsor.
- Access logs and storage facility details must be available upon request.

4.6. Document Access

- Archived documents must be accessible for regulatory audits or inspections.
- Only authorised personnel should access the storage area, and access should be logged.

4.7. Destruction of Documents

- No documents may be destroyed without prior written permission from the sponsor.
- If destruction is permitted, the PI must make a reasonable attempt to inform the sponsor.
- Destruction should follow environmentally approved methods.
- A certificate of destruction should be maintained in site records.

4.8. Hospital Record Storage (if applicable)

- If source documents are stored with hospital records, the person responsible for hospital records should be informed of their importance and the confidentiality requirements.
- Archival details should be reflected in the Clinical Trial Agreement (CTA)

4.9. Archival Costs

- Any associated fees for archival should be determined and approved by the site management.

5. References

- ICH-GCP E6 (R2)
- National Regulatory Guidelines
- Sponsor Protocol & Clinical Trial Agreement
- Mycetoma Research Center Site Management Policies

Prepared by:
Name: Dr Eiman Siddig Ahmed
Title: Research Assistant
Signature: *Eiman*
Date: 20/07/2025

Reviewed by:
Name: Dr Samira Mohammed Hussein
Title: Research Assistant

Signature: *Samira*
Date: 21/07/2025

Approved by:
Name: Prof Ahmed Hassan Fahal
The Mycetoma Research Center, Director
Signature: *Fahal*
Date: 24/07/2025

SOP 12: Investigational Product (IP) Management

1. Purpose

To define the procedures for receiving, storing, handling, dispensing, documenting, returning, and disposing of Investigational Products (IP) at the Mycetoma Research Center to ensure compliance with GCP, protocol requirements, and sponsor instructions.

2. Scope

This SOP applies to all study team members involved in IP management during clinical trials conducted at the Mycetoma Research Center.

3. Responsibilities

- **Principal Investigator (PI):** Overall responsibility for IP accountability and compliance.
- **Pharmacist/Designated IP Custodian:** Responsible for receipt, storage, dispensing, and documentation.
- **Clinical Research Coordinator (CRC):** Assist with tracking, reconciliation, and documentation.
- **Sponsor/Monitor:** Provide instructions, perform audits, and verify accountability records.

4. Procedure

4.1. IP Receipt

- Upon arrival, the designated person verifies the shipment details (name, quantity, batch number, expiry date, and temperature condition) against the shipping documents.
- Record receipt in the IP accountability log.
- Notify the sponsor of any discrepancies or damages immediately.

4.2. Storage

- Store the IP as per the manufacturer/sponsor-provided temperature and light conditions (e.g., 2°C-8°C for refrigerated storage, 15°C-25°C for room temperature).
- Use a dedicated, access-controlled storage area.
- Place clear labeling: "Investigational Product - For Clinical Trial Use Only."
- Monitor and log storage temperature daily using calibrated thermometers.
- Report deviations immediately and take corrective action.

4.3. Access Control

- Only authorised personnel (PI, pharmacist, designated staff) can access IP.
- Maintain an access log for entry into the IP storage area.

4.4. Dispensing

- Dispense IP only after verifying informed consent and subject eligibility.
- Follow the protocol-specific dosage and schedule.
- Record dispensing in the IP accountability log: include subject ID, date, batch number, quantity dispensed, and dispensing staff initials.

4.5. Accountability and Documentation

- Maintain accurate and up-to-date logs for the receipt, storage, dispensing, return, and destruction of IP.
- Perform regular reconciliation of IP inventory.
- Make documents available for sponsor/monitor inspection.

4.6. Return and Disposal

- Collect unused/expired/damaged IPs in a separate labeled box.
- Return to the sponsor or dispose of as per the sponsor's instructions.
- Document all returned or destroyed IPs with quantity, reason, date, and the responsible person's signature.

4.7. Temperature Excursion Management

- Record any temperature deviations.
- Inform the sponsor and follow instructions for assessing product usability.
- Quarantine affected IPs until the disposition decision is received.

