I. **TITLE**: RELEASE OF MEDICAL RECORDS FOR THE PURPOSE OF RESEARCH

II. **PURPOSE**: To delineate a process for maximizing the efficiency, effectiveness, and safety for the release of medical records for the purpose of research.

III. **PATIENT-CENTERED CARE PRINCIPLES**: Knowledge and information are freely shared between and among patients, care partners, physicians, and other caregivers. Patient safety is a visible priority. All caregivers cooperate with one another through a common focus on the best interests and personal goals of the patient.

IV. **SCOPE**: Research Department Medical Records Department

V. **FACILITIES/ENTITIES**: MSHA Corporate Tennessee: FWCH, IPMC, JCCH, JCMC, QRH, SSH, UCMH, WPH, Niswonger Children’s Hospital, New Leaf, Kingsport Day Surgery, IPMC Transitional Care, Princeton Transitional Care, Unicoi County Nursing Home Virginia: DCH, JMH, NCH, RCMC, SCCH, Clearview Psychiatric Unit, Francis Marion Manor Health & Rehabilitation

VI. **DEFINITIONS**: 
A. De-identifiable data for approved research study: Based on institutional review board (IRB) and MSHA approvals including approval of the waiver for Informed Consent Form, researcher may access the protected health information (PHI) but cannot transfer data outside of MSHA. Authorized User (research staff) must de-identify data prior to sharing it with other parties. The patient has not signed consent forms so the patient’s medical record information cannot be removed from the campus of the MSHA facility. All 18 PHI identifiers are removed in accordance with Section 164.514(a) of the HIPAA Privacy Rule.

B. Identifiable data for approved research study: The patient has signed consent forms authorizing disclosure of the patient’s medical record information to be
released to the researcher. All parties that have access to study data including medical records are listed in the Informed Consent Form. Security measurements to protect data are in place.

C. Internal reviewer: Research study generated by MSHA Department of Research
D. External reviewer: Research study generated by anyone outside of the MSHA Department of Research

VII. POLICY:

It is the policy of Mountain States Health Alliance to provide an efficient review process, while maintaining appropriate safeguards to ensure patient confidentiality and safety. Mountain States Health Alliance will ensure that all onsite reviewers will practice responsible and ethical practices through the following procedures.

VIII. PROCEDURE:

A. Reviewers requesting access to medical records will access Mountain States Health Alliance through the Department of Research.
   1. Researchers must have approval from IRB and the MSHA Department of Research before records can be accessed by the researcher. A copy of the IRB Approval Letter must accompany the request.
   2. The Department of Research must determine if the data utilized will be de-identifiable or identifiable per the definitions above.

B. The Department of Research will contact the Medical Records/Health Information Management Master Patient Index (MR/HIM/MPI) Department when it is appropriate to allow researchers access to medical records and when the study is approved for copies of the medical records. The research department will validate that a patient has signed the Informed Consent Form (ICF), if applicable. Signed authorization to obtain information from medical and/or billing records can serve as another supportive document. A copy must be submitted to the MR/HIM MPI department.

C. The Department of Research will notify the MR/HIM MPI Department of opening of the new study by sharing the MSHA Site Open Letter. The MSHA Site Open Letter will contain language specifying whether the data will be de-identifiable or identifiable.

NOTE: Internal reviewers should follow the same process as the external reviewers.

1. If the study allows onsite review of medical records and no transfer offsite of patient identifiable data the following process will be followed:
   a. The MR/HIM MPI Department will document the records in the review log along with other pertinent information regarding the user log on, name of individual researcher, etc.
b. The MR/HIM MPI Department will log on with the appropriate user review identification and verify that there are no existing records in the review queue.
   i. If records are in the queue for review, click the complete button for each to remove it from the queue.
   ii. Continue this process until the queue is empty.

2. The records requested for review will then be placed in the review queue.

3. The MR/HIM MPI Department will schedule review dates with the researcher.

4. The MR/HIM MPI Department will provide training to the researcher on how to navigate the review queue.

5. Once the researcher has completed the review, the MR/HIM MPI Department will log back in to the review queue used and assure that all records have been properly completed from the queue.

6. The review log will be retained by the MR/HIM Department for six (6) years.

7. If the external reviewer was given the user name and password to log on to the EHR system, the MR/HIM MPI team member will notify his/her manager to change the password.

8. Since no patient consent has been signed, the records reviewed must be recorded in the Accounting of Disclosure database.

D. If the study allows transfer offsite of identifiable PHI and the researcher has requested a copy of medical records the following process will be followed:

1. The researcher will be provided with the minimal necessary information on an approved electronic media (thumb drive, CD, DVD, etc.). The electronic media must be approved by the Information Technology Security Officer.

   **NOTE:** If the researcher would prefer printed copies of MSHA medical records, these will also be provided by the MSHA medical record team.

2. Media will be provided and approved by MSHA. No “outside” media brought in will be used; including media initially issued by MSHA and returned for additional data.

3. A new media will be used for any requests for additional or revised information.

4. Media will be prepared using the Electronic Health Record (EHR) Export to Electronic Media Procedure found on policy manager and a secure password will be used to secure the PHI on the media per policy.

E. If the researcher is a workforce member, they must go through the appropriate procedure above when working on a research study. Their personal MSHA logins must only be used within the scope of their role within the organization.

1. If the researcher is a provider and it is within the scope of treatment of the patient, the provider may use their personal logins to access the patient’s
records and review on the premises without having to go through Medical Records since there is a treatment relationship.

2. The MSHA Department of Research study coordinator and/or study staff may use their personal logins to access the patient’s records and review on the premises without having to go through Medical Records.

F. If the research study requires Mountain States Medical Group (MSMG) records, this must go through the MSMG practice. The MR/HIM MPI department does not release MSMG records.

IX. REFERENCES:

A. Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

LINKS:
De-identification of Protected Health Information, IM-900-006

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Corporate Director, Medical Records/HIM, MSHA                                          Date