RESEARCH STUDY- SITE MONITORING/AUDITING TEMPLATE (FOR NON CLINICAL RESEARCH STUDIES)

Type of Monitoring (Routine, Impromptu)					
Title(s) of the research study(s) monitored					
REC Ref number					
UNCST Ref. number		Monitoring Date		Time	
Status of the research study(s) (active or closed)		Approval date		Approval expiry date	
Monitors' names, title and contact Information					
Research study duration					
Name of Principal Investigator					
Names of other research study staff and responsibilities if applicable					
Location of the research site (name and full address)					
Reason research site/project was chosen for monitoring					
Objective of the monitoring					

General information about the research study, study design inclusive	
Scope of the site visit (state the exact documentation reviewed and site facilities monitored. General observations	

A. Regulatory issues

i. Are approvals from UNCST available Yes ☐ No ☐ N/A ☐ ii. REC Approval Yes ☐ No ☐ N/A ☐ iii. Master file available Yes ☐ No ☐ N/A ☐

iv. Availability of progress report ☐ Yes ☐ No ☐ N/A

v. Was a request for renewal submitted to regulators? ☐ Yes ☐ No ☐ N/A

vi. Other observed regulatory issues……..

B. Research participants

i. Date of commencement of recruitment…….. ii. Targeted number of research participants to be recruited…….. iii. Number of research participants recruited so far……. iv. Any withdrawals? Yes ☐ No ☐ If yes, state the number and reasons for withdrawals (if any)……..

v. Challenges with recruitment (please specify)……..

C. Serious Adverse Events (SAEs) and other AEs, if any (applies mainly to clinical trials)

i. Are SAEs documented and/or reviewed by principal investigator ☐ Yes ☐ ☐ No ☐ N/A

ii. Are SAEs reported to the regulatory authorities in a timely manner ☐ Yes ☐ ☐ No ☐ N/A

iii. Are SAEs reported to regulatory authorities ☐ Yes ☐ No ☐ N/A vi. Are SAEs reported in timely manner ☐ Yes ☐ No ☐ N/A If no. average duration of reporting SAEs……

vii. Summary of the nature of SAEs, if any……

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D. Research Study documents

i. Availability of working protocol Yes No N/A ii. Where amendments approved by the REC? Yes No N/A

iii. Where amendments approved by regulatory authorities Yes No. N/A iv. Availability Standard Operating Procedures (SOPs) Yes No N/A

v. Availability of research participant information and informed consent forms Yes No N/A

vi. Availability of Investigator's brochure (for clinical trials) Yes No N/A

vii. Archiving of research study documents (Is documentation adequate?) Yes No N/A

E. Informed consent process

i. Was the consent form approved and stamped by the REC? Yes No N/A

ii. In the opinion of the monitors, did participants receive adequate information about the research study? Yes No N/A

iii. Were consent forms signed by the participants and witnesses (for illiterate participates)? Yes No N/A

F. Working practices

i. Are meetings held with research study staff Yes No N/A

ii. Please specify how regularly meetings are held with research study staff ……

iii. Are minutes of meetings available? Also, are they signed? Yes No N/A

G. Training

i. Evidence of Good Clinical Practice (GCP) training for research study staff Yes No N/A

ii. Evidence of Good Clinical Laboratory Practice (GCLP) training for laboratory staff Yes No N/A

iii. Evidence of Human Participant Protection training for staff Yes No N/A

H. Welfare of research participants

i. Were participants reimbursed for their time and transport as stated in the protocol and consent forms? Yes No N/A If yes, how much? ii. Any other measures taken to ensure that participants' welfare is protected?.....

I. Implication of the research study to research participant's safety, rights and welfare.

J. Implication of the research study to policy.

K. Monitors' recommendations

Declaration We certify that the information provide here is true and accurate. Name and Signature of the Monitors