4.8. Blinding and Randomisation (if applicable)

- Maintain the blind per protocol.
- Follow instructions regarding code break in the event of an emergency.
- Document all code breaks with justification and PI authorisation.

5. Quality Assurance

- Conduct periodic internal checks on IP records.
- Maintain training records of staff handling IP.
- Keep all related documentation in the Trial Master File (TMF).

6. References

- ICH-GCP E6 (R2) Guidelines
- Sponsor Protocol and Pharmacy Manual
- National Regulatory Guidelines (Sudan)
- WHO Good Distribution Practice (GDP)

Prepared by:
Name: Dr Eiman Siddig Ahmed
Title: Research Assistant
Signature: *Eiman*
Date: 20/07/2025

Reviewed by:
Name: Dr Samira Mohammed Hussein
Title: Research Assistant

Signature: *Samira*
Date: 21/07/2025

Approved by:
Name: Prof Ahmed Hassan Fahal
The Mycetoma Research Center, Director

Signature: *Fahal*

SOP 13: Data Management and Case Report Forms (CRFs)

1. Purpose

To define standardised procedures for data collection, entry, verification, and management using Case Report Forms (CRFs) and other tools to ensure data integrity and compliance with Good Clinical Practice (GCP) at the Mycetoma Research Center.

2. Scope

This SOP applies to all study staff involved in data collection, entry, correction, verification, and management for clinical studies conducted at the Mycetoma Research Center Site.

3. Responsibilities

Role	Responsibility
Principal Investigator (PI)	Overall supervision of data quality and integrity.
Clinical Research Coordinator (CRC)	Ensures accurate and timely data entry and resolution of queries.
Data Entry Personnel	Enters data into electronic/printed CRFs.
Monitor/Data Manager	Verifies and queries inconsistencies.
Study Team	Ensures all data is sourced, complete, legible, and verifiable.

4. Procedure

4.1 General Principles

- All data entered in CRFs must originate from verifiable source documents.
- Data entries must be accurate, complete, consistent, and submitted in a timely manner.
- All CRFs and supporting logs must be stored securely and confidentially.

4.2 CRF Completion

- Complete CRFs in ink (for paper CRFs) or using validated electronic systems.
- Avoid blanks; if a field is not applicable, write “N/A” and initial.
- Sign and date each completed CRF page where required.

4.3 Data Entry and Correction

- Corrections must be made by a single line through the incorrect data, with initials, date, and reason (if applicable).
- Use no correction fluid or erasures.
- For electronic CRFs (eCRFs), use the audit trail feature.

4.4 Data Review and Verification

- CRC and PI review CRFs regularly for accuracy.
- Source documents must match the data in CRFs.

- Discrepancies must be corrected and documented.

4.5 Query Management
- All queries raised by monitors or data managers should be resolved promptly.
- Maintain a log of all open and resolved queries.

4.6 CRF and Data Storage
- Completed CRFs must be stored in a locked cabinet or restricted-access system.
- Regular backups of electronic data should be performed.
- Access to data is restricted to authorised personnel.

4.7 Data Confidentiality
- All subject identifiers must be anonymised using subject ID numbers.
- CRFs must not contain names or other identifiable information unless required and approved.

4.8 Final Review and Archival
- Ensure all CRFs are complete and signed off by the PI before archival.
- Retain copies of completed CRFs and logs as per regulatory and sponsor requirements.

5. Quality Control
- Perform periodic checks to ensure completeness and consistency.
- Internal audits may be conducted to verify CRF data against source documents.

