Policy Manual:	Administration/Operational
Manual Section:	Medical Records
Policy Number:	MR-900-055
Effective Date:	July 14, 2014
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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, 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-identified Information:** Information that does not identify the individual and for which there is no reasonable basis to believe the individual can be identified from it.

B. **Internal Review:** Research study generated by MSHA Department of Research.

C. **External Review:** Research study generated by anyone outside of the MSHA Department of Research.

D. **Institutional Review Board (IRB):** The committee contracted by MSHA to review research protocols involving human subjects and to evaluate both risk and protection against risk for those subjects.

1. It is the function of the IRB to:

    a. Determine and certify that all research projects conducted at MSHA conform to the regulations and policies set forth by the Department of Health and Human Services (DHHS), Office for Human Research Protection (OHRP), the Food and Drug Administration (FDA), and other federal entities regarding the health, welfare, safety, rights, and privileges of human subjects; and

    b. Assist the investigator in complying with federal and state regulations.

E. **Research Informed Consent:** An IRB approved document that provides a summary of a medical research trial and explains to a potential subject (patient) their rights as a participant in the study.

F. **Waiver of Informed Consent:** The IRB has approved the research study and waived the requirement to obtain informed consent from the research subjects (patients).

VII. POLICY:

A. 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.

B. **Approved Research Study with a signed Research Informed Consent:**

1. Presence of the IRB approval, MSHA approvals and a signed Informed Consent form including authorization of disclosure of the patient's medical record information is a necessary requirement for obtaining and collecting data for research subjects (patients).

2. All parties that have access to study data, including medical records, are to be identified on the research Informed Consent form.

C. **Approved Research Study with a Waiver of Informed Consent:**

1. Based on IRB approval granting the Waiver for Informed Consent Form and MSHA approval, the researcher may access protected health information (PHI) but may not remove the record or identifiable PHI from MSHA property.

2. Prior to removing data from MSHA, data collected from the record by the approved research staff must be de-identified in accordance with Section 164.514(a) of the HIPAA Privacy Rule.

3. As a general rule, all eighteen (18) PHI identifiers must be removed.

    a. Requests for exceptions to include any of the eighteen (18) PHI identifiers in data collection will be reviewed by the Research Compliance Committee to evaluate the risk to the patient and to MSHA.

VIII. PROCEDURE:

A. The MSHA Department of Research will coordinate all requests for medical records

related to research.

1. Researchers must have approval from the IRB and the MSHA Department of Research before records can be accessed by the researcher.
    a. A copy of the IRB Approval Letter must accompany the request submitted to the MSHA Medical Records / Health Information Management / Master Patient Index (MR/HIM/MPI) Department.
2. The Department of Research must determine, based on type of approved research study, if the data requested to be reviewed and /or collected is to be de-identified.
    a. The method of de-identification should comply with MSHA policy De-Identification of Protected Health Information and HIPAA regulations.
        i. Exceptions will be reviewed/ approved by the Research Compliance Committee when applicable.

B. The MR/HIM/MPI Department will confirm with the MSHA Department of Research when it is appropriate to allow researchers access to medical records and when the study is approved for copies of the medical records.
    1. The MSHA Department of Research and / or MR/HIM/MPI Department will validate that the patient has signed the Research Informed Consent Form (ICF), if applicable.
    2. A signed HIPAA authorization to obtain information from medical and / or billing records can serve as another supportive document.
        a. A copy must be submitted to MR/HIM to place in the record, if obtained.

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.
    1. The MSHA Site Open Letter will contain language specifying whether the data will be de-identifiable or identifiable.
    2. **NOTE:** Internal reviewers should follow the same process as the external reviewers.
    3. If the study allows onsite review of medical records only 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.
                1) Continue this process until the queue is empty.

4. The records requested for review will then be placed in the review queue.
5. The MR/HIM/MPI Department will schedule review dates with the researcher.
6. The MR/HIM/MPI Department will provide training to the researcher on how to navigate the review queue.
7. 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.
8. The review log will be retained by the MR/HIM Department for six (6) years.
9. If the external reviewer was provided with the user name and password to log on the Electronic Health Record (EHR) system, the MR/HIM/MPI team member will notify his / her manager to change the password.
10. If no patient consent has been signed, the records reviewed must be recorded in the Accounting of Disclosure database.

D. If the study allows transfer off site 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 (USB drive, CD, DVD, etc.).
      a. **NOTE:** If the researcher would prefer printed copies of MSHA medical records, these will also be provided by the MSHA medical record team.
   2. The approved media will be provided by MSHA.
      a. 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 MSHA procedure Electronic Health Record (EHR) Export to Electronic Media.
      a. A password will be used to secure the PHI on the media.

E. If the researcher is a workforce member, they must follow the appropriate procedure above when working on a research study.
   1. Personal MSHA logins must only be used within the scope of their role within the organization.
   2. 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 submitting a request to the MR/HIM/MPI department since there is a treatment relationship.
   3. 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 submitting a request to the MR/HIM/MPI department.

F. If the research study requires Blue Ridge Medical Management Corporation

(BRMMC) records, the researcher must contact the BRMMC practice to obtain access, as the MR/HIM/MPI department does not release BRMMC 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 §C.F.R. 164.514 (b). http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html (accessed July 14, 2014).

LINKS:

De-identification of Protected Health Information IM-900-006

Electronic Health Record Export to Electronic Media Procedure PRO-MR-041

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Corporate Director, Medical Records/HIM, MSHA Date