Guideline for Principal Investigators and Research Staff Related to Auditing and Monitoring conducted by a Sponsor/CRO at Shared Health

Purpose

This section provides guidance on the responsibilities of the PI when they are notified that an auditing and/or monitoring visit is to occur on Shared Health premises, and what information can/should be shared with the authorized auditors and monitors of the Sponsor for the research study.

Scope

This guideline applies to all investigators and research staff who will have auditors and monitors conducting on-site auditing and monitoring at facilities and/or service areas which fall under the purview of Shared Health for their study.

Responsibilities

The Principal Investigator (PI) is responsible for contacting Shared Health Research and Innovation (SHRI) promptly once the Sponsor/Contract Research Organization (CRO) identifies the need for an auditing/monitoring visit; this includes site selection, study initiation visit, routine monitoring and audits, and close-out. The PI will ensure that SHRI is provided, at minimum, two weeks written notice before the auditing and/or monitoring is to occur at Shared Health. SHRI will do its best to accommodate a scheduled auditing/monitoring visit, but cannot guarantee that Shared Health can accommodate the proposed dates. All auditing and/or monitoring visits (excluding site selection visits) will only be conducted at Shared Health once the PI has received an Activation Letter from SHRI for the project.

SHRI is responsible for corresponding with the different functional units at Shared Health (such as pharmacy, diagnostic services, labs) in order to organize and schedule in-person auditing/monitoring visits; this is not the role of the PI or the research team. It is mandatory that a member of SHRI is present

during auditing/monitoring visits on Shared Health premises, unless the PI is notified otherwise in writing by SHRI.

It is the PI's responsibility to ensure that all Essential Documents (as described below) are organized and readily available for the Sponsor and/or the CRO to review. If the PI identifies Essential Documents which will need to be provided or made available by Shared Health, they are required to make a written request to SHRI, 2 weeks prior to the audit/monitoring. The PI should ensure that no other documents, confidential information of Shared Health or patients are provided to the Sponsor and/or the CRO. If the PI and/or the research team are unsure whether the document(s) can/should be provided or should be made available to Sponsor and/or CRO, they should contact SHRI for clarification.

The PI is responsible for ensuring that auditors and/or monitors comply with all applicable Shared Health guidelines while on Shared Health premises, as described in a separate document entitled, "*Guideline for Auditors and Monitors while Conducting Visits at Shared Health*". Any or all parts of the responsibilities of the PI outlined in this guideline may be delegated in writing to appropriately trained study team members, but remain the ultimate responsibility of the PI.

Essential Documents

Below is a list of the Essential Documents which should be readily accessible when an auditor and/or monitor attends the site. This list is as described in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH): Good Clinical Practice E6(R2).

Document	Additional Information
Investigational Brochure	
Signed Protocol and any Amendments	
Sample Case Report Form (CRF)	
Information Provided to Subjects (Informed Consent Form, Recruitment Material)	
Financial Aspects of the Trial	Including Financial Disclosures
Insurance Statement Related to Study Subject Injury (where required)	
Signed Agreement/Contract between Institution and Sponsor/CRO	

Document	Additional Information
Dated, Documented Approval of Research Ethics Boards/Institutional Approval	For all documents including: protocol and amendments, case report forms, informed consent, recruitment material, any other documents
Research Ethics Boards Composition	
Regulatory Authority(ies) Authorization	
Curriculum Vitae and/or other Relevant Documents Evidencing Qualifications of Investigator(s) and Sub-Investigator(s)	
Normal Value(s) Range(s) for Medical/Laboratory/Technical Procedure(s) and/or Test(s) included in the Protocol	
Medical/Laboratory/Technical Procedures/Test	Certification, accreditation, established quality control or other validation
Instructions for Handling of Investigational Product(s) and Trial-Related Materials	
Shipping Records for Investigational Product(s) and Trial-Related Materials	Document shipment dates, batch numbers and method of shipping.
Decoding Procedures for Blinded Trials	With respect to the Investigational Product and Placebo
Important/Relevant Communications	Examples: Protocol violations, adverse event reporting
Signed Informed Consent Forms	
Source Documents	These should be available for Sponsor's review and/or access in accordance with SHRI's *Guideline for Shared Health Record Access for Auditors and Monitors* Ensure all source documentation contains the required information OR if missing information ensure there is documentation why unobtainable
Signed, Dated, and Completed CRFs	
Documentation of CRF Corrections	
Notification by Originating Investigator to Sponsor of Serious Adverse Events and Related Reports	

Document	Additional Information
Notification by Sponsor and/or Investigator, where applicable, to Regulatory Authority(ies) and REBs of Unexpected Serious Adverse Drug Reactions and of Other Safety Information	
Notification by Sponsor to Investigators of Safety Information	
Interim or Annual Reports to REB and Authority(ies)	
Subject Screening Log	
Subject Identification Code List	
Subject Enrolment Log	
Investigational Products Accountability at the Site	
Signature Sheet and Delegation of Responsibility Log	To document signatures and initials of all authorized individuals to make entries and/or corrections on CRFs
Record of Retained Body Fluids/Tissue Samples (if any)	To document the location and identification of retained samples
Investigational Product Destruction Documents	If Investigational Product is destroyed at Site
Final Report by Investigator to REB and to Regulatory Authority(ies)	
All Monitoring and Auditing Reports	

For all correspondence related to auditing and monitoring visits being conducted on Shared Health premises, please email SHResearch@sharedhealthmb.ca.

Guideline for Auditors and Monitors while Conducting Visits at Shared Health

Purpose

This section provides guidance on the applicable Shared Health policies and guidelines auditors and monitors should follow while conducting auditing and/or monitoring at facilities and/or service areas which fall under the purview of Shared Health.

Scope

This guideline applies to all auditors and monitors who are conducting on-site auditing and monitoring at facilities and/or service areas which fall under the purview of Shared Health.

Responsibilities

The Principal Investigator (PI) is responsible for ensuring that all applicable Shared Health policies and guidelines are adhered to by any auditors and/or monitors who will be presenting to a Shared Health facility and/or service area. If copies of Shared Health policies and guidelines are requested by the auditor or monitor, it is the PI's responsibility to provide all applicable documents. If the PI is unsure which policies and guidelines are applicable, it is the PI's responsibility to contact Shared Health Research and Innovation to confirm which policies and/or guidelines should be provided to the auditors and/or monitors. Any or all parts of the responsibilities of the PI outlined in this guideline may be delegated to appropriately trained study team members, but remain the ultimate responsibility of the PI.

If the service area is outside of a Shared Health facility, it is the responsibility of the PI to ensure that all relevant non-Shared Health policies and guidelines are adhered to in addition to the Shared Health policies and guidelines.

All inquiries can be sent to: SHResearch@sharedhealthmb.ca.

May 2023

Examples of Applicable Policies and Guidelines

Policy	Policy Number
Audio, Video, and Photographic Recordings	310.150.100
Confidentiality of Personal Health Information	310.140.115
Disclosure of Personal Health Information for Health Research	340.100.105
Dress Code	320.100.139
Smoke and Vapour Free	320.100.101
Fire Safety	370.190.100
Workplace Safety and Health	370.100.104
Public Use of Cell Phones and Other Wireless Communication Devices – Interreference with Medical Equipment	340.150.102
Computer/Internet Usage	340.190.100
Guideline for Accessing Shared Health Medical Records for Auditing and Monitoring	April 2023

*Note: The list incorporated in this guideline is not exhaustive, but provides some examples of Shared Health's pertinent policies and guidelines.

Guideline for Accessing Shared Health Medical Records for Auditing and Monitoring

Purpose

This guideline describes the procedures to be followed when auditors and monitors will be accessing Shared Health records, including accessing records by remote monitoring/auditing.

This guideline ensures a process that complies with Shared Health's obligations as a trustee under *The Personal Health Information Act*, C.C.S.M.c. P33.5 (PHIA).

Scope

This guideline applies to all record access at Shared Health for the purpose of auditing and monitoring, including but not limited to remote monitoring, routine monitoring, site audits, and site close-out visits.

Responsibilities

The Principal Investigator (PI) is responsible for notifying Shared Health Research and Innovation (SHRI) in writing of all auditing and monitoring activities at Shared Health, including remote monitoring prior to auditors and monitors accessing Shared Health records in accordance with the SHRI Guideline "*Guideline for Principal Investigators and Research Staff Related to Auditing and Monitoring*".

The PI is responsible for ensuring that: (1) source documentation does not leave Shared Health; (2) confidentiality is maintained throughout the monitoring and/or auditing visit; (3) the auditor/monitor has access to the minimum amount of information as is necessary to audit/monitor; (4) all monitoring activities proceed as approved by any relevant body (Research Ethics Board, etc); and (5) ensuring the auditor and/or monitor is always supervised while having access to electronic records. The PI must ensure a copy of all required documentation are provided to SHRI, including without limitation, the PHIA pledge form. Any or all parts of the responsibilities of the PI outlined in this guideline may be delegated to appropriately trained study team members, but remain the ultimate responsibility of the PI.

The auditor and/or monitors must agree to comply with this guideline. The auditors and monitors are responsible for: (1) ensuring they do not take screen shots, photographs, or images of any kind of data to ensure that participant confidentiality is maintained; (2) ensuring they are not unsupervised while remote monitoring; and (3) completing the online PHIA LMS module and signing the PHIA pledge form prior to accessing/reviewing charts.

Revised June 2023

Procedure

PHIA Training for Auditors/Monitors

Auditors and monitors need to complete the online PHIA LMS module and sign the PHIA pledge form prior to accessing/reviewing Shared Health records. PHIA pledges are valid for three years.

To complete the online PHIA training using the casual employee account (no tracking or certificate, requires manual pledge):

1. Go to the LMS log in page at https://sharedhealthmb.learnflex.net
   Note: Pop-up blockers must be turned off
2. Log in with the credentials listed below:
   Username: casual.employee
   Password: password123
3. Click the Launch button next to PHIA for Health Care – Manual Pledge
4. Complete the course
   Note: This course must be completed in one sitting as it restarts when re-launched.

Access to Paper Medical Records for Auditors/Monitors

The Shared Health Record Photocopy Request form must be completed by the PI prior to copying any patient records.

The PI is responsible for photocopying only the applicable sections of the participant's medical record which is required for the monitoring visit and such photocopying will be done in the secure area where the medical records are located within Shared Health. Source documentation with personal identifiers are not allowed to leave Shared Health. All photocopies that the auditor/monitor must view should be redacted by using black pen/marker to remove personal identifiers. Each page of source documentation should have the participant ID number. For large volumes of documentation, consider printing a sheet of labels with ID numbers. Each page of source documentation should also be signed and dated by the individual who prepared the document.

The monitor and/or auditor shall be allowed to review the photocopy of the pertinent sections of the participant medical record. The monitor and/or auditor is not allowed to make copies or take the photocopies off-site. Once the auditing and/or monitoring is complete, the PI is responsible for ensuring the photocopies are confidentially destroyed.

Access to Electronic Medical Records for Auditors/Monitor

Access to electronic medical records can occur through two routes:

(1) Access to relevant patient medical information from electronic sources can be printed, redacted and provided to the auditors/monitors for review;
(2) Auditors/monitors can be given supervised access to relevant patient medical information directly from the electronic source.

If the PI and research team print relevant patient medical information from electronic sources for the auditors/monitors, then steps outlined in the section "*Access to Paper Medical Records for Auditors/Monitors*" must be followed by both the PI and the auditors/monitors.

If option two is chosen, then auditors/monitors must be supervised by the PI or other authorized study staff/Shared Health employee at ***all*** times. Auditors/monitors will have limited access to the minimum amount of information as is necessary to conduct their audit/monitoring.

Remote Monitoring Visits

Remote monitoring visits can use institutional Teams accounts.

During the remote monitoring visit, the study staff can open redacted source documentation and share their screen with the monitor; monitors/auditors cannot take screen shots during the remote monitoring visit. The study staff cannot give the auditors/monitors control while viewing the redacted source documentation. Remote access to hospital charting systems for monitoring is not permitted. The PI will ensure that all electronic research data files used for auditing and monitoring purposes will be held within the secure environment of Digital Health and/or UofM MedIT.

After the remote monitoring visit, all source documentation for purposes of a remote monitoring visit should be deleted within 1 business day of the end of the remote monitoring visit.