I. **TITLE:** MSHA RESEARCH CERTIFICATION AND CONFIRMATION OF CREDENTIALS AND/OR PRIVILEGES OF RESEARCHERS

II. **PURPOSE:**
To define certification and credentialing requirements for researchers who are conducting human subject research at MSHA.

III. **SCOPE:**
All persons desiring to conduct or support research involving human subjects at MSHA facilities including researchers who are neither employed by nor credentialed in a MSHA facility.

IV. **FACILITIES/ENTITIES:**
MSHA Corporate
Tennessee: FWCH, IPMC, JCCH, JCMC, SSH, UCMH, WPH, Niswonger Children’s Hospital, New Leaf, Kingsport Day Surgery (a separate legal entity managed by MSHA), Unicoi County Nursing Home
Virginia: DCH, JMH, NCH, RCMC, SCCH, Clearview Psychiatric Unit, Francis Marion Manor Health & Rehabilitation, Green Oak Behavioral Health (Geriatric Behavioral Health Inpatient Program – DCH), Norton Community Physicians Services (NCPS), Community Home Care (CHC), Abingdon Physician Partners (APP)
BRMMC
Home Health/Hospice
ISHN
Wilson Pharmacy, Inc.
Mountain States Pharmacy at Norton Community Hospital

V. **DEFINITIONS:**
A. **Mountain States Certification:** Process to assure that all persons meeting the scope of this policy whose interaction with patients will be limited to viewing patient data, conducting surveys, administering questionnaires or obtaining informed consent and conducting study activities have submitted the required documentation to the MSHA Corporate Department of Research. Certification is granted upon completion of the MSHA Research Orientation training, based on signing MSHA Researcher Agreement and in accordance with IRB approval for completing the study.
B. **Credentialing:** Process to verify credentials of all persons meeting the scope of this policy who will have patient contact as defined by the MSHA Medical Staff By-Laws (refer to patient contact definition below).

   1. This process is initiated through MSHA Medical Staff Services.
   2. MSHA Research department confirms credentials and /or privileges (based on a scope of study procedures).

C. **Human Subject:** A living individual about whom an investigator (whether professional or student) conducting research obtains:

   1. Data through intervention or interaction with the individual, or
   2. Identifiable private information.

D. **MSHA Corporate Department of Research:** The corporate department is responsible for oversight of research activities at MSHA.

E. **Patient Contact:** Any admission, consultation, procedure, response to emergency call, evaluation, treatment, or service performed in the hospital or in any facility operated by the hospital, including outpatient facilities.

F. **Research:** A systematic investigation involving human subjects, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

G. **Mountain States Health Alliance (MSHA) Research:**

   1. If researchers utilize any of the MSHA facilities (hospitals) during a conduct of your research study.
   2. If research is conducted by or under the direction of any employee of MSHA in connection with her/his organizational responsibilities.
   3. If researchers are requesting a completion of a service from any of the MSHA departments (example: MRI from radiology or laboratory service).
   4. If researcher is an investigator requesting access to MSHA medical records or other non-public information maintained by MSHA for collection of data and/or identification of potential participants.
   5. MSHA administrative approval is required in addition to IRB approval for any research conducted by MSHA facilities or using MSHA patients, time or equipment.

VI. **POLICY:**

   A. Any member of a research team whose interaction with patients will be limited to viewing patient data, surveys, administering questionnaires or obtaining informed consent and is not credentialed at MSHA or is not employed by a MSHA not-for-profit facility must complete the certification process prior to involvement in human subject research.

   B. Any member of a research team who will have patient contact as defined by the MSHA Medical Staff By-Laws and is not credentialed at MSHA or is not employed
by a MSHA not-for-profit facility must obtain approval of credentials through MSHA Medical Staff Services prior to involvement in human subject research.

VII. **PROCEDURE:**

A. **MSHA Certification**

1. The following items must be completed and submitted to the MSHA Corporate Department of Research to initiate certification:
   a. Confidentiality agreement (if Non-MSHA employee)
   b. MSHA Researcher Agreement
   c. Proof of review of MSHA research–related Standard Operating Procedures (SOP)
   d. Signed and dated Current Curriculum Vitae (CV)
   e. Research Ethics Education called Collaborative Institute Training Initiative (CITI) in accordance with East Tennessee State University Institutional Review Board (ETSU IRB) requirements
   f. Conflict of Interest form (MSHA accepts ETSU COI form)

B. **Orientation**

1. All researchers who meet the criteria for MSHA certification or approval of credentials will be required to successfully complete research orientation.
   a. Orientation classes are conducted on the third Thursday of each month. To register, researcher must contact research department at 423-431-5654
   b. Researcher will receive Code of Ethics and Business conduct Acknowledgement (if Non-MSHA employee)

C. **Other**

1. All applications for certification will be assessed on an individual basis by the MSHA Corporate Department of Research.
   a. Additional proof of vaccinations or other medical or drug testing may be requested as well as a background investigation.

2. If necessary, identification badges will be issued to non-MSHA researchers obtaining certification or credentialing and must be worn and visible at all times while participating in research within MSHA facilities. A $10 fee for each badge will be collected by Corporate Human Resources department.

3. After obtaining MSHA certification or approval of credentials, researchers may be paired with a MSHA team member while conducting research studies.

4. Based on design of the study, access to the S-drive/Research data folder can be granted for storage of the identifiable data. MSHA Research department will make arrangements with Information Systems department.
5. After a researcher has obtained certification or approval of credentials, research cannot begin until full approval for the study has been granted.
   a. This will include ETSU IRB approval and MSHA Corporate Department of Research administrative approval.
   b. Certification or credentialing alone is not approval to begin a research study.

6. Research scope of practice for credentialing:
   a. A credentialed researcher’s patient contact will be limited to those procedures and/or services described in the IRB approved protocol.
   b. The researcher may not perform procedures solely for clinical diagnosis or treatment unrelated to the approved study protocol.
   c. The researcher may document procedures or services in the medical record but may not issue orders without consulting with provider.
   d. The researcher may not act as a representative or on behalf of Mountain States Health Alliance.

7. Certification or approval of credentials may be revoked at any time by MSHA Corporate Department of Research administration or MSHA Medical Staff Services.
   a. The following are examples of reasons for revocation; they are not intended to be all-inclusive:
      i. The researcher is found to be a danger to patients or staff.
      ii. The researcher does not comply with restrictions regarding access to patients or patient areas.
      iii. Failure to follow MSHA policies or procedures or failure to comply with MSHA Corporate Department of Research procedures.
      iv. Behavior inconsistent with MSHA mission, vision, values or program of Patient-Centered Care.
      v. Failure to follow the IRB approved protocol.
      vi. Failure to comply with the law, rules or regulation governing human subject research.

8. Questions and requests for information regarding MSHA certification or credentialing for research should be directed to the MSHA Corporate Department of Research at 423-431-5647.

VIII. REFERENCES:
   A. Department of Health and Human Services CFR Regulations: Title 45 CFR Part 46 Public Welfare; Protection of Human Subjects (also known as the Common Rule).

LINKS:
Institutional Review Board (IRB) Fee - MSHA Research Department, RES-100-002
Clinical Research Administration RES-100-004

______________________________________________  __________________________
Corporate Director, MSHA Research Department  Date

______________________________________________  __________________________
Executive Vice President, Chief Medical Officer, MSHA  Date

I have read and agree to comply with this procedural manual for clinical research.

______________________________________________  __________________________
Research Staff Member, MSHA Research Department  Date