RESEARCH PROPOSAL REQUEST FORM FOR MODIFICATION SUBMISSION

THIS FORM MUST BE COMPLETED AND SUBMITTED ALONG WITH THE 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 the MSHA Research Department at 423-431-5647 or e-mail 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 ETSU/VA IRB by 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 www.mountainstateshealth.com/about-us/research (research information is under “about us” tab) $500 MSHA Administrative fees may apply to funded studies.

3. Protocols will not be accepted by the 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. **IF YOU ARE REQUESTING THE OPENING OF AN ADDITIONAL SITE AT MSHA WHERE RESEARCH PROCEDURES WILL BE CONDUCTED** (check all that apply):

<table>
<thead>
<tr>
<th>Facility</th>
<th>In-patient</th>
<th>Out-patient</th>
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<tbody>
<tr>
<td>Johnson City Medical Center Hospital</td>
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<td>Niswonger Children’s Hospital at JCMC</td>
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<td>Franklin Woods Community Hospital</td>
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<td>Regional Cancer Center at Johnson City Medical Center</td>
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<td>Sycamore Shoals Hospital</td>
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<td>Indian Path Medical Center</td>
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<td>Unicoi County Memorial Hospital</td>
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<td>Woodridge Hospital</td>
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<td>Kingsport Day Surgery</td>
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<td>Princeton Transitional Care</td>
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<td>Johnson County Community Hospital</td>
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<td>Dickenson Community Hospital</td>
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<td>Johnston Memorial Hospital</td>
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<td>Norton Community Hospital</td>
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<td>Russell County Community Hospital</td>
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<td>Smyth County Community Hospital</td>
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<td>Other:</td>
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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:**
   NEW SERVICE ONLY (check all that apply, describe in DETAIL 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
     - Specify if any:
       - Processing
       - Shipment

   - Radiology/Imaging
     - CPT
     - Specify if any:
       - Reading
       - Data Transfer

   - Pharmacy
     - NO
     - YES
     - SOC
     - NSOC
     - IP
     - Describe: ____

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8. RESEARCH TEAM: [LIST NEW STAFF ONLY]
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.

<table>
<thead>
<tr>
<th>Research Team Member Name (List new staff only)</th>
<th>Title (MD, LPN, RN, etc.)</th>
<th>Affiliated w/ETSU Y/N</th>
<th>Affiliated/Credentialed w/MSHA Y/N</th>
<th>Completed MSHA Research Orientation</th>
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9. 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 __________________________________________________________________________________________

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, to be approved by the MSHA legal department prior to study implementation.

10. ATTESTATION OF PI: By signing this form:

I understand that I will alert the Research Department of study changes and provide revised versions of the following
documents for their review (if not available as Part of Form 103 via ETSU IRB Manager):

- Complete protocol, study schema/plan
- Informed Consent including HIPAA language, if applicable (or waiver of ICF)
- Investigator brochure, if applicable
- Budget and contract, if applicable
- Sponsor contact information
- Project narrative
- Data collecting tools
- Advertisement material, if any
- Proof of training (CITI training), signed and dated CV, licenses
- MSHA Certified Researcher Agreement, Non-MSHA employee confidentiality agreement (if applicable) for new research staff- 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 suspend or terminate research projects within any MSHA facility as deemed necessary.
- I understand that PI is responsible for MSHA Research Department Regulatory fees (based on the 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

__________________________     ______________________
Signature of MSHA Corporate Director of Research     Date

Additional approvals by CMO’s are required only in case of adding new facility or service.
Minimum changes of service may require a manager approval only.

☐ MSHA Engaged in Human Subject Research     ______________________

☐ Approved by ETSU/VA IRB     ______________________