

Submission Documents Details/Instructions

Change In Principal Investigator (PI) Form	<ul style="list-style-type: none"> • Please complete all applicable sections in entirety • Current Principal Investigator digitally signs form • New Principal Investigator completes COI & attestation and digitally signs form • Dean/Department Chair/Authorized Signatory completes COI & Authorization and signs form
Amended Items that require PI Change. Submit if documents included the name and contact information for the current PI	Amended Version
Advertising Materials & items given to participants	<ul style="list-style-type: none"> • 1 copy of current document • 1 clean revised copy for IRB approval stamp (revised documents revision/version dates must be updated) • 1 highlighted revised version
Protocol Revisions	<ul style="list-style-type: none"> • 1 highlighted version with revised protocol/proposal date and version number
Consent, Assent, Information Sheets	<ul style="list-style-type: none"> • 1 copy of current document • 1 clean copy for IRB approval stamp (revised documents revision/version dates must be updated) • 1 highlighted revised version
HIPAA Forms	<ul style="list-style-type: none"> • 1 current approved version • 1 highlighted revised version indicating the changes
Other	<ul style="list-style-type: none"> • 1 copy of current document • 1 clean revised copy for IRB approval stamp, if documents will be provided to participants (revised documents revision/version dates must be updated) • 1 highlighted revised version

Submissions Instructions

Open and save form using Adobe or software that allows for digital signature.

Clearly label all documents with the name of the document and version number/date.

Place the Change in PI Form, any attachments (e.g. consents, assents advertisements, information sheets), in a single zip file and email to: eIRBManager@wayne.edu

Email Subject Line should indicate: **Change In PI Amendment (Current PI's Name and IRB#).**



Change in Principal Investigator

PI changes that require a full board IRB review:

- All VA PI changes, all initially full board reviewed protocols (have an “F” at end of the IRB #) and all expedited studies that have changed into full board review protocols.
- See IRB committee deadlines at: <http://irb.wayne.edu/meetings-deadlines.php>

PI changes that may receive expedited review:

- All expedited and exempt studies that are still categorized as such.
- Expedited and exempt studies: Submit the original form with original signatures (no faxed or copied signature pages).

All studies:

- If there are PI name and contact info changes (ONLY) needed to the consent, etc., you may submit these documents with this form for review (see section D).
- 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.
- *If the current PI is no longer with your **institution** and has not responded to repeated communication, the Chair of the Department may sign, but must indicate this in Section A.
- ****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.
- Please call us if you have any questions along the way: (313) 577-1628

Section A: CURRENT Principal Investigator (PI)

1.	Name of current PI		Department	
2.	Current PI digital SIGNATURE	To provide a digital signature open and save this form using Adobe or the digital signature function will not work properly.		
3.	Address		Pager	
			**E-Mail	
			Telephone	
	Faculty Supervisor		**E-Mail	
4.	Form Completed By		Date	
	Telephone		**E-Mail	
	Should the current PI be:	<input type="checkbox"/> Removed from the study <input type="checkbox"/> Added as key personnel in the research role of:		
5.	Is the current PI available to provide an original signature on this form?	<input type="checkbox"/> Yes – go directly to Q#6 <input type="checkbox"/> No – answer sub-questions (5a, 5b) and obtain a signature from the Department Chair, Dean, or Signatory Official authorizing the PI change		

	<p>a. State why the current PI is unable to provide an original signature (include details regarding attempts to obtain a signature):</p>	
	<p>b. Include documentation (e.g. e-mail) from the current PI acknowledging that a PI change is appropriate, or explain why it is not possible to obtain documentation:</p>	<input type="checkbox"/> Documentation from the current PI is being submitted
Department Chair, Dean, or Signatory Official please go to question 13 to authorize the Change in PI by signing this form.		

Section B: Protocol Information

6.	Coeus Number			
7.	IRB Protocol Number (ex.#####MP2E)			
8.	Current Project Title			
9.	Is this a change in a VAMC PI?	<input type="checkbox"/> Yes (Please attach VA CIC approval memo; VA PI changes will always go full board) <input type="checkbox"/> No		
10.	Expiration Date or Status Check In Date	Is this protocol closed to recruitment?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Section C: Proposed (NEW) Principal Investigator

11.	Proposed PI Information Information for the proposed new Principal Investigator:	Name of new PI:				
		Department				
		Address		Pager		
				E-Mail		
				Telephone		

Reason for the change in PI:	
What are the proposed PI's professional and/or educational qualifications for being the PI on this study?	
What is the plan to inform participants of the change in Principal Investigator?	<p>Participants will not be informed because of the following:</p> <p><input type="checkbox"/> Study is closed to accrual with no participants on treatment or follow-up</p> <p><input type="checkbox"/> Other (explain):</p>
Please also attach a bio-sketch or CV.	<input type="checkbox"/> The proposed PI's bio-sketch or CV is attached
<p>New PI's CITI Training</p> <p>PI must have completed the CITI training program at https://www.citiprogram.org/Default.asp</p> <p>Further directions at: http://irb.wayne.edu/mandatory-training.php Affiliate with WSU for courses to count.</p> <p>HIPS= Health Information, Privacy & Security RCR= Responsible Conduct of Research (under "Human Subject Research" tab)</p> <p>a) Have you taken: <input type="checkbox"/> HIPS <input type="checkbox"/> RCR & <input type="checkbox"/> Basic/Refresher Course for Human Subjects?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No - STOP: do not submit this form until above trainings are complete.</p> <p>b) If taken under a former name (maiden), what is that name?</p>	

12.

