RESEARCH PROPOSAL REQUEST FORM FOR EXTERNAL IRB

THIS FORM MUST BE COMPLETED AND SUBMITTED ALONG WITH THE IRB PROPOSAL WHEN COMPLETING IRB SUBMISSION OR SEND TO MSHA RESEARCH DEPARTMENT PRIOR TO REQUESTING ETSU IRB APPROVAL.

NOTE: INSTITUTIONAL REVIEW BOARD AUTHORIZATION AGREEMENT (IAA) WITH ETSU/VA IRB MAY BE REQUIRED. MSHA RPRF DOCUMENTS MSHA APPROVAL, NOT SUPPLEMENTAL 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 ETSU/VA IRB by the MSHA Department of Research. Regulatory services and fees are posted on www.mountainstateshealth.com/about-us/research (research information is under “about us” tab) $500 MSHA Administrative fees applies to funded studies. PI may be responsible for IRB fees.

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____________

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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 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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<tr>
<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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<tr>
<td>Johnson County</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>BRMMC:</td>
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<td>Other:</td>
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5. How many research subjects do 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 “yes” or “no” for areas that will be impacted by this project. Final determination and accountability will remain with MSHA Research Dept. 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: _____
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.

<table>
<thead>
<tr>
<th>Research Team Member Name</th>
<th>Title (MD, LPN, RN, etc.)</th>
<th>Affiliated w/ETSU Y/N</th>
<th>Affiliated w/MSHA Y/N</th>
<th>Completed MSHA Research Orientation</th>
<th>Any conflict of Interest?</th>
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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/billing contact (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, to be approved by the MSHA legal department prior to study implementation.

11. Is study approved by Central IRB? □ NO □ YES  Please list ____________  (Submit copy of IRB Approval letter.)

12. 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:

- ETSU X-Form
- Approved protocol, study schema/plan
- Approved Informed Consent including HIPAA language, if applicable (or waiver of ICF).
  Note: ETSU IRB and MSHA representatives must be listed as participating parties in “Confidentiality” and “HIPAA” sections of ICF
- Investigator brochure, if applicable
- Budget and contract, if applicable
- Sponsor contact information
- Data collecting tools
- Advertisement material, if any
- Proof of training (CITI training, MSHA Research Orientation Training), signed and dated CV, licenses
  *Note: Do not submit a second copy of the above mentioned documents if you submitted them via ETSU IRB Manager.

- 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 will cooperate with MSHA representative during completion of the monitoring activities, if any.
- I understand that the PI is responsible for MSHA Research Dept. Regulatory fees (based on the requested service)
- I understand that I am responsible for notifying MSHA Research department of the closure of the study and terminating MSHA accesses, if any granted during completion of the study (ex: S-drive to keep Master List)
- 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

9. MSHA APPROVAL:

_________________________  ____________________
Signature of MSHA Corporate Director of Research Date

☐ Approved by MSHA Administration  ___________ Date
☐ Approved by ETSU/VA IRB  ___________ Date
☐ MSHA engaged in human subject research *  ___________ Date

*Following approval, the IRB administration will forward copies of the following documents to MSHA Research department:

- Initial IRB Registration of Study Approved by External IRB, signed by the Chair (available via ETSU IRB Manager). Letter can be uploaded based on receipt of e-mail notification.
- Unaffiliated Investigator Agreement