Human Research Protection Program

GUIDANCE: Third Party Access to Data for Non-Sharp Staff						
NUMBER	DATE	AUTHOR	APPROVED BY	AUDIENCE	USE	PAGE
HRP-092	9/15/2015	Center For Research	Institutional Official	Director of Research, Center for Research Staff, Non-SHC Investigators, Monitors, Auditors or Federal Regulatory Auditors	Required: **X** Elective:	Page **1** of **2**

1 PURPOSE

1.1 This guidance establishes the process for Sharp HealthCare (SHC) research-related third party access to data.

1.2 The guidance begins when there is a request for access to protected health information related to research activities.

1.3 The guidance ends when the access is no longer required.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY STATEMENT

3.1 All requests for research-related third party access to data to be approved by the Director of Research or internal SHC research managers.

3.2 Under federal regulations 21 CFR 312.53(D), external research personnel, such as sponsor clinical trial monitors, sponsor auditors, and federal regulatory agencies (e.g., Food and Drug Administration [FDA]) have a right and obligation to review source documents for the purposes of collection of patient information for auditing or monitoring of research activities

3.3 Non-SHC employee or medical staff investigators will be given access to data limited to that associated with participants in protocols approved by the SHC Institutional Review Board (IRB). Only researchers whose names appear on form FDA 1572, and/or the *FORM: Initial IRB Review Application (HRP-211)*, *FORM: Modification Request (HRP-213)* or FORM: Update Site Personnel (HRP-224) will be provided access.

3.4 Clinical trial sponsor and Contract Research Organization (CRO) monitors and auditors will be given access to data limited to that associated with participants in the clinical trials they sponsor or manage.

3.5 Federal regulatory agencies (e.g. FDA and Office of Human Research Protections [OHRP]) will be given access to data limited to that associated with participants associated with the research they are inspecting or auditing.

3.6 Access to SHC computer systems will be granted as 'read only' and is for 'onsite use only.'

3.7 Non-SHC researchers requiring access to the SHC computer systems (i.e., Cerner Millennium) must complete the required training specified on *FORM: Non-SHC Credentialing Compliance and Safety Requirements (HRP-240)*.

4 RESPONSIBILITIES

4.1 The Director of Research or designee carries out these procedures.

4.2 Investigators, sub-investigators, and study coordinators, as applicable, must fulfill the required training and information requirements set forth in this guidance and *GUIDANCE: Badge ID and Credentialing for Non-Sharp Staff (HRP-093)*.

4.3 The Center for Research maintains all files associated with non-SHC employees, medical staff investigators, clinical trial monitors, auditors, or federal regulatory auditors third party access to data.

5 PROCEDURE

5.1 Sponsor clinical trial monitors, auditors, and federal regulatory auditors:

5.1.1 Upon completion of *FORM: Confidentiality and Non-Disclosure Agreement for Non-Sharp Researchers and Sponsor/CRO Monitors and Auditors (HRP-238)*, the Director of Research or research site manager/lead completes a Technical Assistance Center's New Account Request (SharpNET Online Form) for access to SHC computer systems. This request specifies the access required (e.g., Cerner) to be 'read only'

and 'onsite use only' dates access requested (if additional days), and date access granted by Director of Research or research site manager/lead.

5.1.2 Notifies sponsor clinical trial monitor, auditors, or federal regulatory auditor when data access is approved.

5.2 Non-SHC investigators and their staff:

5.2.1 The Director of Research or designee validates the completion of requirements.

5.2.2 Upon fulfillment of the required system training *(GUIDANCE: Badge and Credentialing for Non-Sharp Staff [HRP-093])* and *FORM: Non-SHC Credentialing Compliance and Safety Requirements (HRP-240*), the Director of Research completes a Technical Assistance Center's New Account Request (SharpNET Online Form) for access to the SHC computer systems. This request specifies the access required (e.g., Cerner) to be 'read only' and 'onsite use only' and access expiration date.

5.2.3 Notifies researcher when data access is approved.

5.3 Termination of Non-SHC medical staff or employee researcher access:

5.3.1 IRB specialist or designee:

5.3.1.1 Receives notification of study completion or change in study staff status.

5.3.1.2 Submits request to deactivate the individual's badge access to SHC facilities.

5.3.1.3 Submits request to revoke individual's access to SHC computer systems, if necessary.

5.3.1.4 Records termination on *DATABASE: Site Personnel Information Tracking Sheet (HRP-608)*.

6 MATERIALS

6.1 GUIDANCE: Badge and Credentialing for Non-Sharp Staff (HRP-093)

6.2 FORM: Initial IRB Review Application (HRP-211)

6.3 FORM: Modification Request (HRP-213)

6.4 FORM: Update Site Personnel (HRP-224)

6.5 FORM: Badge ID and Credentialing (HRP-234)

6.6 FORM: Technical Assistance Center's New Account Request (SharpNET Online Form)

6.7 FORM: Confidentiality and Non-Disclosure Agreement for Non-Sharp Researchers and Sponsor/CRO Monitors and Auditors (HRP-238)

6.8 FORM: Non-SHC Credentialing Compliance and Safety Requirements (HRP-240

6.9 DATABASE: Site Personnel Information Tracking Sheet (HRP-608)

7 REFERENCES

7.1 21 CFR 312.56

This document is available on www.sharp.com/research, IRBANA, or by contacting research@sharp.com.