MOUNTAIN STATES HEALTH ALLIANCE
RESEARCH DEPARTMENT

RESEARCH PROPOSAL REQUEST FORM FOR INITIAL SUBMISSION

THIS FORM MUST BE COMPLETED AND SUBMITTED ALONG WITH IRB PROPOSAL WHEN COMPLETING ETSU IRB SUBMISSION.

NOTE: APPROVAL MUST BE OBTAINED FROM ETSU/VA IRB. A COMPLETED MSHA RESEARCH REQUEST FORM DOCUMENTS MSHA'S PERMISSION, NOT IRB APPROVAL!

For information, call MSHA Research Department at 423-431-5647 or e-mail the Research Assistant, Christy Adkins at Adkinsce2@msha.com

Directions:

1. **Complete this Research Request Form to request review and approval of research activities at any MSHA location. All human subject research proposals must be submitted to the MSHA Department of Research prior to submission to the IRB or simultaneously.**

   The Department of Research will work with the Principal Investigator to ensure that all protocols are approved by the impacted service lines and are in compliance with all MSHA policies.

   No research studies involving MSHA facilities, patients or team members will be approved by the IRB without approval from the MSHA Department of Research.

2. **A signed copy of this approval request form will be returned to the PI and a copy will be sent to the ETSU/VA IRB by the MSHA Department of Research. After completion of this IRB submission at MSHA Research Department, the PI will receive an invoice for the provided service. Regulatory services and fees are posted on https://www.mountainstateshealth.com/about-us/research(research information is under "about us" tab) $500 MSHA Administrative fees apply to funded studies.**

3. **Protocols will not be accepted by ETSU/VA IRB for review without the completed Research Request Form if the research is to be conducted at any MSHA location.**

4. **The PI must notify the MSHA Department of Research of any changes in the research that affect the rights or well-being of human subjects or of any changes affecting subject billing.**

MSHA Use Only

Research Group #:

Date received:

IRB#:
Name of IRB: ETSU IRB___
Central IRB_____

MSHA RESEARCH PROPOSAL REQUEST FORM

1. **PRINCIPAL INVESTIGATOR:** **EMAIL:**
2. **CONTACT NAME:** **PHONE:**
3. **TITLE OF RESEARCH PROJECT:**

4. **MSHA SITE(S) WHERE RESEARCH PROCEDURES WILL BE CONDUCTED (check all that applies):**

Facility	In-patient	Out-patient
Johnson City Medical Center Hospital	☐	☐
Niswonger Children's Hospital at JCMC	☐	☐
Franklin Woods Community Hospital	☐	☐
Regional Cancer Center at Johnson City Medical Center	☐	☐
Sycamore Shoals Hospital	☐	☐
Indian Path Medical Center	☐	☐
Unicoi County Memorial Hospital	☐	☐
Woodridge Hospital	☐	☐
Kingsport Day Surgery	☐	☐
Princeton Transitional Care	☐	☐
Johnson County Community Hospital	☐	☐
Dickenson Community Hospital	☐	☐
Johnston Memorial Hospital	☐	☐
Norton Community Hospital	☐	☐
Russell County Medical Center	☐	☐
Smyth County Community Hospital	☐	☐
BRMMC:	☐	☐
Other: _____	☐	☐

5. **How many research subjects you plan to enroll? _____**

6. **Which type of data you will be utilizing(check): ☐ identifiable ☐ de-identifiable**

   Please explain when and how you will de-identify data:

   _____

   _____

7. **Does PI need access to MSHA secure drive to store identifiable data (data not allowed to leave MSHA)? ☐NO ☐ YES**

8. **MSHA SERVICES/DEPARTMENTS IMPACTED (check all that apply, describe in DETAILS including billing arrangements):**
   Check either "yes" or "no" for the areas that will be impacted by the proposed project. Final determination and accountability will remain with the MSHA Research Department to identify services that may be impacted. Use separate spreadsheet if necessary (list type & number of procedures, text, and standard of care (SOC) versus non-standard of care procedures (NSOC, etc.)

