I. TITLE: CLINICAL RESEARCH ADMINISTRATION

II. PURPOSE:
The purpose is to set forth the procedures for the administration and oversight of human subjects research at Mountain States Health Alliance (MSHA) facilities.

III. SCOPE:
All personnel who conduct or support research involving human subjects at all MSHA facilities.

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. Certification: Process to assure that all persons not affiliated or credentialed by MSHA, whose interaction with patients will be limited to viewing patient data, conducting surveys, administering questionnaires or obtaining informed consent have submitted the required documentation to the MSHA Corporate Department of Research.

B. Clinical Trial: A clinical trial is a research study to answer specific questions about vaccines, devices, new therapies, or new ways of using known treatments in human subjects.
   1. Clinical trials (also called medical research and research studies depending
on the scope) are used to determine whether new drugs, devices or treatments are both safe and effective.

2. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people.

C. **Credentialing:** Process to verify credentials of all persons not affiliated with or credentialed by MSHA, who will have patient contact as defined by the MSHA Medical Staff By-Laws (definition below).

   1. This process is initiated through MSHA Medical Staff Services.

D. **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.

      a. Private Information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

E. **Institutional Review Board (IRB):** A committee established by law that oversees all research involving human subjects at an institution.

   1. The IRB is legally viewed as the protector of integrity and ethical standards of all research and has the authority to enforce these standards.
   2. The main functions of the IRB review are to assure that risks are minimized and are reasonable in relation to anticipated benefits, there is voluntary informed consent, and rights and welfare of subjects are protected.

F. **MSHA Corporate Department of Research:** The corporate office responsible for oversight of MSHA research activities (administrative, regulatory, financial oversight of research studies, educational sessions)

G. **Office of Human Research Protections (OHRP):** An agency under the Department of Health and Human Services (DHHS), responsible for providing guidance to research institutions; has compliance oversight to evaluate compliance with HHS research regulations; provides educational programs, etc.

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

VI. **POLICY:**

   A. All human subject research studies performed at MSHA facilities will be under the administrative oversight of the MSHA Corporate Department of Research.

   B. **General Information**

      1. MSHA contracts with East Tennessee State University (ETSU) to provide the
IRB function for all MSHA facilities. Under special circumstances, MSHA will recognize Central IRB approvals.

a. Collaborative Institute Training Initiative (CITI) training is required for all study personnel.

b. No human subject research studies shall be conducted at MSHA facilities without obtaining IRB approval or an exemption from the IRB.

c. Principal Investigator must complete MSHA Research Orientation training and receive MSHA administrative approval (Site Open Letter) prior to starting research activities.

2. In accordance with the Office for Human Protection (OHRP), all MSHA facilities are covered under the Health and Human Services (HHS) Federal Wide Assurance (FWA) agreement which is on file in the MSHA Corporate Department of Research and must be renewed every year.

a. The FWA is the only type of compliance accepted and approved by OHRP for institutions conducting certain human subject’s research.

b. Under the FWA, an institution such as MSHA commits to the Department of Health and Human Services (DHHS) that it will comply with the requirement of Title 45 CFR Part 46.

3. An IRB-approved informed consent document (ICD) must be signed by the participant or legally authorized representative prior to enrollment in any research study.

a. If Informed Consent form is presented at MSHA facility, then documentation of the informed consent process and copy of the informed consent document must be placed in the patient’s medical record.

b. If research patient is scheduled for study procedure at MSHA, then copy of signed ICD must be presented. ICD will become part of medical record.

VII. PROCEDURE:

A. General Requirements for Human Subjects Research Conducted Within MSHA

1. Request for Research Approval

a. All human research proposals must be submitted to the ETSU IRB via IRB Manager electronically. Notifying MSHA Corporate Research Department (RD) of new protocol submission is recommended. In case of utilizing Central IRB service for Class B or C studies, Principal Investigator (PI) may contact MSHA RD first.

b. All researchers must complete the MSHA Research Proposal Request Form for all research proposals at MSHA facilities; available on the Institutional Review Board (IRB) website.

c. If completing MSHA Research Proposal Request Form (RPRF) as
attachment (based on type of IRB submission), Investigators will be responsible for completing page 2 and 3 of the MSHA Research Proposal Request Form.

i. Section 5, page 2 is for description of the service lines that will be impacted throughout the study.

ii. The MSHA Corporate Department of Research is responsible for obtaining all service lines and administration approvals.

iii. The MSHA Corporate Department of Research staff will sign to indicate approval once all departments and service lines have agreed to move forward with study. The e-signatures should begin with the MSHA Corporate Department of Research and move along the leadership in ranking order to end with the SVP CMO.

iv. MSHA credentials will be verified by the MSHA Corporate Department of Research
   1) Refer to policy MSHA Research Certification and Confirmation of Credentials and - or Privileges of Researchers.

v. Each Primary Investigator will be given an information packet including signature documents for confidentiality, ethics, and IRB information.

vi. If necessary, according to policy MSHA Research Certification and Confirmation of Credentials and - or Privileges of Researchers, the investigator will attend an orientation class in order to be MSHA certified; attendance should be recorded.
   1) In the case that the investigator has multiple studies over time, they will only be required to attend the orientation class once.
   2) Principal Investigator will be responsible for providing training to all members of his/her research team.
      a) Proof of training must be submitted to MSHA RD.
      b) Documentation of training must be filed in the regulatory binder.

d. In addition, the Principal Investigator (PI) must submit the following documents with the MSHA Research Proposal Request Form (via ETSU IRB Manager)
   i. Complete Protocol (device trials, and drug trials)
   ii. Protocol Synopsis (if available)
   iii. Investigator Brochure
   iv. Signed and dated Curriculum Vitae (CV) for all study staff
   v. ETSU Project Narrative
   vi. Any other required documents
vii. In case of using Central IRB, documentation can be submitted directly to MSHA RD.

e. The Department of Research can provide consulting services with budget, contracts, and IRB submissions if requested and/or contracted to do so.

f. Throughout the study, documentation will be required for submission to the MSHA Corporate Department of Research (directly or via ETSU IRB Manager)

i. Based on Study Classification (A,B or C), these items include but are not limited to the following:
   1) Initial budget and contract
   2) Final budget and contract
   3) Grant information (if applicable)
   4) All documents submitted to, and received from the ETSU IRB throughout the study
   5) A legal agreement may be required between MSHA and the PI, Institution, or Sponsor.

g. No clinical research studies involving MSHA facilities, patients or team members can be conducted without prior approval from the MSHA Corporate Department of Research and ETSU IRB.

h. The PI must notify the MSHA Corporate Department of Research of any changes in the research study.

2. **Badges**

   a. A picture badge will be issued by the MSHA Human Resources (HR) Corporate Department based on submission of the request form by MSHA Research department to all study staff conducting research within MSHA facilities that are not employed by a MSHA not-for-profit facility or are not credentialed medical staff.

   b. Badges will be valid for the duration of the IRB approval given.

   c. Badges are to be worn at all times while in MSHA facilities.

3. **Enrollment Logs**

   a. Principal Investigators are responsible for maintaining a chronological list of research subjects enrolled in their clinical research studies as part of the Essential Documents detailed in International Conference on Harmonization (ICH) E6Good Clinical Practices.

   b. Enrollment logs at a minimum should include specific information about the study to which it pertains and provide unique identifiers for each individual subject enrolled in the clinical trial.

   c. Principal Investigators may use an enrollment log which the study sponsor provides or a log that they have created as long as it provides
sufficient information to be able to document specific details about the subjects’ enrollment, which may include but is not limited to: the screening number/subject number/randomization number, date of entry into the study and/or date of randomization (if applicable), name/initials and date of birth.

d. Completion of the enrollment log may be delegated to appropriately-qualified study staff by the Principal Investigator.

e. The enrollment log may be kept in hard copy or electronically on a computer with limited access.

i. If kept in hard copy, the log needs to be held in a secure area which has limited access and is locked when study staff members are not present.

ii. If kept electronically, it needs to be maintained in a secure, password-protected computer for which study staff has their own unique usernames/passwords to access the available information.

iii. Information containing Patient History Information (PHI) for studies utilizing de-identifiable data must be accessed, protected and maintained under Release of Medical Records for the Purpose of Research.

iv. In this case, access for MSHA S-drive /Research Data must be requested via MSHA research department.

v. In either case, it needs to be easily accessible for sponsor review (if requested) or in the event of an audit by the regulatory authorities, sponsor or institutional review board.

f. The enrollment log should be maintained for the life of the study and upon study completion held in a secure location with other important study documents for the time required to meet local, state and federal regulations.

4. Certification and Credentialing Process

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.
B. **Fees**
   1. The MSHA Corporate Department of Research will collect IRB fees for Class A studies and administrative and/or contract development/negotiation fees for industry sponsored and grant funded studies (Class A, B-1, B-3 or C funded)
   2. Please see policy MSHA Corporate Department of Research Institutional Review Board for Non-MSHA Affiliated Researchers for more information regarding fees or visit

C. **Compliance**
   1. All researchers are expected to comply with all federal, IRB regulatory and MSHA requirements. Research projects are subject to audit or review by the MSHA Corporate Department of Research and/or the MSHA Corporate Audit and Compliance Services Department. Research study may be a subject of audit based on random selection.
   2. All findings of serious, continuing noncompliance will be reported to the IRB as appropriate.
   3. MSHA Administration reserves the right to suspend or terminate research projects involving MSHA patients or occurring within MSHA facilities as deemed necessary.

D. **Forms**
   1. Research forms may be found on the following websites:
      a. [Institutional Review Board](#)
      b. [MSHA intranet, Research Department](#)
      c. [MSHA Research Department](#)

E. **Research Concerns**
   1. Concerns regarding research studies should be directed to the MSHA Corporate Department of Research via phone 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:**
MSHA Research Certification and Confirmation of Credentials and - or Privileges of Researchers RES-100-003
Institutional Review Board (IRB) Fee - MSHA Research Department RES-100-002
Release of Medical Records for the Purpose of Research MR-900-055

Executive Vice President, Chief Medical Officer, MSHA  ____________________________  ____________________________  ____________

Corporate Director, MSHA Research Department  ____________________________  ____________________________  ____________

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

Research Staff Member, MSHA Research Department  ____________________________  ____________________________  ____________