



ETSU

Humanitarian Use Devices (HUDS)



Submission and Review



Definitions

- a. Humanitarian Use Device (HUD): A Humanitarian Use Device is a device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect fewer than 4,000 individuals per year in the United States.
- b. Humanitarian Device Exemption (HDE): A Humanitarian Device Exemption (HDE) is an application that is similar to a premarket approval application (PMA), but exempt from the effectiveness requirements of a PMA.

Initial Application

The initial review of a HUD will be completed by the full, convened IRB Committee. For an initial HUD submission, the documents listed below must be submitted to the ETSU/VA IRB by the submission deadline for the subsequent convened ETSU/VA IRB meeting (Submission deadlines are posted on the website, www.etsu.edu/irb).

Required Documents

- ⇒ 30 Signed copies of Form 200 (Request for Review of Humanitarian Use Device (HUD))
- ⇒ 30 copies of the FDA HDE approval letter and any other pertinent correspondence
- ⇒ 30 copies of the manufacturer-provided patient information.
- ⇒ 30 copies of the HUD manufacturer's product labeling, clinical brochure, and/or other pertinent manufacturer informational materials (i.e., Summary of Safety and Probable Benefit and Product Information Summary)
- ⇒ If at MSHA, completed MSHA Research Request Form
- ⇒ One original Unaffiliated Investigator Agreement, as applicable

The Form 200, MSHA Research Request Form and Unaffiliated Investigator Agreement are all available on the IRB web page, www.etsu.edu/irb.

[Note: If the HUD is the subject of a clinical investigation (one in which safety and effectiveness data is being collected to support a PMA), Form 200 may not be used. Instead, a complete IRB submission packet (Form 103, narrative, informed consent and all applicable attachments per policy) is required.] Please contact the IRB Office at 439-6055 if you have questions or need more information.

Training

Before HUD approval is issued, the PI must complete with passing scores (overall score of 85% or above), the following three Collaborative Institutional Training Initiative (CITI) modules:

1. History and Ethical Principles
2. Basic IRB Regulations and Review Process
3. FDA Regulated Research

First Time Users of CITI Training Program

1. Go to www.citiprogram.org and click on " Register Here ", then submit
2. Under Participating Institutions, Choose "East Tennessee State University" and submit
3. Select your Username and Password, then submit. This is what you are going to use to go in and out of the program. DO NOT FORGET IT!!!!
4. Fill out Registration Page, then submit information
5. Select IRB Reference Resource Group
6. Select the three modules above and complete those three modules.
7. Inform the ETSU/VA IRB Coordinator at 439-6055 that you are submitting a HUD and have completed these three modules. You will not be able to print a certificate when you are only completing these modules, but the ETSU CITI administrator will be able to verify completion.

Previous Users of CITI Training Program

1. Check your CITI Completion Report to determine if you have completed these three modules in the past 3 years. If yes, notify the ETSU/VA IRB Coordinator at 439-6055 for verification.
 2. If you have not, go to www.citiprogram.org and enter your username and password.
 3. Click "Add a course or update your learner groups" then click on "update groups"
 4. Change your learner group to IRB Reference Resource Group and click "continue"
 5. Click "go back to learner's main menu"
 6. Enter this course group, select the three modules above and complete those three modules.
 7. Inform the ETSU/VA IRB Coordinator at 439-6055 that you are submitting a HUD and have completed these three modules. You will not be able to print a certificate when you are only completing these modules, but the ETSU CITI administrator will be able to verify completion.
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IRB Review

The ETSU/VA IRB may approve the use of the device in general, use of the device for groups of patients meeting a certain criteria, or use of the device under a treatment protocol. The use of the device should not exceed the scope of the FDA approved indication. If the IRB wishes, the IRB may specify limitations on the use of the device based upon one of more measures of disease progression, prior use and failure of any alternative treatment modalities, reporting requirements to the IRB or IRB Chair, appropriate follow-up precautions and evaluations, or any other criteria it determines to be appropriate.

Use of HUD Outside of Approved Indication For Emergency Use

For use of the HUD outside of its approved indication of use in an emergency situation, refer to the procedures in IRB Policy 20, Emergency Use of a Test Article (Appendix A).

