

## Key Personnel Changes

- Key personnel changes may receive expedited review (review by one IRB member).
- All IRB submission forms must be the current form date (down load from <http://irb.wayne.edu/forms-requirements-categories.php>) and typed or computer generated.
- NOTE: Minor changes that involve no more than minimal risk and minor changes in approved research as stated in 45 CFR 46.110 of the federal regulations may qualify for expedited review.
- **\*Forward your @wayne.edu e-mail** to your @med.wayne.edu, @karmanos.org, etc. e-mail in order to receive important e-mail communications regarding your study if you do not access your @wayne.edu e-mail **OR** go to **Pipeline** and enter the e-mail account that you wish to use. Non-WSU employees, please enter your e-mail. An e-mail address is required.
- Submit this form with original signatures—no faxed or copied signatures.
- Please call us if you have any questions along the way: (313) 577-1628

### Section A: Principal Investigator (PI)

1.	Name of PI		Department	
2.	<b>PI's SIGNATURE</b>		Fax	
3.	Address		Pager	
			<b>*E-Mail</b>	
			Telephone	
4.	Form Completed By		Date	
	Telephone		<b>*E-mail</b>	
	Name of Faculty Sponsor:	<input type="checkbox"/> N/A	<b>*E-mail</b>	

### Section B: Protocol Information

5.	COEUS#	
6.	IRB # (ex.#####MP2E)	
7.	Project Title	
8.	Is this a change to a VAMC personnel?	<input type="checkbox"/> Yes (Please attach VA CIC approval memo) <input type="checkbox"/> No
9.	Expiration Date	
10.	Is this protocol closed to recruitment?	<input type="checkbox"/> Yes <input type="checkbox"/> No

**Section C: Proposed Amendment**

<b><u>Deletion of Key Personnel</u></b>																																	
11.	Print the names and research roles of people to be <b>deleted</b> from study:  Add an additional page if more space is needed	<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 40%; border-bottom: 1px solid black;">Name</th> <th style="width: 55%; border-bottom: 1px solid black;">Research Role</th> </tr> </thead> <tbody> <tr><td>1)</td><td></td><td></td></tr> <tr><td>2)</td><td></td><td></td></tr> <tr><td>3)</td><td></td><td></td></tr> <tr><td>4)</td><td></td><td></td></tr> </tbody> </table>		Name	Research Role	1)			2)			3)			4)			<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 5%;"></th> <th style="width: 40%; border-bottom: 1px solid black;">Name</th> <th style="width: 55%; border-bottom: 1px solid black;">Research role</th> </tr> </thead> <tbody> <tr><td>5)</td><td></td><td></td></tr> <tr><td>6)</td><td></td><td></td></tr> <tr><td>7)</td><td></td><td></td></tr> <tr><td>8)</td><td></td><td></td></tr> </tbody> </table>		Name	Research role	5)			6)			7)			8)		
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<b><u>Addition of Key Personnel</u></b>																																	
12.	<p><b>CITI Training:</b>  <u>ALL</u> personnel being added must have completed the <u>CITI training</u> program at <a href="https://www.citiprogram.org/Default.asp">https://www.citiprogram.org/Default.asp</a>                      Affiliate with WSU for courses to count. Further directions at: <a href="http://irb.wayne.edu/mandatory-training.php">http://irb.wayne.edu/mandatory-training.php</a>                      HIPS= Health Information, Privacy &amp; Security RCR= Responsible Conduct of Research (under "Human Subject Research" tab)</p> <p>a) Have <b>all</b> of the personnel taken:    <input type="checkbox"/> HIPS        <input type="checkbox"/> RCR &amp;        <input type="checkbox"/> Basic/Refresher Course for Human Subjects?                         <input type="checkbox"/> Yes        <input type="checkbox"/> No - <b>STOP</b>: do not submit this form until above trainings are complete for <b>ALL</b> personnel.</p> <p>b) If taken under a former name (maiden), what is that name?</p>																																

13.

**Financial Conflict of Interest (FCOI) and Research Role:**

**If any response below is "yes,"** there must be a "Financial Conflict of Interest Detailed Disclosure Form" submitted directly to the Financial Conflict of Interest Committee **prior** to the time of this amendment submission and then annually or when changes occur.

**If any response below is "yes,"** the FCOI committee communication for this amendment **must be included** with this submission. If this communication is not included, then the amendment *cannot* be submitted to the IRB.

- FCOI form and more information are available at [www.research.wayne.edu/coi](http://www.research.wayne.edu/coi) For additional information please contact the Conflict of Interest Coordinator at Phone 313-577-9064, 5057 Woodward, Suite 6304, Detroit, MI 48202, Fax 313-577-2159
- **\*Research Role:** Briefly describe their role in the research project. (co-investigator, research nurse, research coordinator, etc)
- **Additional space:** To add more people, use this form: [http://irb.wayne.edu/forms/additional\\_key\\_personnel\\_page\\_11\\_2011.doc](http://irb.wayne.edu/forms/additional_key_personnel_page_11_2011.doc)

**Endorsements and Financial Conflict of Interest Disclosure:**

Objectivity in research is a key component of any research project. One method for maintaining objectivity is to have **all** individuals involved in research design, development, or data evaluation/analysis disclose any potential and/or real financial conflict of interest.

