Faculty of Health Sciences Research Ethics Committee

Standard Operating Procedure:
Active monitoring of ethically approved studies

1. Purpose of this document

The purpose of the SOP is to describe the procedures for active monitoring of ethically approved studies. This SOP was accepted by resolution of the Faculty of Health Sciences Research Ethics Committee on 27 September 2023 and replaces all previous SOPs in this regard. It should be reviewed within 3 years after this date of approval.

_____Date: 27 September 2023

Signed by the Chairperson

2. Scope of this SOP

The SOP is intended to inform and guide members of the Research Ethics Committee (REC) and the REC in its deliberations. It gives effect to the Ethics Guidelines of the Department of Health (2015), especially Section 4.5.1.10. This SOP should be interpreted within the Terms of Reference of the REC.

3. Definitions

3.1 **Active monitoring:** Active monitoring by the REC of ethically approved research includes research site visits and auditing of research documents, conducted by a delegation of the REC, any regulatory body (e.g. the HPCSA, FDA, SAHPRA) and reviewing the routine monitoring reports compiled by the Clinical Research Associates / Site managers.

3.2 **Passive monitoring**: Passive monitoring by the REC includes regular reports by the principal investigator, and information that becomes known to the REC through the submission of amendments, other documents, and any other source of information on a study.

4. Requirements from researchers

4.1 A Principal Investigator must submit to the REC a copy of all visitation and audit reports by a regulatory body (e.g. the HPCSA, FDA, SAHPRA) and the routine monitoring reports compiled by the Clinical Research Associates / Site managers in case of clinical trials. The Principal Investigator is responsible to obtain these reports as soon as possible after the audit or visitation, and submit these within 10 days after receiving it.

4.2 A Principal Investigator must receive a delegation of the REC upon a site visitation when the REC requests thus.

4.3 A Principal Investigator must make available all research documents to a delegation of the REC when the REC requests thus. The REC's delegation may choose to access these documents at the research site or require that selected documents be delivered to the REC offices.

5. Responsibilities of the REC

The REC has the responsibility to do active monitoring including the review all submitted reports as prescribed above. Submitted reports will be acknowledged by the REC and it will correspond with the Principal Investigator for the purposes of the clarification and implementing corrective measures when this is required.

6. Procedures

6.1 Principal Investigators will submit audit and visitation reports to the REC on PeopleSoft platform as "other submissions" within 10 days of their receiving a report.

6.2 Audit and visitation reports will be reviewed by members of the REC. Substantive ethical issues, especially those issues posing a substantive risk to research participants, will be identified and considered by the REC.

6.3 The REC may commission a delegation to do a research site visit and/or audit.

6.4 The REC will identify research studies and research sites for visitation by a delegation or review of research documents at its sole discretion.

6.5 The REC will determine the scope of an audit and/or visitation that its delegation should perform at its sole discretion.

6.6 The REC will provide written feedback to the principal investigator upon receiving reports and/or visitation after deliberating on the report and/or findings of its delegation according to a resolution whereby to:

6.6.1 accept the reports and/or findings of a visitation as acceptable with no cause for further action.

6.6.2 request the PI to provide additional information, or take some other form of corrective action, which may involve the suspension of approval of the research study until proof of corrective action has been provided;

6.6.3 withdraw study approval; and/or

6.6.4 refer the matter to line management, the Dean, the Registrar, and/or Vice-principal for Research for further investigation and action.

7. Site visitations by a delegation of the REC

7.1 Site visitations will adhere to the above specifications of the SOP.

7.2 Procedures for site visitations may draw on the form below at the discretion of the REC as selectively may be relevant to the objectives of the site visitation.

FORM FOR SITE VISITATIONS[1]

STUDY TITLE:…….

PI TITLE, INITIALS, NAME: …….

STUDY SITE:…….

DATE OF SITE VISIT: …….

REC REF. NO: …… REC DATE OF FINAL APPROVAL: ……

NAME(S) OF REC's DELEGATION:……

[1] This is for a research ethics site visit, not a GCP audit.