Use of HUD Outside of Approved Indication For Compassionate Use

For compassionate use of the HUD outside of its approved indication, **prior to use**, the PI must provide both the HDE holder and the ETSU/VA IRB with the following information:

- ⇒ a description of the patient's condition and
- ⇒ the circumstances necessitating use of the device,
- ⇒ a discussion of why alternative therapies or diagnostics are unsatisfactory
- ⇒ information to address the patient protection measures
- ⇒ a schedule for monitoring the patient, taking into consideration the specific needs of the patient and the limited information available regarding the risks and benefits of the device for this unapproved use.

The request for compassionate use must be reviewed and approved by the ETSU/VA IRB Chair prior to the proposed use. The ETSU/VA IRB Chair will obtain FDA guidance and/or approval as necessary.

Informed Consent

The regulations do not require informed consent because an HDE provides for marketing approval, and so use of the HUD does not constitute research or an investigation which would normally require informed consent. Although consent is not required by the FDA regulations, consent may be required by State law or institutional policy. The manufacturer-provided patient information must be provided to each patient and prospectively reviewed with the patient to allow the patient to make an informed decision. The patient file must document this provision of information as well. The IRB may impose the requirement for written informed consent or more stringent restrictions for use of the HUD as deemed necessary.

If the HUD is the subject of a clinical investigation (one in which safety and effectiveness data is being collected to support a PMA), IRB approval and informed consent are required.

When the use of a HUD is for diagnosis or treatment, and not for research or data collection, HIPAA regulations for research do not apply. However, HIPAA regulations for hospital medical records per the Institutional Policies are applicable.

Approval Period

The IRB may approve the use of the device for a period not to exceed one year. The IRB may choose to approve the device for a specific number of patients and require a summary report before approving the use in additional patients.

Reporting

The PI must promptly report any FDA action(s) regarding the HUD to the IRB. Amendments, Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSOs) and continuing reviews are required to be reported according to IRB Policies and Procedures. In addition, these occurrences are to be reported to the FDA and/or manufacturer per 21 CFR 803.30. IRB submissions of amendments, UPIRTSOs and continuing review will be reviewed at the level for which criteria is met. Form 207 is submitted to request continuing review or closure.

Source: IRB Policy 35 (available on website)

Appendix A– IRB Policy 20: IRB Emergency Use Policy Revision Date May 15, 2007

I. Summary Policy

The policy of both the East Tennessee State University Campus Institutional Review Board (ETSU IRB) and the East Tennessee State University/Veterans Affairs Institutional Review Board (ETSU/VA) IRB is that all applicable rules and regulations will be followed in the Emergency Use of a Test Article / Single-Patient Use.

II. Definition

Emergency use is defined as the use of a test article (e.g., investigational drug, device or biologic) on a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval for the use. The investigator is still required to obtain consent under these circumstances. The FDA exempts from IRB review the emergency use of a test article so long as the emergency use is reported to the IRB within five working days of its occurrence. Any subsequent use of the test article is subject to IRB review [21 CFR 50.23; 21 CFR 56.104(c)]. When emergency care involves investigational drugs, devices, or biologics, FDA requirements must be satisfied.

III. Emergency Use

When an investigator identifies a need for emergency use of a test article, the following procedures must be implemented:

- The IRB Chair or Vice Chair, or in their absence, a physician member of the IRB should be contacted. If the Chair is not an M.D., the Chair will make immediate contact with a qualified physician who is either 1) a member of the IRB, or 2) referred to the Chair by the member-physician as a qualified consulting-physician for concurrence on the emergency use approval. When the IRB Chair or Director receives a request for emergency use from a clinical investigator, the IRB Chair will examine each case, receive a collaborating statement from a physician associated with neither the patient nor the current attending physician (consult) supporting the emergency use and, upon request, assure the institution that the emergency use was justified. A copy of the FDA 1572 and approved IND or IDE will be requested of the investigator.

- The investigator must report the emergency use of the test article to the IRB within five (5) working days. The ETSU/VA IRB Chair reviews this report using the ETSU/VA Form 100 checklist and determines whether the circumstances of the emergency use complied with regulatory requirements. If the use meets the regulatory requirements, the investigator is notified of this determination by phone and in writing. If the use does not meet the regulatory requirements, the investigator is notified verbally and in writing that if the investigator goes forward with the use, the use will likely be in non-compliance with federal regulations.

IV. Subsequent Use

Any subsequent use of the test article is subject to full IRB review. Subsequent use means any use of the test article that occurs after its initial emergency use. Should the investigator or IRB anticipate a subsequent need to use the test article, a complete formal application must be made for IRB review at a convened meeting.