6. References
- ICH-GCP E6(R2)
- Sponsor Data Management Plan (if applicable)
- Study Protocol
- Local and international regulatory guidelines

Prepared by:
Name: Dr Eiman Siddig Ahmed
Title: Research Assistant
Signature: *Eiman*
Date: 20/07/2025

Reviewed by:
Name: Dr Samira Mohammed Hussein
Title: Research Assistant
Signature: *Samira*
Date: 21/07/2025

Approved by:
Name: Prof Ahmed Hassan Fahal
The Mycetoma Research Center, Director
Signature: *Fahal*

SOP 14: Protocol Deviations

1. Purpose
To define the procedure for identifying, documenting, assessing, reporting, and managing protocol deviations during clinical trials conducted at the Mycetoma Research Center, in compliance with GCP and regulatory guidelines.

2. Scope
This SOP applies to all protocol deviations—whether minor or major—identified during the conduct of any clinical study at the Mycetoma Research Center.

3. Responsibilities

Role	Responsibility
Principal Investigator (PI)	Reviews and classifies the deviation, signs off the report, and ensures reporting to the sponsor and EC as applicable.
Clinical Research Coordinator (CRC)	Detects, documents, and maintains records of deviations.
Study Team	Reports deviations to the PI and follows CAPA plans.

4. Definitions
- Protocol Deviation: Any departure from the approved protocol, study plan, GCP, or regulatory requirements.
    - Minor Deviation: No significant impact on participant safety or data integrity (e.g., missed visit window by 1–2 days).
    - Major Deviation: May impact participant safety, rights, or data reliability (e.g., failure to follow critical procedures, failure to obtain informed consent).

5. Procedure
5.1 Identification
- Study staff should immediately notify the PI upon noticing a deviation.
- PI classifies the deviation as minor or major.

5.2 Documentation
- Document in the Protocol Deviation Log with:
    - Participant ID
    - Date and nature of deviation
    - Impact assessment
    - Corrective & Preventive Action (CAPA)

5.3 Reporting
- Major deviations must be reported to:
    - Sponsor within 24–48 hours.
    - Ethics Committee as per their guidelines.

- Minor deviations are tracked but reported in summary unless EC/Sponsor requests otherwise.

5.4 CAPA (Corrective and Preventive Action)

- PI ensures root cause analysis and prepares CAPA.
- Ensure implementation and follow-up.

6. Quality Review

- Regular internal review of deviation trends by PI/monitor.
- Deviations are used for staff retraining if necessary.

7. Record Retention

- All deviation logs and reports are filed in the Site File.
- Maintain for the duration defined by the sponsor and applicable regulations.

8. References

- ICH-GCP E6(R2)
- Local Ethics Committee and Regulatory Authority Guidelines

Prepared by:
Name: Dr Eiman Siddig Ahmed
Title: Research Assistant
Signature: *Eiman*
Date: 20/07/2025

Reviewed by:
Name: Dr Samira Mohammed Hussein
Title: Research Assistant
Signature: *Samira*
Date: 21/07/2025

Approved by:
Name: Prof Ahmed Hassan Fahal
The Mycetoma Research Center, Director
Signature: *Fahal*
Date: 24/07/2025

SOP 15: Protocol Amendments

1. Purpose
To describe the procedure for submission, approval, and implementation of protocol amendments at the Mycetoma Research Center in accordance with applicable ethical and regulatory requirements.

2. Scope
This SOP applies to all clinical studies conducted at the Mycetoma Research Center, where amendments to the original protocol are required.

3. Responsibilities

Role	Responsibility
Principal Investigator (PI)	Reviews the amendment, ensures EC and sponsor approval, and ensures implementation and training.
Clinical Research Coordinator (CRC)	Assists with documentation, tracks version control, and maintains amendment records.
Sponsor	Provides rationale and revised documents for submission.
EC	Reviews and approves the amendment before it is implemented.

4. Definitions
- **Protocol Amendment**: Any official change, clarification, or update to the study protocol.
    - **Substantial Amendment**: May impact participant safety, study objectives, or data integrity.
    - **Administrative Amendment**: Minor changes (e.g., correction of typographical errors).

5. Procedure
5.1 Preparation
- The sponsor provides an amended protocol with a summary of the changes.
- PI reviews and ensures it is scientifically and ethically sound.

