RESEARCH PROPOSAL REQUEST FORM FOR EXTERNAL IRB

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

NOTE: INSTITUTIONAL REVIEW BOARD AUTHORIZATION AGREEMENT (IAA) WITH ETSU/VA IRB MAY BE REQUIRED. RESEARCH PROPOSAL RESEARCH FORM DOCUMENTS BALLAD HEALTH APPROVAL, NOT SUPPLEMENTAL 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 Ballad Health service lines (see para #8) and are in compliance with all Ballad Health policies.

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

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 approval 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 completion of this 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: __________
**BALLAD HEALTH RESEARCH PROPOSAL REQUEST FORM**

1. **PRINCIPAL INVESTIGATOR:**  
   WORK EMAIL:  
2. **CONTACT NAME:**  
   PERSONAL EMAIL:  
   PHONE:  
3. **TITLE OF RESEARCH PROJECT:**  
4. **BALLAD HEALTH FACILITIES WHERE RESEARCH PROCEDURES WILL BE CONDUCTED** (check all that apply):

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Group 2</th>
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<tbody>
<tr>
<td><strong>MSHA</strong></td>
<td><strong>Wellmont</strong></td>
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<tr>
<td>Johnson City Medical Center Hospital</td>
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<tr>
<td>Niswonger Children’s Hospital</td>
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<tr>
<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>Laughlin 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 Medical Center</td>
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<td>Smyth County Community Hospital</td>
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<td>BRMMC: 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:**  
   - [ ] 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, 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 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

   - Radiology/Imaging  
     - CPT [ ] NO  
     - [ ] YES  
     - [ ] SOC  
     - [ ] NSOC  
     - [ ] CONTRAST  
     - [ ] IP  
     - Describe:  

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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 (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/billing contact ____________________________

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)

11. Is study approved by Central IRB?  ☐ NO  ☐ YES  Please list IRB _________________________________

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 submitted through ETSU IRB Manager:

- Approved Complete protocol, study schema/plan
- Approved Informed Consent including HIPAA language, if applicable (or waiver of ICF). ETSU IRB and Ballad Health 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, Ballad Health Research Orientation Training), signed and dated CV, licenses
- Ballad Health Certified Researcher Agreement, Non-Ballad Health employee confidentiality agreement (if applicable) - forms must be submitted to Ballad Health Research Coordinator directly.

- I agree to obtain written ETSU/VA 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 (based on the requested service)
- I understand that I am responsible for notifying Ballad Health Research of the closure of the study and terminating Ballad Health accesses, if any, granted during completion of the study (ex: S-drive where master list is kept)
- 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

__________________________________  _____
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.

☐  Approved by Ballad Health Administration  __________________________
         Date

☐  Approved by ETSU/VA IRB  __________________________
         Date

☐  Ballad Health engaged in human subject research  __________________________
         Date