V. Emergencies for which Informed Consent is not Feasible

In some emergency circumstances, it may not be feasible to obtain informed consent prior to using the test article. The regulations [21 CFR 50.23(a)(1-4) and (b-c)], [.116(d)(3) and .116(d)(4)(f)], therefore provide an exception for informed consent requirements for such situations. Except as stated below, in order for the exception to apply, both the investigator and a physician who is not otherwise participating in the clinical investigation must certify in writing all of the following: (1) the subject is confronted by a life-threatening situation necessitating use of the test article; (2) the subject is unable to provide effective consent; (3) there is insufficient time in which to obtain consent from the subject's legal representative; and (4) there is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the subject's life.

If, in the investigator's opinion, immediate use of the test article is necessary to save the life of the subject and there is insufficient time to obtain the independent certification required before using the test article, the investigator is to make his or her own written determinations as outlined above, and within five (5) working days after the use of the test article, obtain the written review and evaluation of a physician who is not participating in the clinical investigation.

Documentation, in both instances, must be submitted to the IRB Coordinator within (5) working days after the use of the test article. The ETSU/VA IRB Chair reviews this report using the ETSU/VA Form 100 checklist and determines whether the use of the exception for informed consent requirements complied with regulatory requirements. If the use meets the

regulatory requirements, the investigator is notified of this determination in writing. If the use does not meet the regulatory requirements, the use is handled according to the IRB non-compliance policy.

References:

21 CFR 56.101 (d)

45 CFR 46.103(b)

45 CFR 46.116 (f)

OHRP Guidance

OHRP Compliance Activities: Common Findings and Guidance

Appendix B– Form 200 (Initial Submission) and Form 207 (Continuing Review/ Closure submission)

Note: For submission, please obtain forms from the IRB website, www.etsu.edu/irb. The forms may undergo revisions and the most current form must be submitted. The forms are included here to assist you understand the type of information the IRB will require to review a HUD.

REQUEST FOR REVIEW OF HUMANITARIAN USE DEVICE (HUD)

Form 200 Version Date 5/23/07

ETSU/VA IRB

ALL INFORMATION MUST BE TYPED ♦ ENSURE ALL QUESTIONS ARE ANSWERED.

1.	Proposed Performance Sites:	<input type="checkbox"/> James H. Quillen VAMC <input type="checkbox"/> JCMC <input type="checkbox"/> Other MSHA Site(s) List: <input type="checkbox"/> Other site(s) List:		
2.	Principal Investigator:		Contact for IRB Correspondence (<i>write "self" if applicable</i>):	
Department:			Department:	
Campus Box #:			Campus Box #	
Off-Campus Address:			Off-Campus Address:	
Email Address:			Email Address	
Work Phone:			Work Phone:	
Alternate Phone:			Alternate Phone:	
Fax Number:			Fax Number:	
3.	Device Manufacturer Information: Name: Address: Contact Name: Telephone Number:			
4.	Generic Name of HUD: Trade Name of HUD: FDA Humanitarian Device Exemption (HDE) number: Date of HUD Designation:			
5.	Is the HUD the subject of a clinical investigation (one in which safety and effectiveness data is being collected to support a PMA)? <input type="checkbox"/> Yes* <input type="checkbox"/> No If yes, do not complete this form. Instead submit a complete IRB submission packet.			
6.	Description of the HUD: <ol style="list-style-type: none"> a. Describe the device. b. Describe the indication(s) for use of the device. c. Describe the contraindications, warnings and precautions for the use of the device. d. Describe the alternative practices and procedures. e. Provide a summary of studies using the device. 			
7.	Description of the patient population: <ol style="list-style-type: none"> a. Does the list of potential participants include vulnerable populations (populations that are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally 			

disadvantaged persons)?

If yes, describe the additional safeguards included to protect the rights and welfare of the participants.

b. List the criteria for inclusion and exclusion below (must be within the scope of the FDA approved indication).

c. Explain the procedures that will be used to determine eligibility.

8. Description of the consent process:
- a. Describe how information will be provided to patients.

 - b. Describe how this process will be documented.

9. Description of the risks:
- a. Describe the adverse effects of the device on health and the potential risks and discomforts to patients.