5.2 Submission and Approval
- Submit the amendment, summary of changes, and updated ICF (if applicable) to:
    - Ethics Committee (mandatory)
    - Regulatory Authorities (if required)
- Maintain approval letters in the **Site File**.

5.3 Implementation
- **Do not implement** until EC approval is received (unless to eliminate immediate hazard).
- Ensure version control:
    - Archive old versions
    - Clearly label the new version as “Current” with version number and date

5.4 Training

- PI ensures that training on the amended protocol is provided to all relevant staff.
- Document training in the **Site Training Log**.

6. Record Keeping

- Maintain:
  - Amendment submission documents
  - Approval letters
  - Updated protocol version
  - Training records

7. References

- ICH-GCP E6(R2)
- Sponsor Guidelines
- Ethics Committee Requirements

Prepared by:
Name: Dr Eiman Siddig Ahmed
Title: Research Assistant
Signature: *Eiman*
Date: 20/07/2025

Reviewed by:
Name: Dr Samira Mohammed Hussein
Title: Research Assistant
Signature: *Samira*
Date: 21/07/2025

Approved by:
Name: Prof Ahmed Hassan Fahal
The Mycetoma Research Center, Director
Signature: *Fahal*
Date: 24/07/2025

SOP 16: Monitoring Visits & Audits

1. Purpose

To define the procedures for preparation, conduct, documentation, and follow-up of monitoring visits and audits to ensure clinical trial compliance, participant safety, data integrity, and site readiness.

2. Scope

This SOP applies to all types of monitoring visits (pre-study, site initiation, interim, and close-out) and audits (sponsor, CRO, EC, and regulatory) conducted at the Mycetoma Research Center, for any clinical study.

3. Responsibilities

Role	Responsibility
Principal Investigator (PI)	Oversees site readiness, cooperates with monitors/auditors, and implements corrective actions.
Clinical Research Coordinator (CRC)	Coordinates logistics, ensures the availability of documents, and accompanies the monitor/auditor.
Study Staff	Provides access to data, responds to queries, and participates in discussions when required.

4. Types of Visits & Audits

Type	Description
Pre-study Visit (PSV)	To assess site feasibility before trial initiation.
Site Initiation Visit (SIV)	To train the site on the protocol and study procedures.
Interim Monitoring Visit (IMV)	To review ongoing study progress, data quality, and compliance.
Close-out Visit (COV)	To ensure proper closure, document completion, and archival.
Audit	Systematic review by sponsor, regulatory authority, or third-party.

5. Procedure

5.1 Visit Planning

- The site is informed in advance via email or letter, which includes the date, purpose, and agenda.
- PI/CRC ensures the availability of:
    - Site staff
    - Participant files
    - Source documents
    - CRFs
    - Logs (screening, consent, IP, deviation, AE, etc.)
    - Regulatory binder
    - Pharmacy & laboratory records (if applicable)

5.2 During the Visit/Audit

- Host a site tour if required (for PSV or SIV).
- Provide access to all requested documents and facilities.
- Address queries raised by the monitor/auditor.
- Document visit details in the **Monitoring Visit Log**.

5.3 After the Visit

- Receive and review the **Monitoring Visit Report** or **Audit Report**.
- Discuss findings and necessary **Corrective and Preventive Actions (CAPA)** with the study team.
- Submit CAPA response to sponsor or auditor (if required).

6. Documentation

- Maintain records of:
    - Visit notification emails
    - Monitoring/Audit reports
    - Completed Monitoring Visit Log
    - CAPA plans and implementation proof
    - Sign-in logs of monitors/auditors

7. Quality Assurance

- Regularly review monitoring findings for recurring issues.
- Train staff if gaps are identified during audits or visits.
- Ensure timely resolution of queries and findings.

8. Confidentiality

- All monitors/auditors must sign a **Confidentiality Agreement** before accessing patient-related or proprietary information.

