

HRPP Office received on:

**REVISION SUBMISSION- Human Use**  
**VA Human Research Protection Program (HRPP)**  
**NF/SG VHS Gainesville, FL (573)**  
*Please Print or Type*

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

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

<b>Proj Coord Name:</b>	<b>Tele #:</b> <u>352-376-1611</u> <b>Ext:</b>
<b>Email:</b>	

<input type="checkbox"/> <b>This study has a UF PI, Name:</b>	<b>Tele #:</b>
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**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 processed.**

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

**NOTE:** The IRB **does NOT** approve the separate HIPAA Authorization.  
If you have changes to the HIPAA Authorization, please submit a clean (in word format) and tracked change copy to the HRPP Office ([Regina.Redman@va.gov](mailto:Regina.Redman@va.gov)) prior to submitting a revision to the IRB. The authorization will be sent to the Privacy Officer for review and approval. Once approved, the **HRPP Office will provide** an approved authorization back to you to submit with your revision packet to the IRB.

**1. myIRB Documents:**

myIRB Submission – if this is a myIRB submission, just check this box and the HRPP Office will pull the myIRB revision submission from the myIRB database.

**2. Paper IRB Submissions (prior to myIRB submissions):**

- IRB Approval Letter for the Revision
- IRB Revision Complete Packet – clean and tracked changes
- Stamped Approved ICF – (if applicable)

**3. VA Required Documents:**

- Medical Center – please submit if there are any changes that will impact the support form.
- Abstract – *word format*
- Safety Evaluation – please visit the following link to see if you need to submit a new safety evaluation or an amendment.  
<http://www.northflorida.va.gov/NORTHFLORIDA/Research/SafetyCom.asp>
- Other Attachments included are:

**4. If adding study personnel to the study, we would need one of each of the following documents for each person:**

- CITI Training Certificates – please just fill out the 2<sup>nd</sup> page of this coversheet with the dates of the training.
- Conflict of Interest Forms
- Scope of Practice/Clinical Privileges – if this is a new person to the VA and has not submitted one of the following, one would need to be submitted with the revision.

**CONTACT INFORMATION:**

- You can email the continuing review submission to the HRPP Specialist: [Regina.Redman@va.gov](mailto:Regina.Redman@va.gov).
- If you do not have access to scan and email the documents, please drop off the submission in an inter-office envelope and in the document safe located in the 5<sup>th</sup> Floor Copier room# E584-1.

**Should you have any questions, please feel free to contact the HRPP Office at x5310 or x4994.**

<b>Principal Investigator Signature:</b>	<b>Date:</b>
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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:** Scopes of Practices are collected once a year at the beginning of each fiscal year. If you have a new study staff person being added to the study, please submit a Scope of Practice with the Revision paperwork.

**ALL personnel on the study must have one of the following: Scope of Practice, a Functional Statement or Clinical Privileges.**

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.	Conflict of Interest Form (Must include for each person on the study)	VA CITI: Human Research Curriculum - Good Clinical Practice Training
				Form Attached	Date of Training:
		VA PI		<input type="checkbox"/>	
				<input type="checkbox"/>	
				<input type="checkbox"/>	
				<input type="checkbox"/>	
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				<input type="checkbox"/>	

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