1. Circumstance of site inspection (tick one or more of following):

To verify the accuracy and reliability of data that has been submitted	YES	NO
As a result of complaints about the conduct of the study		
Upon termination of clinical/study site		
During ongoing clinical trials to provide real-time assessment of the conduct of the trial/study and protection of human subjects		
At the request of an authorized authority		
Routine ('not-for-cause') REC monitoring visit		

2. Person who performed the following aspects of the protocol:
    a. verified application of study inclusion and exclusion criteria…….
    b. obtained informed consent…….
    c. collected adverse event data……..

3. Date first study participant enrolled: ……
4. REC approval of:
    a) protocol:

YES	NO	N/A

    b) current informed consent form:

YES	NO	N/A

    c) amendments to protocol prior to implementation:

YES	NO	N/A

    d) date of most recent recertification …….

5. Were the protocol and investigational plan adhered to?

YES	NO	N/A

6. Were protocol deviations documented and reported?

YES	NO	N/A

7. Were informed consent forms signed by the participant or a legally authorised representative prior to entry to study?

YES	NO	N/A

8. Was the authority to conduct the study delegated to a third party?

YES	NO	N/A

9. Were all aspects of the investigation performed?

YES	NO	N/A

Comments on sections 2-9:.....

10. Types of data collected:

Questionnaires	☐	
Clinical	☐	
Lab Studies	☐	
Case Records	☐	
Other	☐	Describe:.....

11. Where were the data stored?.....

12. Was confidentiality of data maintained?

YES	NO	N/A

a. If yes, how was confidentiality of data maintained?

……

b. If no, provide details:…….

13. Is there a file of protocol deviations and violations?

YES	NO	N/A

If so, have these all be reported to the REC/Sponsor/DSMB?

14. Is there a file of Adverse events and Serious adverse events?

YES	NO	N/A

If so, have these all been reported to the REC/DSMB/Sponsor within required timeframes?

15. Was confidentiality of HBMs (samples) maintained?

YES	NO	N/A

16. If so, how was confidentiality of HBMs (samples) maintained?

……

N/A

17. Who is accountable for the investigational product?

…….

N/A

18. Are shipping records available for investigational drugs?

YES	NO	N/A

19. Are shipping records available for HBMs (samples)?

YES	NO	N/A

20. Are there valid export permits?

YES	NO	N/A

21. Is there a signed MTA in DoH format?

YES	NO	N/A

22. How are unused investigational product(s) disposed of?

    .....

23. Is there evidence of communication between study monitor with PI/Clinical investigator?

YES	NO	N/A

24. Are there any written records from the monitor available on progress of the investigation?

YES	NO	N/A

25. Proof of corrective actions in response to previous inspections?

YES	NO	N/A

26. Proof/copies of any regulatory correspondence with sponsor and/or monitor?

YES	NO	N/A

    ……
    ……

27. If a clinical trial, is it registered with SA Clinical Trials Registry?

YES	NO	N/A

    a. If Yes, provide SACTR number:.....

28. If a clinical trial, is there a copy of current SAHPRA approval?

YES	NO	N/A

29. Current GCP/ethics training certificates for PI?

YES	NO	N/A

30. Current GCP/ethics training certificates for Co-Investigators and senior study staff?

YES	NO	N/A

32. POST-INSPECTION INTERVIEW WITH PI/SITE REPRESENTATIVE:

1. Issues that arose from inspection
2. Suggested remedial measures
3. Other Comments from:
    i. PI:
    ii. REC Delegate(s)
4. Any urgent matters?

The REC delegate(s) may also examine the study data by comparing data filed with REC and/or the sponsor, with records related to the clinical investigation. Such records may include case report forms and supporting source documentation including signed and dated consent forms and medical records (notes of physician, participants' hospital charts and nurses' notes etc).

END OF VISIT

POST-VISIT EVALUATION

33. OVERALL EVALUATION CATEGORY:

1. Excellent
2. Acceptable; no serious or urgent concerns
3. Minor concerns requiring attention
4. Serious concerns about participant safety/protocol adherence

34. TABLED AT REC MEETING Date:……..
1. REC full meeting resolution:
2. Feedback to PI:
3. Date of feedback to PI: