INVESTIGATORS USING MSHA FACILITIES OR PATIENTS

Welcome to Research at Mountain States Health Alliance (MSHA). The MSHA Corporate Department of Research team is eager to assist you in making your research aspirations a reality. The information provided below will guide you through the MSHA Research journey.

Investigators who use Mountain States Health Alliance (MSHA) facilities or patients while conducting research are required to be members of MSHA medical staff, credentialed as allied health professional or MSHA certified researchers. All research is submitted to the MSHA Research Department on the MSHA Research Proposal Request Form prior to submission to the ETSU/VA IRB. Researchers must complete CITI training prior to commencement of approved research studies (available on the ETSU IRB website). No research study can begin within MSHA facilities without approval from the ETSU/VA IRB and the MSHA Corporate Department of Research.

RESEARCHERS WITH AN UNDEVELOPED PROPOSAL

1. Complete a MSHA Research Proposal Request Form with available information. [www.etsu.edu/irb/formsdoc.html](http://www.etsu.edu/irb/formsdoc.html). MSHA Team members can access this form through the Intranet/Forms/Non-Clinical/Research.
2. Call the MSHA Corporate Department of Research at 431-5656 or 431-5645 to arrange an initial meeting to discuss the necessary steps for developing a proposal. Further direction will be provided by the MSHA Research team.

RESEARCHERS WITH A DEVELOPED PROPOSAL

1. Complete MSHA Research Proposal Request Form with available information. [www.etsu.edu/irb/formsdoc.html](http://www.etsu.edu/irb/formsdoc.html). MSHA Team members can access this form through the Intranet/Forms/Non-Clinical/Research.
2. Call the MSHA Corporate Department of Research at 431-5656 or 431-5645 to arrange an initial meeting to discuss the proposal.
3. Bring the following information to the meeting:
   - MSHA Research Proposal Request Form
   - Form 103
   - Narrative Description of the Project
   - Informed Consent (if applicable)
   - HIPAA Form
   - CITI Training
   - Assurance Statement (students only)
   - Application for Research Certification (if needed)
   - Current CV
   - Professional Medical License (if applicable)
   - Protocol
   - Protocol Synopsis
   - Budget
   - Contracts
   - Investigator Brochure
4. Studies that have been reviewed by the MSHA Corporate Department of Research and determined to be a feasible project for MSHA will be submitted for administrative approval which includes an assessment of impact on related service lines and facilities. Status of the studies will be communicated to the PI and/or study staff throughout the process.

5. If the study receives MSHA approval and the PI is eligible to conduct research at MSHA a packet will be submitted to the ETSU/VA IRB, a copy will be given to the PI and a copy will be retained by the MSHA Corporate Department of Research. If the study then receives full IRB approval, the MSHA Corporate Department of Research will meet with the PI or study staff to coordinate study start-up.

6. If the study is approved pending modifications, a packet will be given to the PI and a copy will be retained by the MSHA Corporate Department of Research. For the study to move forward at MSHA, the PI must incorporate the required modifications into the study and resubmit to the MSHA Corporate Department of Research. The study will be reviewed and reconsidered for approval. Studies receiving approval will follow the process for approval outlined above.

7. If the study is denied, MSHA will not participate in the study as proposed. The IRB will be notified, a packet will be given to the PI, and a copy will be retained by the MSHA Corporate Department of Research.
RESEARCH PROCESS FOR INVESTIGATORS USING MOUNTAIN STATES HEALTH ALLIANCE (MSHA) FACILITIES OR PATIENTS

INVESTIGATOR OBTAINS MSHA RESEARCH PROPOSAL REQUEST FORM FROM ETSU/IRB WEBSITE, MSHA INTRANET FORMS OR MSHA CORPORATE DEPARTMENT OF RESEARCH

INVESTIGATOR COMPLETES FORM AND CALLS MSHA CORPORATE DEPARTMENT OF RESEARCH 431-5656 OR 431-5645 GUIDANCE WILL BE GIVEN REGARDING SUBMISSION OF FORM AND PROTOCOL AND A MEETING WILL BE SCHEDULED TO DISCUSS THE STUDY

PROPOSAL REVIEWS BY MSHA CORPORATE DEPARTMENT OF RESEARCH FOR FEASIBILITY

PI AND IRB NOTIFIED MSHA WILL NOT PARTICIPATE IN STUDY AS PROPOSED

PROPOSAL FEASIBLE?

Yes

PROPOSAL SUBMITTED FOR ADMINISTRATIVE APPROVALS

PI NOTIFIED STUDY IS APPROVED PENDING MODIFICATIONS

STUDY STATUS DETERMINED

DENIED

PI AND/IRB NOTIFIED MSHA WILL NOT PARTICIPATE IN STUDY AS PROPOSED

APPROVED

PI MAKES MODIFICATIONS?

NO

MSHA WILL NOT PARTICIPATE IN STUDY AS PROPOSED

PI IS NOTIFIED OF APPROVAL PI RECEIVES A COPY OF COMPLETED PACKET IRB IS NOTIFIED THAT STUDY HAS BEEN MSHA APPROVED IRB RECEIVES ORIGINAL PACKET FROM MSHA RESEARCH DEPARTMENT

PI NOTIFIED STUDY IS APPROVED PENDING MODIFICATIONS

Conditional Approval