

GUIDANCE: Badge ID and Credentialing for Non-Sharp Staff						
NUMBER	DATE	AUTHOR	APPROVED BY	AUDIENCE	USE	PAGE
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1 PURPOSE

- 1.1 This guidance establishes the process for credentialing and obtaining a temporary identification badge to access Sharp HealthCare (SHC) facilities and health records (Cerner) for research purposes.
- 1.2 The guidance begins when the SHC Institutional Review Board (IRB) grants initial approval, or an approval letter for adding a person to a study has been issued.
- 1.3 The guidance ends when the researcher access is terminated.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.

3 POLICY STATEMENT

- 3.1 Once initial study approval is granted from the IRB or a FORM: Research Team Updates (HRP-224) is completed adding a person to a study and an IRB approval letter has been issued, an investigator or their designee is eligible to receive a temporary identification badge and read-only, onsite-only access to SHC health records.
- 3.2 Badge and health record access authorization must be renewed annually.
- 3.3 Compliance and safety training and related agreements and forms must be completed annually by research site personnel (as applicable).
- 3.4 Eligibility to request access for health records is dependent on completion of all required training.

4 RESPONSIBILITIES

- 4.1 Director of Research, IRB specialists, or designee carry out these procedures.
- 4.2 Non-SHC medical staff or employee researchers and staff must fulfill the required training and information requirements set forth in *FORM: Non-SHC Credentialing, Compliance, and Safety Requirements (HRP-240)* and *FORM: Confidentiality and Non-Disclosure Agreement for Non-Sharp Researchers and Sponsor/CRO Monitors and Auditors (HRP-238)*.
- 4.3 IRB Specialist or designee completes *FORM: Badge ID and Cerner Access (HRP-234)*.
- 4.4 Director of Research submits electronic request for access to health records.

5 PROCEDURE

- 5.1 Non-SHC medical staff or employee researchers complete requirements set forth in *FORM: Non-SHC Credentialing, Compliance, and Safety Requirements (HRP-240)* and submit required attestation to the Center for Research.
 - 5.1.1 Director of Research, IRB Specialist, or designee confirms satisfactory completion of requirements and completes *FORM: Badge ID and Cerner Access (HRP-234)*.
- 5.2 IRB specialist or designee accompanies researcher to security at SHC Spectrum Corporate Offices to obtain badge photograph and identification badge using completed *FORM: Badge ID and Cerner Access (HRP-234)*.
 - 5.2.1 Records receipt of badge and expiration.
 - 5.2.2 The Director of Research submits electronic request for access to health records:
 - 5.2.2.1 Determines length of access – based on projected protocol enrollment timetables - but not to exceed one year.
 - 5.2.2.1.1 If access is required past one (1) year, researchers must review the training and retake the tests and updated applicable forms listed in 5.1.
- 5.3 IRB specialist or designee maintains *DATABASE: Site Personnel Information Tracking Sheet (HRP-608)* of non-Sharp medical staff or employee researchers access throughout study.
- 5.4 Termination of non-SHC medical staff or employee researcher access:
 - 5.4.1 IRB specialist or designee:
 - 5.4.1.1 Receives notification of study completion or change in study staff status.

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- 5.4.1.2 Submits request to deactivate the individual's badge access to SHC facilities.
- 5.4.1.3 Submits request to revoke individual's access to SHC computer systems, if necessary.
- 5.4.1.4 Records termination on *DATABASE: Site Personnel Information Tracking Sheet (HRP-608)*.

5.5 Director of Research conducts periodic review of non-Sharp researchers status.

6 MATERIALS

- 6.1 FORM: Research Team Updates (HRP-224)
- 6.2 FORM: Badge ID and Cerner Access (HRP-234)
- 6.3 FORM: Confidentiality and Non-Disclosure Agreement for Non-Sharp Researchers and Sponsor/CRO Monitors and Auditors (HRP-238)
- 6.4 FORM: Non-SHC Credentialing, Compliance, and Safety Requirements (HRP-240)
- 6.5 DATABASE: Site Personnel Information Tracking Sheet (HRP-608)

7 REFERENCES

- 7.1 None.

This document is available on [IRBANA](#), or by contacting research@sharp.com.