9. References

- ICH-GCP E6(R2)
- Sponsor Monitoring Plans
- Regulatory Guidelines

Prepared by:
Name: Dr Eiman Siddig Ahmed
Title: Research Assistant
Signature: *Eiman*
Date: 20/07/2025

Reviewed by:
Name: Dr Samira Mohammed Hussein
Title: Research Assistant
Signature: *Samira*
Date: 21/07/2025

Approved by:
Name: Prof Ahmed Hassan Fahal
The Mycetoma Research Center, Director
Signature: *Fahal*
Date: 24/07/2025

SOP 17: Confidentiality & Data Privacy

1. Purpose

To outline the procedures to protect the confidentiality of study participants and ensure secure handling, storage, and sharing of sensitive research data at the Mycetoma Research Center site in accordance with Good Clinical Practice (GCP), sponsor policies, and applicable regulations.

2. Scope

This SOP applies to all personnel involved in clinical studies at the Mycetoma Research Center, including Principal Investigators, sub-investigators, CRCs, data entry staff, pharmacists, and any other delegated staff accessing participant data.

3. Responsibilities

Role	Responsibility
Principal Investigator (PI)	Ensures compliance with confidentiality and data privacy practices.
CRC/Study Coordinator	Implements and monitors routine practices for privacy and access control.
All Study Staff	Maintains confidentiality and protects data according to this SOP and signed agreements.

4. Procedure

4.1 Confidentiality Agreements

- All study team members must sign a **Confidentiality Agreement** prior to trial initiation.
- Agreements should be filed in the site staff file and retained for audit/inspection purposes.

4.2 Participant Identity Protection

- Assign unique study IDs to each participant.
- Do not include names or identifiers in Case Report Forms (CRFs) or shared documents.
- Store consent forms and source documents securely with access limited to authorised staff.

4.3 Data Collection and Access

- Only trained, delegated study staff may collect, enter, or access study data.
- Data should be entered using password-protected systems or forms.
- Limit access to physical or electronic files to authorised individuals only.

4.4 Data Storage

- Store paper documents (source forms, CRFs) in locked cabinets.
- Store electronic data on secure, password-protected devices or servers.
- Daily backup procedures should be followed as per sponsor/data management guidelines.

4.5 Data Sharing and Transmission

- Do not email or transfer personal health information (PHI) without encryption.
- Only share data with sponsor/CRO personnel who are listed in study correspondence and agreements.
- Maintain logs of data shared externally (if applicable).

4.6 During Monitoring or Audit Visits

- Provide only de-identified documents unless required and authorised.
- Ensure that monitors/auditors sign a **Visitor Confidentiality Form**.

4.7 Breach of Confidentiality

- Any suspected breach must be reported immediately to the PI and documented.
- The PI must notify the sponsor and Ethics Committee as per their SOPs.
- Corrective and Preventive Actions (CAPA) must be taken and documented.

5. Training

- All staff must receive training on this SOP at the time of joining and during periodic site training updates.
- Maintain training logs and attendance records.

6. Documentation

- Signed Confidentiality Agreements
- Staff training records
- Data access logs (if applicable)
- CAPA records for any breaches

7. References

- ICH-GCP E6 (R2)
- National and local data protection regulations
- Sponsor's Data Privacy and Confidentiality Policies

Prepared by:
Name: Dr Eiman Siddig Ahmed
Title: Research Assistant
Signature: *Eiman*
Date: 20/07/2025

Reviewed by:
Name: Dr Samira Mohammed Hussein
Title: Research Assistant
Signature: *Samira*
Date: 21/07/2025

Approved by:
Name: Prof Ahmed Hassan Fahal
The Mycetoma Research Center, Director
Signature: *Fahal*
Date: 24/07/2025

SOP 18: Complaints & Feedback Handling

1. Purpose

To define the standard procedure for receiving, documenting, investigating, and resolving complaints and feedback from study participants, staff, visitors, or other stakeholders to ensure continuous improvement and compliance with ethical standards.

