RESEARCH PROPOSAL REQUEST FORM FOR INITIAL SUBMISSION

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

NOTE: APPROVAL MUST BE OBTAINED FROM THE IRB. A COMPLETED BALLAD HEALTH RESEARCH REQUEST FORM SHOWS DOCUMENTED ADMINISTRATIVE PERMISSION, NOT IRB APPROVAL!

For information, call Ballad Health Research Program Coordinator at 423-431-5647 or e-mail the Research Assistant, Christy Adkins at Christy.Adkins@balladhealth.org

Directions:

1. Complete this Request Form to request review and approval of research activities at any Ballad Health facility.

   Note: The Research Coordinator will work with the Principal Investigator to ensure that all protocols are approved by the impacted service lines (see para # 8) and are in compliance with all Ballad Health policies.

2. Completion of Ballad Health RPRF is mandatory.
   Note: For studies completed within Group 1 facilities, the RPRF form should be submitted along with IRB application.

3. A signed copy of this request form will be returned to the PI. After approval of the research proposal through the IRB and Ballad Health, the PI may receive an invoice for the provided service when funded, if applicable. Administrative services and fees are posted on https://www.balladhealth.org/ (research information is under “about us” tab).

4. Protocols will not be accepted by the IRB for review without the completed Research Request Form, if the research is to be conducted at any Ballad Health facility.

5. The PI must notify the Ballad Health Research Coordinator of any changes in the research that affect the rights or well-being of human subjects or of any changes affecting subject billing.

   BALLAD HEALTH Use Only

   Research Group#:
   Date received:
   IRB#:
   Name of IRB: ETSU IRB___
   Central IRB__________
   Wellmont IRB__________
1. PRINCIPAL INVESTIGATOR:  
   WORK EMAIL:  
   PERSONAL EMAIL:  
2. CONTACT NAME:  
   PHONE:  
3. TITLE OF RESEARCH PROJECT:  
4. BALLAD HEALTH FACILITIES WHERE RESEARCH PROCEDURES WILL BE CONDUCTED (check all that apply):  

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<tr>
<th>Group 1</th>
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<th>Group 2</th>
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<tr>
<td>MSHA</td>
<td>In-patient</td>
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<td>Wellmont</td>
<td>In-Patient</td>
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<td>Johnson City Medical Center Hospital</td>
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<td>Bristol Regional Medical Center</td>
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<td>Niswonger Children’s Hospital</td>
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<td>Hancock County Hospital</td>
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<td>Franklin Woods Community Hospital</td>
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<td>Hawkins County Memorial Hospital</td>
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<td>Regional Cancer Center at Johnson City Medical Center</td>
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<td>Holsten Valley Medical Center</td>
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<td>Indian Path Medical Center</td>
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<td>Mountain View Regional Hospital</td>
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<td>Unicou County Memorial Hospital</td>
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<td>Smyth County Community Hospital</td>
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5 How many research subjects do you plan to enroll? __________

6. Which type of data will be utilized:  
   ☐ Identifiable with ICF  ☐ de-identifiable (Master list on s-drive)  ☐ NO ☐ YES
   
   Please explain when and how you will de-identify data: ____________________________________________________________  
   _________________________________________________________________________________________________________  
   _________________________________________________________________________________________________________

7. Does PI need access to the secured drive to store identifiable data (PHI not allowed to leave Ballad Health)?  
   ☐ NO ☐ YES

8. SERVICES/DEPARTMENTS IMPACTED (check all that apply):  
   
   Check “yes” or “no” for the areas that will be impacted by this project. Final determination and accountability will remain with the Research Program to identify services that may be impacted. Use separate spreadsheet, if necessary (list type & number of procedures, text, and standard of care (SOC) vs. non-standard of care procedures (NSOC, etc.)

   Laboratory CPT______ ☐ NO ☐ YES ☐ SOC ☐ NSOC Describe: _____
   *Specify if any ☐ Processing ☐ Shipment
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 Ballad Health and whether or not each team member has been credentialed (if applicable) by Ballad Health Medical Staff Services. Attach additional page if necessary.

<table>
<thead>
<tr>
<th>Research Team Member Name</th>
<th>Title/Role (PI, Co-PI, SC, MD, LPN, RN, etc.)</th>
<th>Affiliated w/ETSU Y/N</th>
<th>Ballad Health Affiliated/ Credentialed Y/N</th>
<th>Any conflict of interest?</th>
<th>Completed Ballad Health Research Orientation</th>
<th>Verified research training? (RD use only)</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 (Ballad Health is main contractor) □ NO □ YES Describe: __________

What is the status of study contract? Describe: ____________________________

Does PI have a service agreement with Ballad Health □ NO □ YES Describe: ____________________________

Does PI request a new service agreement with Ballad Health? □ 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: __________

(Charlie.Sagona@balladhealth.org)

The Ballad Health Research Coordinator will notify the PI of the need for a clinical trial agreement with appropriate budget. CTA must be approved by the Ballad Health legal department prior to study implementation.
11. REGULATORY: Are you requesting: 1) ☐ Full Study, 2) ☐ Exempt Study or 3) ☐ Expedited Study (check one) 
If yes, you are required to send an annual report 12 months from date of approval to Christy.Adkins@balladhealth.org. The annual report form can be found on the Ballad Health Research Site under forms. ______ (Initial if accepted)

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 (if not available as part of New Protocol Submission):

- Complete protocol, study schema/plan
- Informed Consent including HIPAA language, if applicable (or waiver of ICF) Ballad Health 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
- Data collecting tools
- Advertisement material, if any
- Proof of training (CITI training), signed and dated CV
- Ballad Health Certified Researcher Agreement, Non-Ballad Health employee confidentiality agreement (if applicable) for all research staff- forms must be submitted to Ballad Health Research Coordinator directly.

- I agree to obtain written IRB approval before initiating any human subject research at Ballad Health and to abide by all applicable IRB policies.
- I agree to abide by all applicable Ballad Health policies and practices while conducting research at Ballad Health.
- I understand that Ballad Health Administration can audit, suspend or terminate research projects within any Ballad Health facility as deemed necessary.
- I understand that the PI is responsible for Ballad Health Research administrative fees (calculated based on the requested service(s)).
- I understand that as Principal Investigator, I certify if a 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
________________________________________________________________________________

BALLAD HEALTH APPROVAL:

Signature of Research Administrator __________________________ 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.

☐ Ballad Health engaged in human subject research Date __________________

☐ Approved by IRB Date __________________