10. Description of benefits:
- 11. Describe the potential benefits to patients.

11. Description of alternatives:
- a. Discuss any alternative treatments or procedures (if any) that the patient may wish to consider in lieu of clinical application of the HUD.

12. Description of costs:
- 13. Describe what the patient will be told about the cost of the device and procedure and how insurance/Medicare will handle billing for this device and procedure.

13. Description of device storage plan:
- a. Describe how the device will be handled, dispensed and stored to ensure that it is used only for appropriate patients.

14. List any other physicians for whom you are requesting authorization to use this HUD:

Name	Dept or Affiliation

15. Provide a bibliographic listing of pertinent literature:

<p>16.</p>	<p>Conflict of Interest</p> <p>17. Is there a potential conflict of interest for the Principal Investigator or other personnel? <input type="checkbox"/> yes <input type="checkbox"/> no</p> <p><i>The thresholds of ownership described below apply to the aggregate ownership of an individual investigator, his/her spouse, domestic partner and dependent children (e.g., if an investigator, his/her spouse, domestic partner and dependent children own together \$10,000 or 5% worth of equities in the sponsor, it should be reported below). Do not consider the combined ownership of all investigators.</i></p> <p>b. If "Yes", check all that apply and provide explanation:</p> <p><input type="checkbox"/> financial interest in the research with value that can not be readily determined</p> <p><input type="checkbox"/> financial interest in the research with value that exceeds the specified monetary threshold (\$10,000) or 5% ownership</p> <p><input type="checkbox"/> has received or will receive compensation whose value could be affected by the study outcome.</p> <p><input type="checkbox"/> has a proprietary interest in the research included but not limited to, a patent, trademark, copyright or licensing agreement, or the right to receive royalties from product commercialization.</p> <p><input type="checkbox"/> has received payments from the sponsor that exceed the specified monetary threshold (\$10,000) in the past year.</p> <p><input type="checkbox"/> is executive or director of the agency or company sponsoring the research</p>
<p>17.</p>	<p>PI Attestation:</p> <p>The information contained in this request for HUD review accurately represents the HUD and the proposed use of this device.</p> <p>I will promptly inform the Institutional Review Board of (1) any proposed changes in approved research and will not initiate changes without IRB review and approval with the following exception: a change can be made prior to IRB approval when necessary to eliminate apparent immediate hazards to the research subjects. In such a case, I will inform the IRB promptly of the change following its implementation (within 10 working days). I will promptly inform the IRB of (2) any unanticipated problems involving risks to participants or others (within 10 working days). I agree to fulfill continuing review requirements at the designated ETSU/VA IRB intervals. In addition, I agree to report events to the FDA and/or manufacturer as required in 21 CFR 803.30. I agree to promptly report any FDA action(s) regarding the HUD to the ETSU/VA IRB. I agree to follow ETSU/VA IRB policy regarding the off-label use of a HUD in emergency or compassionate situations.</p> <p>_____</p> <p>Signature of PI Date</p> <p>Printed PI name:</p>
<p>18.</p>	<p>REQUIRED SUBMISSION DOCUMENTS (collated):</p> <ol style="list-style-type: none"> 1. 30 Signed copies of this form 2. 30 copies of the FDA HDE approval letter and any other pertinent correspondence 3. 30 copies of the manufacturer-provided patient information. 4. 30 copies of the HUD manufacturer's product labeling, clinical brochure, and/or other pertinent manufacturer informational materials (i.e., Summary of Safety and Probable Benefit and Product Information Summary) 5. If at MSHA, completed MSHA Research Request Form 6. One original Unaffiliated Investigator Agreement, as applicable

4.	CURRENT HUD STATUS
<input type="checkbox"/>	The HUD has not been used in any patients since the most recent IRB approval.
<input type="checkbox"/>	The HUD has been used in one or more patients since the most recent IRB approval.
<input type="checkbox"/>	Use of the HUD is complete, and all contact with recipients, records, and/or specimens is complete. Please close this study. <u>If this option is selected</u> , please provide the reason for closure: IN ADDITION, PLEASE FORWARD FINAL REPORTS, ANY PROGRESS REPORTS, AND PUBLICATIONS TO THE IRB AS AVAILABLE.
<input type="checkbox"/>	Never Initiated/Terminated. Sign last page and submit.