2. Scope

This SOP applies to all clinical studies conducted at the Mycetoma Research Center and covers all verbal or written complaints or feedback related to study procedures, staff behaviour, facilities, or participant experience.

3. Responsibilities

Role	Responsibility
Principal Investigator (PI)	Overall oversight of complaints/feedback handling, resolution, and reporting.
Clinical Research Coordinator (CRC)	First point of contact for receiving and documenting complaints/feedback.
Site Staff	Report any complaints received and assist in resolution as needed.
Site Administration (if applicable)	Support in the resolution of administrative issues and ensure appropriate follow-up.

4. Procedure

4.1 Receiving Complaints or Feedback

- May be received through:
    - Direct verbal communication from participants
    - Written forms
    - Suggestion/feedback box (if available)
    - Observations by site staff
- All complaints must be taken seriously and acknowledged respectfully.

4.2 Documentation

- Complaints/feedback should be recorded in the **Complaint & Feedback Log**.
- Each entry must include:
    - Date and time received
    - Complainant (if willing to disclose)
    - Nature of complaint or feedback
    - Person receiving it
    - Immediate action taken (if any)

4.3 Initial Review and Acknowledgement

- CRC or delegated staff will notify the PI within 24 hours.
- Acknowledge receipt of the complaint and assure them of timely resolution.
- For anonymous complaints, document receipt and proceed with internal review.

4.4 Investigation and Resolution

- The PI or delegated team member investigates the issue in a confidential and unbiased manner.
- Interview relevant parties and review related documents if needed.
- Categorise the complaint as:
    - **Minor**: Easily correctable with minimal impact.
    - **Major**: Affects study conduct, participant safety, or site integrity.
- Take corrective and preventive action (CAPA) as appropriate.

4.5 Reporting and Communication

- If the complaint is related to protocol, consent, safety, or a regulatory matter:
    - Notify Sponsor and/or Ethics Committee per requirement.
    - Report major issues within 7 days of resolution.
- Maintain all correspondence and actions taken in the site file.

4.6 Feedback Closure

- Once resolved, document the resolution in the log.
- Inform the complainant of the outcome (if known).
- Unresolved complaints must be escalated to the site head or sponsor representative.

5. Training

- All staff should be trained on handling complaints with empathy, professionalism, and confidentiality.
- Periodic refreshers during team meetings or site trainings.

6. Documentation

- Complaint & Feedback Log
- Correspondence or forms received
- Investigation notes and CAPA reports
- Ethics Committee and Sponsor notifications (if applicable)

7. Confidentiality

- Ensure all information is treated confidentially.
- Do not disclose identities or complaint details unnecessarily.
- Store related records securely with access restricted to authorised personnel.

8. References

- ICH-GCP Guidelines
- Local regulatory and ethics requirements
- Sponsor-specific guidelines on complaint handling (if provided)

Prepared by:
Name: Dr Eiman Siddig Ahmed
Title: Research Assistant
Signature: *Eiman*
Date: 20/07/2025

Reviewed by:
Name: Dr Samira Mohammed Hussein
Title: Research Assistant

Signature: *Samira*
Date: 21/07/2025

Approved by:
Name: Prof Ahmed Hassan Fahal
The Mycetoma Research Center, Director

Signature: *Fahal*
Date: 24/07/2025

SOP 19: External Laboratory Services

1. Purpose

To define the procedures for selecting, qualifying, using, and maintaining oversight of external laboratories contracted to perform clinical trial-related laboratory assessments that cannot be conducted at the Mycetoma Research Center.

2. Scope

This SOP applies to all clinical studies at the Mycetoma Research Center that require laboratory assessments to be performed by external laboratories (including central labs, referral diagnostic centers, or third-party testing labs).