Examples of relevant relationships for potential conflict of interest include but are not limited to:

- (1) receiving past, current, or expecting future income in the form of salary, stock or stock options/warranties, equity, dividends, royalties, profit sharing, capital gain, forbearance or forgiveness of a loan, interest in real or personal property, or involvement in a legal partnership with the sponsor
- (2) receiving past, current, or expecting future income in the form of consulting fees, honoraria, gifts, gifts to the University, or payments resulting from seminars, lectures, or teaching engagements, or service on a non-federal advisory committee or review panel
- (3) serving in a corporate or for-profit leadership position, such as executive officer, board member, fundraising officer, agent, member of a scientific advisory board, member of a scientific review committee, or member of a data safety monitoring committee, regardless of compensation
- (4) inventor on a patent or copyright involving technology/processes/products licensed or expected to be licensed to the sponsor.

See Financial Conflict of Interest policies: <http://research.wayne.edu/coi/docs/wsu-financial-conflict-of-interest-and-commitment-research-policy.pdf> and <http://www.irb.wayne.edu/policies-human-research.php>

Key Personnel Name to be Added	Division/Department	Research Role*	e-Mail Address
1)			
Do you, your spouse or domestic partner, or any of your dependent children have a potential and/or real financial conflict of interest with the sponsor of this project, including all secondary sources? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Signature			
2)			
Do you, your spouse or domestic partner, or any of your dependent children have a potential and/or real financial conflict of interest with the sponsor of this project, including all secondary sources? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Signature			
3)			
Do you, your spouse or domestic partner, or any of your dependent children have a potential and/or real financial conflict of interest with the sponsor of this project, including all secondary sources? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Signature			

4)			
Do you, your spouse or domestic partner, or any of your dependent children have a potential and/or real financial conflict of interest with the sponsor of this project, including all secondary sources? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Signature			

# Stop (IRB Use Only)

IRB Administration Office Review	
1) <b>CITI</b> : Have <b>all</b> persons identified in question 12 completed all required CITI training modules?	<input type="checkbox"/> Yes, all have completed all CITI. <input type="checkbox"/> No - <b>Tell PI and Hold</b> <b>PI told?:</b> <input type="checkbox"/> Yes, on: _____ # 1 Needs: <input type="checkbox"/> HIPS <input type="checkbox"/> RCR <input type="checkbox"/> Basic or Refresher # 2 Needs: <input type="checkbox"/> HIPS <input type="checkbox"/> RCR <input type="checkbox"/> Basic or Refresher # 3 Needs: <input type="checkbox"/> HIPS <input type="checkbox"/> RCR <input type="checkbox"/> Basic or Refresher # 4 Needs: <input type="checkbox"/> HIPS <input type="checkbox"/> RCR <input type="checkbox"/> Basic or Refresher # __ Needs: <input type="checkbox"/> HIPS <input type="checkbox"/> RCR <input type="checkbox"/> Basic or Refresher # __ Needs: <input type="checkbox"/> HIPS <input type="checkbox"/> RCR <input type="checkbox"/> Basic or Refresher # __ Needs: <input type="checkbox"/> HIPS <input type="checkbox"/> RCR <input type="checkbox"/> Basic or Refresher # __ Needs: <input type="checkbox"/> HIPS <input type="checkbox"/> RCR <input type="checkbox"/> Basic or Refresher
2a) <b>Conflict of Interest</b> Have all persons identified in question 12 answered and signed the Conflict of Interest question?	<input type="checkbox"/> Yes <input type="checkbox"/> No <b>Tell PI and Hold</b> <b>PI told?:</b> <input type="checkbox"/> Yes, on: _____
2b) <b>If anyone answered "yes" to the Conflict of Interest question</b> , is the <b>FCOI Committee communication</b> attached?	<input type="checkbox"/> Yes: <input type="checkbox"/> Memo for Category 1 FCOI    or <input type="checkbox"/> FCOI Management plan and Memo of Understanding <b>(Must go to the Full Board)</b> <input type="checkbox"/> No - <b>Return to PI</b> Returned on: _____
3) If <b>VA</b> , is CIC memo attached?	<input type="checkbox"/> Yes <input type="checkbox"/> No - <b>Tell PI and Hold</b> <b>PI told?:</b> <input type="checkbox"/> Yes
4) Is the change in key personnel <b>approved</b> ?	<input type="checkbox"/> Yes <input type="checkbox"/> <b>No, because this MUST GO FULL BOARD</b> <input type="checkbox"/> <b>No: why not?</b>

IRB Administration Staff 's Signature \_\_\_\_\_ Date \_\_\_\_\_

Printed name \_\_\_\_\_