5.	MODIFICATIONS		
A.	Is a modification being submitted with this form 207?		<input type="checkbox"/> YES <input type="checkbox"/> NO
B.	Since the most recent IRB approval have there been any changes (including amendments or modifications)?	<input type="checkbox"/> YES <input type="checkbox"/> NO	<u>If YES</u> , have those changes been reported to the IRB? <input type="checkbox"/> YES <input type="checkbox"/> NO <u>If NO</u> , please submit a Modification Request with this Form 207
C.	Please summarize the changes and comment specifically on whether the changes alter the risk to patients:		
D.	Since the most recent IRB approval, has there been a change to the HUD FDA status, manufacturer's product labeling, clinical brochure, manufacturer-provided patient information and/or other pertinent manufacturer informational materials (i.e., Summary of Safety and Probable Benefit and Product Information Summary)?	<input type="checkbox"/> YES <input type="checkbox"/> NO	<u>If YES</u> , has the updated information been submitted to the IRB and if applicable, the VA R&D? <input type="checkbox"/> YES <input type="checkbox"/> NO <u>If NO</u> , please submit with this Form 207.
E.	Have there been any changes to the HUD, adverse events, or any other matters that make it necessary to change the manufacturer-provided patient information at the time of this submission?	<input type="checkbox"/> YES <input type="checkbox"/> NO	<u>If YES</u> , attached the revised patient information and Modification Request Form detailing the changes.

6.	PATIENT POPULATION:		
A.	ENROLLMENT		
	Total number of patients who have received a HUD at local site since the initial ETSU/VA IRB HUD approval was granted (including any withdrawals by participant, PI or sponsor)		
	Total number of patients who received a HUD at local site since the most recent IRB approval (including any withdrawals by participant, PI or sponsor)		
	Since the initial ETSU/VA IRB approval was granted, how many patients have withdrawn?		
B.	Are adequate security measures in place to prevent unauthorized access to patient identifiers?	<input type="checkbox"/> YES <input type="checkbox"/> NO	
C.	Was each use of the HUD since the most recent IRB approval within the FDA-approved clinical indication?	<input type="checkbox"/> YES <input type="checkbox"/> NO* (* If NO , attach explanation and label 6C) <input type="checkbox"/> N/A, No HUDs used since last approval	
C.	Summarize the clinical outcomes of patients who received the HUD since the most recent IRB approval.	<input type="checkbox"/> N/A, No HUDs used since last approval	

7. PATIENT CONSENT INFORMATION			
A.	Did the IRB require the use of a written informed consent document for this study?	<input type="checkbox"/> YES <input type="checkbox"/> NO	If YES , submit a copy of the currently approved informed consent document and two (2) clean copies of the identical informed consent document for approval and date stamping for use during the next approval period. (However, if modification that revises ICD is being submitted with this Form 207, then submit two (2) clean copies of the revised ICD for approval and date stamping - see Question #5)
B.	Was the manufacturer-provided patient information reviewed with all patients prior to the use of the HUD?	<input type="checkbox"/> YES <input type="checkbox"/> NO	If NO , provide explanation.

8. ADVERSE EVENTS/UPIRTSO'S/COMPLAINTS/PROTOCOL DEVIATIONS			
A.	Since the previous IRB approval, have there been any unanticipated problems involving risks to participants or others (including non-local sites)?	<input type="checkbox"/> YES <input type="checkbox"/> NO	If YES , attach a brief description summarizing the unanticipated problems involving risks to subjects or others and specifically confirm that the events have been reported to the IRB. (Label 8a)
B.	Since the most recent IRB approval have there been any participant complaints regarding the HUD?	<input type="checkbox"/> YES <input type="checkbox"/> NO	If YES , attach a brief description summarizing the complaints and specifically confirm that complaints have been reported to the IRB. (Label 8b)
C.	Since the most recent IRB approval have there been any violations and/or deviations from the FDA approval indication or the ETSU/VA IRB HUD approval?	<input type="checkbox"/> YES <input type="checkbox"/> NO	If YES , please complete the following: Have those violations/deviations and been reported to the IRB? <input type="checkbox"/> YES <input type="checkbox"/> NO Please attach a description summarizing these violations/deviations and comment specifically on whether the changes alter the risks to participants. (Label 8c)
D.	Have any ADVERSE EVENTS or UNEXPECTED EVENTS occurred during this reporting period?	<input type="checkbox"/> YES <input type="checkbox"/> NO	
If YES , please complete the following: Have ALL EVENTS and their OUTCOMES been reported to the ETSU/VA IRB? <input type="checkbox"/> YES <input type="checkbox"/> NO			
Note: Please attach a description summarizing the events (or attach log or spreadsheet), and comment specifically on whether the events alter the risks to participants. (Label 8d)			
E.	Were patients informed of updated ADVERSE REACTIONS and SIGNIFICANT NEW FINDINGS associated with the HUD and given the OPTION of CONTINUING or WITHDRAWING?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	