3. Responsibilities

Role	Responsibility
Principal Investigator (PI)	Oversight of lab selection, contracts, and result review.
Study Coordinator / CRC	Coordinating logistics (sample dispatch, forms, report tracking).
Sponsor / CRO (if applicable)	May provide pre-qualified labs or set specific requirements.
External Lab Representative	Responsible for timely, accurate testing and reporting.

4. Procedure

4.1 Selection & Qualification of External Laboratory

- Choose labs with appropriate accreditation (e.g., ISO 15189, NABL, or equivalent).
- Ensure the lab follows Good Laboratory Practices (GLP).
- Confirm ability to handle study-specific tests with defined TAT (Turnaround Time).
- A contract or agreement must be in place, defining:
    - Scope of services
    - Sample handling and reporting
    - Responsibilities
    - Confidentiality
    - Quality standards
- Document lab qualification (e.g., site visit report, audit checklist, or sponsor qualification letter).

4.2 Sample Handling & Dispatch

- Prepare samples according to the protocol/lab manual (labelling, timing, and temperature).
- Use designated containers, packaging, and transport methods.
- Maintain a **Sample Dispatch Log** with:
    - Subject ID
    - Date/time of collection
    - Sample type and quantity
    - Date/time of dispatch

    - Courier/lab person details
- If required, use cold chain monitoring (2–8°C or as per requirement).
- Maintain chain-of-custody documents if applicable.

4.3 Lab Result Receipt & Review

- CRC or PI to collect electronic or hard copy lab reports.
- PI (or designee) to review results for:
    - Accuracy
    - Abnormalities
    - Clinical significance
- Document review with initials and date on each report.
- Results must be filed in participant's source file and noted in the Case Report Form (CRF).

4.4 Data Management & Reporting

- Transfer of data from an external lab to the site or sponsor should follow secure and approved methods.
- Ensure that lab results are accurately captured in CRFs or electronic data systems.
- Investigators must address any out-of-range or clinically significant values.

4.5 Quality Assurance

- Maintain copies of:
    - Lab accreditations/licenses
    - Temperature logs (if applicable)
    - Lab manuals and updates
    - Communication with the lab
- Report any delays, quality concerns, or errors in reports to the PI and sponsor (if applicable).
- Conduct periodic review or audit of lab services (directly or via sponsor/CRO).

4.6 Storage & Archival

- Lab reports and related documents should be filed with the source data and archived according to the study's SOP and regulatory guidelines.
- Ensure long-term access in the event of an inspection or audit.

5. Training

- All site staff handling lab coordination should be trained on:
    - Sample labeling
    - Handling/shipping procedures
    - Lab manual use
    - External lab communication

6. Documentation

- External Lab Agreement/MoU
- Lab Accreditation Certificates

- Sample Dispatch & Receipt Log
- Lab Result Reports
- Communication Records
- Temperature Monitoring Logs (if applicable)

7. References

- Study Protocol and Lab Manual
- GCP Guidelines
- Local Regulatory Requirements
- Sponsor/CRO SOPs (if applicable)

Prepared by:
Name: Dr Eiman Siddig Ahmed
Title: Research Assistant
Signature: *Eiman*
Date: 20/07/2025

Reviewed by:
Name: Dr Samira Mohammed Hussein
Title: Research Assistant

Signature: *Samira*
Date: 21/07/2025

Approved by:
Name: Prof Ahmed Hassan Fahal
The Mycetoma Research Center, Director

Signature: *Fahal*
Date: 24/07/2025

SOP 20: Use of Electronic Systems

1. Purpose
To outline procedures for the use, access, security, and management of electronic systems used in clinical research at the Mycetoma Research Center, including Electronic Data Capture (EDC), trial master files, and other digital platforms.

2. Scope
Applies to all staff involved in the use of sponsor-provided or site-maintained electronic systems related to study conduct, data entry, documentation, and communication.

3. Responsibilities

Role	Responsibility
PI / Co-PI	Ensure compliance and oversight of electronic system use.
CRC / Study Staff	Use systems as per training and assigned roles.
Sponsor / CRO	Provide access, training, and support.

