

**CONTINUING REVIEW/CLOSURE SUBMISSION/ADVERSE EVENT- Human Use**

VA Human Research Protection Program (HRPP)

NF/SG VHS Gainesville, FL (573)

*Please Print or Type and Do Not Staple*

HRPP Office rcvd on:

You are submitting a:  Continuing Review  Closure  Adverse Event

Date of Submission: \_\_\_\_\_ IRB#: \_\_\_\_\_ Mail Code: \_\_\_\_\_

VA PI Last Name: \_\_\_\_\_ VA PI First Name: \_\_\_\_\_

PI Tele #: 352-376-1611 Ext: \_\_\_\_\_ VA PI Email Address: \_\_\_\_\_

Title of Protocol (as submitted to IRB-01): \_\_\_\_\_

Proj Coord Name: \_\_\_\_\_

Email: \_\_\_\_\_ Tele #: 352-376-1611 Ext: \_\_\_\_\_

This study has a UF PI, Name: \_\_\_\_\_ Tele #: \_\_\_\_\_ Ext: \_\_\_\_\_

**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>

**1. VA Required Documents:**

- VA Annual Renewal Form
- VA Annual Renewal Form for Exempt or Non-Human Studies
- Abstract – *word format*
- Safety Renewal (*if applicable*) – if the study originally had safety concerns, please submit the safety renewal to the Safety Coordinator and the forms and contact information can be found at the following link:  
<http://www.northflorida.va.gov/NORTHFLORIDA/Research/SafetyCom.asp>
- Date Submitted to the Safety Coordinator:

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

- CITI GCP 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 – the HRPP Office will obtain the COI Administrators Signature.
- If **Closing** the study, the COI or CITI training documents are **not required**.

**3. myIRB Documents:**

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

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

- IRB Approval Letter for Continuing Review or Closure
- IRB Continuing Review Packet or IRB Closure Packet
- Stamped Approved ICF – (*if applicable*)

**5. Adverse Event (page 2 of this coversheet is not needed):**

- IRB Approval Letter  Date of A/E: \_\_\_\_\_  IRB A/E packet/myIRB submission
- Serious  Unexpected **and**  Local  Non-Local

**ADDITIONAL INFORMATION:**

- You can email the continuing review/closure/AE submission to the HRPP Specialist: [Regina.Redman@va.gov](mailto:Regina.Redman@va.gov).
- If you do not have access to scan the documents, please drop off the submission in an inter-office envelope and place them 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.**

Principal Investigator Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**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"/>	
				<input type="checkbox"/>	
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				<input type="checkbox"/>	
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				<input type="checkbox"/>	

**NOTE:** If you are submitting a Closure or an Adverse Event, this page is not required.

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