

New Study Cover Sheet - Human Use
VA Human Research Protection Program (HRPP)
NF/SG VHS Gainesville, FL (573)

HRPP Office received on:

Please Print or Type

Please check all items included in attached packet/Do Not Staple:

Form/Packet Date of Submission:	
VA PI Last Name:	VA PI First Name:
IRB#:	
PI Tele #: <u>352-376-1611</u> Ext:	
VA PI Email Address:	
Mail Code:	
Title of Protocol (as submitted to IRB-01):	

Proj Coord Name:	Email:	Tele #: <u>352-376-1611</u>	Ext:
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This study has a UF PI, Name:	Tele #:	Ext: <u> </u>
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Note: myIRB will **NOT** accept New VA Submissions without the approved HRPP Documents – these will be provided to you **after** the study has gone through the Pre-Review Process.

When filling out the following forms, please ensure that all sections are completed and where signatures are required, they are obtained. Incomplete submissions will NOT be sent out for Pre-Review.

* Make sure that you have visited the website for the latest forms:
<http://www.northflorida.va.gov/NORTHFLORIDA/Research/SCICOM.asp>

VA Required Documents:

- Medical Center Support Form – *please ensure that you have your Director/Section/Service Chief's Signature.*
- For new PIs Only:** Page 18
- Abstract – *word format*
- Research Safety Coversheet and Safety Evaluation Form
- If you are going to be requesting data from Clinical Informatics -** VA Form 10-0403
- If Study includes Investigational Device:** Investigational Device Information Sheet (IDE)
- If Study includes Investigational Drugs: (IDS)**
 - Investigators Brochure
 - FDA Form 1572
 - VA Form 10-9012

For Each VA Person involved in the study, please include the following:

- CITI Training Certificates - only attach Human Subjects Protection and Good Clinical Practices module
- Research Scope of Practice, Clinical Privileges or Functional statement
- Conflict of Interest Forms

myIRB Documents:

- myIRB Submission – add Hattie Grant and Regina Redman as Guest to the study
- VA Informed Consent
- HIPAA Authorization – in word format
- Addendum V
- Protocol
- Questionnaires, Ads, etc
- Data Collection Form – this can be a word or excel document
- Other:

Do not upload any attachments into the myIRB section labeled “Privacy & Security” Assessment. These documents will be provided to you after the study has gone through the Pre-Review Process.

Please remember that NO Research can begin until you have received Final R&D Committee Approval

Principal Investigator Signature (Required):	Date:
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NF/SG VHS Gainesville, FL (573)
VA Research Human Protection Program (HRPP) Coversheet
Please Print or Type, Do Not Staple, No Double-siding

Training, Conflict of Interest, Research Scope of Practice for VA Personnel on Study

TRAINING NOTE: VA CITI training (Human Subjects Protection and Good Clinical Practices) must be completed before research will be approved by the R&DC. CITI Training must be updated every 2 years thereafter (within 730 days of the previous training).

RESEARCH SCOPES OF PRACTICE NOTE: All VA research personnel must have a research scope of practice statement or functional statement that has been approved by the individual's immediate supervisor and the ACOS/R&D that defines the duties the person is allowed to perform for research purposes unless the individual's clinical privileges, scope of practice or functional statement include all of the duties necessary for a specific research study. If there are additional duties, these need to be included in a research scope of practice statement. Research Office is required to maintain current research scopes of practice for all non-privileged research personnel.

Name(s): (Last, First) <i>-List only VA personnel</i>	Degree(s)	Project Role*	VA Appt (VA, WOC, IPA). If VA appt, please indicate percentage e.g. 5/8.	Clinical Privileges, Scope of Practice or Functional Statement. One of the following must be submitted.	Conflict of Interest Form (Must include for each person on the study)	VA CITI: Human Research Curriculum - Good Clinical Practice Training	
				Form Attached	Form Attached	Certificate Attached:	Date of Training:
		VA PI		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

***Project Role, please note:** VA PI, Co-PI or SI, Sub-I, Coordinator, Research Assistant, and Other