4. Procedure
4.1 System Access
- Access will be granted only after GCP/system training.
- Each user must have a unique username and password.
- Do not share login credentials.
- Maintain a **User Access Log**.

4.2 Data Entry & Review
- All source-verified data must be entered accurately in EDC systems.
- The PI or delegate should review and electronically sign CRF entries.
- All entries must be audit-trailed (date, user, reason for change if applicable).

4.3 System Security
- Ensure proper password protection and secure storage of login credentials.
- Lock the screen when away from workstations.
- Use only authorised devices for system access.

4.4 Backup & Maintenance
- Systems should have automatic backups.
- The site must retain a printout/PDF of key e-records as a backup, if required.
- Follow sponsor/CRO instructions for data exports or downloads.

4.5 Technical Issues

- Report system access issues or data errors immediately to the sponsor's helpdesk or IT contact.
- Document all issues and resolutions.

5. Documentation

- User Access Log
- Training Records
- Signed CRFs or e-sign logs
- Audit Trails (maintained by the system)
- Email communication with IT/sponsor

6. References

- GCP Guidelines
- Sponsor/CRO System Manuals
- ICH E6(R2)

Prepared by:
Name: Dr Eiman Siddig Ahmed
Title: Research Assistant
Signature: *Eiman*
Date: 20/07/2025

Reviewed by:
Name: Dr Samira Mohammed Hussein
Title: Research Assistant
Signature: *Samira*
Date: 21/07/2025

Approved by:
Name: Prof Ahmed Hassan Fahal
The Mycetoma Research Center, Director
Signature: *Fahal*
Date: 24/07/2025

SOP 21: Quality Risk Management & Corrective and Preventive Actions (CAPA)

1. Purpose

To define the process for identifying, documenting, investigating, and addressing quality issues, protocol non-compliance, deviations, and implementing CAPA at the Mycetoma Research Center.

2. Scope

Applicable to all deviations, deficiencies, audit findings, and potential quality risks identified during clinical research conduct.

3. Responsibilities

Role	Responsibility
PI / Co-PI	Review deviations, lead investigations, and approve CAPA.
CRC / Site Team	Report issues, support investigation, and implement CAPA.
Sponsor / Monitor	May suggest CAPA based on monitoring/audit.

4. Procedure

4.1 Identification of Quality Issues

- Issues may arise from monitoring, audit, internal review, or staff observations.
- Examples include protocol deviations, data entry errors, missed visits, and improper documentation.

4.2 Documentation

- Complete a **Deviation/Issue Form**.
- Include: description, date, impact, and immediate action taken.

4.3 Root Cause Analysis (RCA)

- Conduct RCA to understand why the issue occurred.
- Tools: 5-Why technique, Fishbone diagram (if complex).

4.4 Corrective and Preventive Action (CAPA)

- **Corrective Action**: What was done to fix the issue.
- **Preventive Action**: Steps to avoid recurrence.
- Assign a responsible person and a deadline for each action.

4.5 Follow-up and Closure

- PI or Quality Lead to verify actions were completed.
- Mark CAPA as closed once verified.
- Maintain **CAPA Log**.

5. Documentation

- Deviation/Issue Forms
- Root Cause Analysis reports
- CAPA Plan and Completion Records
- CAPA Log
- Communication with monitors/sponsors

6. Training

- All team members must be trained to identify deviations and follow the CAPA process.

7. References

- ICH GCP E6(R2)
- WHO Guidelines
- Sponsor-Specific QA Procedures

Prepared by:
Name: Dr Eiman Siddig Ahmed
Title: Research Assistant
Signature: *Eiman*
Date: 20/07/2025

Reviewed by:
Name: Dr Samira Mohammed Hussein
Title: Research Assistant

Signature: *Samira*
Date: 21/07/2025

Approved by:
Name: Prof Ahmed Hassan Fahal
The Mycetoma Research Center, Director

Signature: *Fahal*
Date: 24/07/2025