



## 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.
- For information regarding the definition of key personnel see the [IRB's Key Personnel Guidance Document](#)
- **Digital Signatures are required for this form. Open and save form using Adobe or a software that allows for digital signature.**
- 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.	PI's SIGNATURE			
3.	Address		Pager	
			*E-Mail	
			Telephone	
4.	Form Completed By		Date	
	Telephone		*E-mail	
	Name of Faculty Sponsor:	<input type="checkbox"/> N/A	*E-mail	

### 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 or Status Check-in 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.	Type the names and research roles of personnel to be <b>deleted</b> from study:  Add an additional page if more space is needed	Name	Research Role
		1)	
		2)	
		3)	
		4)	
		Name	Research Role
		5)	
		6)	
		7)	
		8)	

<b><u>CITI Training and Key Personnel</u></b>	
12.	<p><b><u>ALL</u></b> 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></p> <p><b>Standard Mandatory Courses:</b></p> <p>(I) Basic Course in Human Subjects Research: Biomedical or Social Behavioral Investigators (Refresher course is required every 3 years)  (II) Responsible Conduct of Research (RCR) Biomedical or Social Behavioral Investigators  (III) Health Information Privacy and Security (HIPS) Module (per research role)</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: do not submit this form until above trainings are complete for ALL personnel.</b></p> <p><b>Additional Courses based on Participant Population enrolled in study and research type:</b></p> <ul style="list-style-type: none"> <li>• Children included as participants (CITI module: 152332 or 152335)</li> <li>• Pregnant Women, Fetuses or Neonates included as participants (CITI module: 152332 or 152335)</li> <li>• Prisoners included as participants (CITI module: 152333 or 152336)</li> <li>• Students included as participants (CITI module: 152334 or 152337)</li> <li>• Internet Research (CITI module: 152338)</li> <li>• International Research (CITI module: 153207)</li> </ul> <p>b) If any of the key personnel completed training under a different name (e.g. maiden name), what is that name?</p>

### 13. Key Personnel 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.

#### **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>

- **FCOI Disclosure:** 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 the Additional Key Personnel Form available on the IRB’s website

**\*Key personnel** are persons engaged in the collection of data or have access to data through intervention or interaction with the participant, including the consent process, or have access to the participant’s identifiable private information. This may include collaborators, fellows, residents, research assistants, research nurses, Co-investigators, etc. Co-PIs are not allowed— only Co-Investigators.

**Key Personnel Research Role and Obligations. By signing below key personnel are attesting to the following:** (I) Agree to complete the required human participant research training and update every three years and (II) Agree to follow the direction of the Principal Investigator to adhere to the IRB approved study protocol, institutional policies, and research regulations.

**The individual key personnel must complete the response for the COI question below, and then digitally sign this form.**

**Digital Signatures are required for this form. Open and save form using Adobe or software that allows for digital signature.**

## 14. Addition of Key Personnel

Key Personnel to be Added	Division/Department	Research Role*	E-Mail Address
1) Name:			
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 <span style="color: red;">If Yes, see FCOI instructions above.</span>			
Signature			
2) Name:			
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 <span style="color: red;">If Yes, see FCOI instructions above.</span>			
Signature			
3) Name:			
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 <span style="color: red;">If Yes, see FCOI instructions above.</span>			
Signature			
4) Name:			
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 <span style="color: red;">If Yes, see FCOI instructions above.</span>			
Signature			
5) Name:			
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 <span style="color: red;">If Yes, see FCOI instructions above.</span>			
Signature			
6) Name:			
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 <span style="color: red;">If Yes, see FCOI instructions above.</span>			
Signature			