9. UPDATED INFORMATION			
A.	Since the most recent IRB approval has any literature relevant to the HUD been published?	<input type="checkbox"/> YES <input type="checkbox"/> NO	If YES , attach a summary of relevant findings and a brief description. (Label 9a)
B.	Since the most recent IRB approval have there been any interim findings, progress reports, or other reports?	<input type="checkbox"/> YES <input type="checkbox"/> NO	If YES , attach copies and a brief description. (Label 9b)
C.	Since the most recent IRB approval has there been any other information relevant to this HUD discovered, especially information about the risks and benefits associated with the HUD?	<input type="checkbox"/> YES <input type="checkbox"/> NO	If YES , attach copies of the information. (Label 9c)

10.	Since the most recent IRB approval, have the local HUD records been audited?	<input type="checkbox"/> YES <input type="checkbox"/> NO
If YES, please complete the following: 1. Who conducted the audit: 2. Date the audit was conducted: 3. If the audit was not conducted by the IRB, has the Human Research Protections Program IRB Administration been notified of the visit/audit and the outcome? <input type="checkbox"/> YES <input type="checkbox"/> NO If NO, please attach report.		

11.	INVESTIGATOR'S CONFLICT OF INTEREST (COI) STATEMENT	
Has a NEW conflict of interest developed since the previous IRB approval for the Principal Investigator or other study staff (authorized physicians)? <input type="checkbox"/> *YES <input type="checkbox"/> NO Note: Assessment should include anyone listed as Principal Investigator, or other research personnel on study. The thresholds of ownership described below apply to the aggregate ownership of an individual investigator, his/her spouse, domestic partner, and dependent children (e.g., if an investigator, his/her spouse, domestic partner and dependent children own together \$10,000 or 5% worth of equities in the sponsor, is should be reported below). Do not consider the combined ownership of all investigators. If YES, has the COI been reviewed by ETSU, and VA R&D (if applicable) <input type="checkbox"/> YES <input type="checkbox"/> NO		

12.	PRINCIPAL INVESTIGATOR'S ASSURANCE STATEMENT	
I certify that the information provided herein is complete and accurate to the best of my knowledge and that the conditions of the ETSU/VA IRB HUD approval were followed during the period covered by the PROJECT REPORT. <hr style="width: 50%; margin-left: 0;"/> <div style="display: flex; justify-content: space-between;"> Principal Investigator's Signature Date </div>		

PLEASE BE ADVISED THAT TO APPROPRIATELY AND COMPLETELY REVIEW HUMAN SUBJECT RESEARCH, AND IN COMPLIANCE WITH THE FEDERAL MANDATES, THE DEADLINE MUST BE STRICTLY ENFORCED. INCOMPLETE FORMS WILL NOT BE ACCEPTED.
IRB approval will expire if the completed Form 207 along with any pertinent documents are not received and approved prior to the expiration date.
Return Form to: IRB Administration, PO BOX 70565, Johnson City, TN 37614

IRB STAFF

Janine Richardson, HRPP Director

423- 439-6054
richardf@etsu.edu

Teresa Doty, IRB Coordinator (Medical)

423-439-6055
doty@etsu.edu

Aracelis Vasquez, IRB Coordinator (Campus)

423- 439-6002
vasqueza@etsu.edu

Beth Aimee Every

IRB Administrative Assistant

423-439-6053
every@etsu.edu

VA Administrative Staff

Owen Murnane, Ph.D.

Interim Associate Chief of Staff for Research

423-979-2859
Owen.murnane@va.gov

Paul Williamson

VA Administrative Officer

423-979-2662
Paul.williamson@va.gov

Sharon Neas

Research Administrative Assistant

423-979-2859
Sharon.neas@va.gov



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Office for the Protection of Human Research Subjects

PO Box 70565
Johnson City, TN 37614
Phone: (423) 439-6053
Fax: (423)0439-6060
Website: www.etsu.edu/irb