Financial Conflict of Interest (FCOI) & Attestation of New Principal Investigator

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 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*

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>

New Principal Investigator FCOI & Attestation Statements

New Principal Investigator's Name

Title

FCOI Statement:

Do you, your spouse or domestic partner, and/or dependent children have a potential and/or real financial conflict of interest with the sponsor of this project (including all secondary sources)?

NO

YES (*if yes, please include the FCOI Management Plan with this submission*)

In signing the description of this research project, the as the PI:

1. Attests to the accuracy of the information provided in this application,
2. Agrees to accept primary responsibility for the scientific and ethical conduct of the research, as approved by the IRB
3. Agrees to abide by the IRB's policies and procedures.
4. Agrees to submit unanticipated problem reports in a timely manner.
5. Agrees to submit a closure report at the conclusion of the study

The PI change does not take effect until the investigator has received documentation of IRB review and final approval.

Is the Principal Investigator's CITI Training up-to-date? Yes No

Signature of Principal Investigator

Date

13.

Department Chair, Dean or Authorized Signatory Official FCOI and Authorization for Change in PI

Open and save form using Adobe or software that allows for digital signature.

Name of the authorized signatory, Dean/Chair

Title

FCOI Statement:

Do you, your spouse or domestic partner, and/or dependent children have a potential and/or real financial conflict of interest with the sponsor of this project (including all secondary sources)?

NO

YES *(if yes, please include the FCOI Management Plan with this submission)*

In signing for submission of this research project: I attest that I am the authorized signatory for the Department Chairperson, Dean, and Institute/Center Director for the above noted College/Department/Institute/Center and agree to the change in Principal Investigator as noted above.

I certify that:

(a) appropriate support will be provided for the research project including adequate facilities and staff;

(b) appropriate scientific and ethical oversight has been and will be provided; and

(c) the research uses procedures consistent with sound research design;

(d) the research design is sound enough to yield the expected knowledge.

Signature of Chair/Dean of the WSU Faculty or authorized signatory

Date

Section D: PI Name Change in Research Documents

14.

Changes to Documents

You may submit any of the following documents with changes to the PI name and contact info **ONLY**.

Please indicate the documents you are submitting:

Consent forms

Assent forms

Oral assent script

Information sheets

Recruiting materials

Other:

Other:

Change in PI Submission Checklist

<input type="checkbox"/>	Current PI signed form if available.
<input type="checkbox"/>	New PI completed the FCOI questions and signed form.
<input type="checkbox"/>	Authorized Signatory completed the FCOI questions and signed form.
<input type="checkbox"/>	New PI CV or bio-sketch attached.
<input type="checkbox"/>	FCOI committee communication attached (if needed).
<input type="checkbox"/>	VA CIC Memo attached (if needed).
<input type="checkbox"/>	All Digital Electronic Signatures completed.
<input type="checkbox"/>	Consent form, etc. and copies (if needed).

Stop (IRB Use Only)

IRB Administration Office Intake & Checklist

1) CITI : Has PI completed required CITI trainings?	<input type="checkbox"/> Yes <input type="checkbox"/> No - <i>Tell PI and Hold</i> PI told?: <input type="checkbox"/> Yes, on: _____ Needs: <input type="checkbox"/> HIPS <input type="checkbox"/> RCR <input type="checkbox"/> Basic or Refresher
2a) Conflict of Interest Has PI answered and signed a Conflict of Interest Statement?	<input type="checkbox"/> Yes <input type="checkbox"/> No <i>Tell PI and Hold</i> PI told?: <input type="checkbox"/> Yes, on: _____
2b) <i>If any person answered "yes" to the Conflict of Interest question</i> , is the FCOI Committee communication attached?	<input type="checkbox"/> Yes: <input type="checkbox"/> Memo for Category 1 FCOI <input type="checkbox"/> FCOI Management plan and Memo of Understanding <i>(Must go to the Full Board)</i> <input type="checkbox"/> No - <i>Return to PI</i> Returned on: _____
3) If VA , is the CIC memo attached?	<input type="checkbox"/> Yes <input type="checkbox"/> No - <i>Tell PI and Hold</i> PI told?: <input type="checkbox"/> Yes If Yes, this MUST go Full Board
4) Is the new PI's bio-sketch or CV attached?	<input type="checkbox"/> Yes <input type="checkbox"/> No - <i>Tell PI and Hold</i> PI told?: <input type="checkbox"/> Yes
5) Are the consent forms, etc. and copies attached, if applicable (see section D)?	<input type="checkbox"/> Yes <input type="checkbox"/> No - <i>Return to PI</i> Returned on: _____
6) Is this amendment ready for the IRB reviewer?	<input type="checkbox"/> Yes <input type="checkbox"/> No, because:

IRB Reviewer's Recommendation

(If Full Board, please complete after meeting discussion and decision is made.
This is the reviewer checklist for Change in PI submissions.)

Name of IRB Reviewer Assigned:	Committee Assigned:	
Does the proposed PI have the appropriate scientific expertise for study oversight?	<input type="checkbox"/> Yes <input type="checkbox"/> No If No, provide comments below	
Have all participant documents been updated with the new PI's name and contact information?	<input type="checkbox"/> Yes <input type="checkbox"/> No If No, provide comments below	
<input type="checkbox"/> Approve	<input type="checkbox"/> Specific Minor Revisions <i>(Response to issues can be reviewed by the Chair or designee)</i>	
<input type="checkbox"/> Tabled <i>(Response to issues will return to the committee for review)</i>	<input type="checkbox"/> Disapprove <i>(Rejected. PI must address issues and resubmit a new protocol)</i>	<input type="checkbox"/> Deferred <i>(Not reviewed: not posted/given to reviewers, both reviewers unable to review, etc.)</i>

Comments:

Reviewer's signature:

Date:

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