   Laboratory **CPT_____☐NO ☐YES ☐SOC ☐NSOC Describe: _____**
   ***Specify if any** **☐Processing** **☐Shipment**

   Radiology/Imaging **CPT_____ ☐NO ☐YES ☐ SOC ☐NSOC ☐CONTRAST ☐IP Describe: _____**
   ***Specify if any** **☐Reading** **☐Data Transfer**

   Pharmacy **☐NO ☐YES ☐ SOC ☐NSOC ☐IP Describe: _____**

   Nursing Unit(s) **CPT_____☐NO ☐YES ☐SOC ☐NSOC Describe: _____**

Cardiovascular **CPT_____☐NO ☐YES ☐SOC ☐NSOC Describe: _____**

Surgery **ICD-9_____ ☐NO ☐YES ☐SOC ☐NSOC ☐ANESTHESIA Describe: _____**

Radiation Oncology ICD-9___ ☐NO ☐YES ☐SOC ☐ NSOC Describe: _____

Other: _____ Describe: _____
Other: _____ Describe: _____

9. RESEARCH TEAM:
Beginning with the Principal Investigator, list the names of ALL members of the research team (sub/co-investigator, study coordinator, research nurse, research technician, consultant, pharmacist, members listed on FDA Form 1572, etc.). Indicate if affiliated with ETSU or MSHA and whether or not each team member has been credentialed (if applicable) by MSHA Medical Staff Services. Attach additional page if necessary.

Research Team Member Name	Title (MD, LPN, RN, etc.)	Affiliated w/ETSU Y/N	Affiliated/ Credentialed w/MSHA Y/N	Completed MSHA Research Orientation	Any conflict of interest?

10. CONTRACTUAL ARRANGEMENTS: Check either "yes" or "no" for the areas that will be impacted by the proposed project:

External study (PI is main contractor) **☐NO ☐YES Describe: _____**

Internal study (MSHA is main contractor) **☐NO ☐YES Describe: _____**

What is the status of study contract? **Describe: _____**

Does PI have a service agreement with MSHA? **☐NO ☐YES Describe: _____**

Does PI request a new service agreement with MSHA? **☐NO ☐YES Describe: _____**

Is there a need to develop a study specific CTA? **☐NO ☐Yes Describe: _____**

Procedures to be billed to **☐Insurance ☐Sponsor ☐PI ☐None**

Details (use another page if needed)

_____

Have you applied for a Grant? **☐NO ☐ N/A ☐ YES Describe: _____**
(grants@msha.com)

The MSHA Research Department will notify the PI of the need for a clinical trial agreement with appropriate budget. CTA must be approved by the MSHA legal department prior to study implementation.

11. ATTESTATION OF PI: By signing this form:

- **I understand that I will alert the Research Department of potential study and provide the following documents for their**

review (if not available as part of ETSU Form 103 via ETSU IRB Manager):

- Complete protocol, study schema/plan
- Informed Consent including HIPAA language, if applicable (or waiver of ICF). Note: MSHA must be listed in the Confidentiality section of the ICD and HIPAA form
- Investigator brochure, if applicable
- Budget and contract, if applicable
- Sponsor contact information
- ETSU form 103 and project narrative
- Data collecting tools
- Advertisement material, if any
- Proof of training (CITI training), signed and dated CV,
- MSHA Certified Researcher Agreement, Non-MSHA employee confidentiality agreement (if applicable)- forms must be submitted to MSHA Research department directly

- **I agree to obtain written ETSU/VA IRB approval before initiating any human subject's research at MSHA and to abide by all applicable ETSU/VA IRB policies.**
- **I agree to abide by all applicable MSHA policies and practices while conducting research at MSHA.**
- **I understand that MSHA Administration can audit, suspend or terminate research projects within any MSHA facility as deemed necessary.**
- **I understand that PI is responsible for MSHA Research Department Regulatory fees (calculated based on the amount of requested service)**
- **I understand that as Principal Investigator I certify if the patient qualifies to receive Medicare coverage I am responsible in meeting the criteria as stated in the Medicare National Coverage Determinations Manual Chapter 1, Part 4 Section 310.1.**

_____ _____

Signature of Principal Investigator **Date**

DO NOT WRITE BELOW THIS LINE
For Administrative Use Only

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9. MSHA APPROVAL:

_____ _____

Signature of MSHA Corporate Director of Research **Date**

☐ **MSHA engaged in human subject research** _____

Date

☐ **Approved by ETSU/VA IRB** _____

Date