

Administrative Application Instructions:

DIRECTIONS FOR INITIAL PROTOCOL SUBMISSION

All Initial Submissions

- (a) Administrative Application
- (b) Entire descriptive protocol/grant
- (c) Any other documentation.

WSU researcher using a non-WSU IRB as the IRB of record

- (a) Authorization to use another IRB for Protocol Review Agreement located at <https://research.wayne.edu/irb/forms-requirements-categories>)
- (b) The non- WSU IRB approval letter.

Applications can be submitted to the IRB Administration Office at any time by emailing eIRBManager@wayne.edu

DIRECTIONS FOR AMENDMENT SUBMISSION

All Amendment Submissions

- (a) Administrative Application
- (b) Revised protocol/grant
The amended and unamended version with the revisions indicated (highlighted).
- (c) Any other documentation
The amended and unamended version with the revisions indicated (highlighted).

WSU researcher using a non-WSU IRB as the IRB of record

- I. The non- WSU IRB approval letter.

Applications can be submitted to the IRB Administration Office at any time by emailing eIRBManager@wayne.edu

DIRECTIONS FOR CONTINUATION SUBMISSION

All Continuation Submissions

- (a) The Administrative Application

Collaborating Institution Agreement to Use a Non-WSU IRB

- (a) The continuation approval from the Collaborating Institution

Please complete and submit this form at least six weeks from the date noted on the IRB approval letter. Continuation applications must be emailed to eIRBManager@wayne.edu

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

[Instructions: Steps for Signing a PDF Form with a Digital ID](#)

Place the Administrative Application along with all other supporting documents in a single zip file and email to: eIRBManager@wayne.edu

Email Subject Line should indicate “Administrative Application” the type of submission, PD/PI’s Name



IRB Administration Office

87 E. Canfield,
 Second Floor
 Telephone# (313) 577-1628
 Detroit, MI 48201

<http://irb.wayne.edu/index.php>

Administrative Application

- All IRB submission forms must be the current form date from <http://irb.wayne.edu/forms-requirements-categories.php>. Form must be typed or computer generated. Handwritten forms will not be accepted.
- **Digital Signatures are required for the PI and Authorized Signatory**
- ***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 *Academica* and enter the e-mail account that you wish to use. Non-WSU employees, please enter your e-mail.**
- Please call us if you have any questions along the way: (313) 577-1628 or email irbquestions@wayne.edu

IRB Number _____ IRB Use ONLY

Type of Submission: Initial Application Amendment Continuation

Section A: Project Director (PD)/ Principal Investigator (PI)

2.	Address	Pager	
		*E-Mail	
		Telephone	
3.	Form Completed By	Date Form Completed	
	Telephone	*E-Mail	
1.	Name of PD/PI	Department	

Section B: Submission Information

4.	IRB Number If this is a new submission, leave blank.	
5.	Grant/Project Title	
6.	<p>Check the type of grant/project for which you are applying for:</p> <p><input type="checkbox"/> WSU researcher using a non-WSU IRB as the IRB of record. Complete Appendix A at the end of this form and the Authorization to use another IRB for protocol approval agreement.</p> <p><input type="checkbox"/> Program Project/Center Grant – Complete Appendix B</p> <p><input type="checkbox"/> Training Grant – Complete Appendix B</p> <p><input type="checkbox"/> Planning Grant – <i>answer below</i></p> <p><input type="checkbox"/> Just in Time – <i>answer below</i></p> <p><input type="checkbox"/> Other: <i>answer below</i></p>	
7.	<p>If yes to “Planning Grants” or “Other” category in Question #6, please read and sign, below:</p> <p>As part of this application, I have disclosed to the IRB that this application is for planning and developing the research protocol only. No human participants will ever be enrolled in the protocol in the planning grant phase, which requires IRB approval. As a result of the IRB approved planning grant, all future research projects involving human participants will require individual review and IRB approval prior to the initiation of the research. I understand that I am to submit a closure form for this administrative application upon receipt of IRB approval for the individual research project.</p> <hr/> <p>Signature of Project Director/Principal Investigator</p> <p>Title: _____ Date: _____</p>	
8.	Expiration Date If this is a new submission, leave blank.	
9.	Funding Source:	
	Contact Name:	

	Address:		
	Phone:		
10.	Status of Funds:	<input type="checkbox"/> Approved	<input type="checkbox"/> Pending
11.	<p>Where will all clinical and research related activities be performed? If using a Non-WSU IRB as the IRB of record and if any direct participant interface is going to take place at WSU and/or WSU affiliates (i.e. DMC, KCI, etc) then this project DOES NOT qualify for this administrative review.</p>		

12. For **initial submission**, please provide a concise description of the protocol:

N/A

13. For **initial submission**, describe the precise role of the WSU principal investigator in the research project:
 N/A

14. For **continuation submission**, please provide a concise description of the project's purpose and progress to date:
 N/A

15. For **Amendments**, please provide a concise description of the changes to be made.

N/A

Please Note:

- **The submission type of “Planning Grants”, “Just In Time,” or “Other”, a Closure Form for this administrative application must be completed and submitted upon receipt of IRB approval for the individual research project.**

Administrative Application Appendix A

When WSU IRB's agrees to allow another institution to be the IRB of record, the IRB must determine that the rights of the participants and WSU investigators are protected. The IRB will not approve a request to use another institution to be the IRB of record when any of the following conditions exist.

- When **any** direct participant activities will take place at WSU and/or WSU affiliates (DMC, KCI etc)
- When the PI is a WSU student **and** it is determined that WSU IRB review is required.

The IRB may determine that the request to rely on another IRB must be completed via an [External IRB submission](#) request. Please see the Reliance Agreements tab of the IRB's website for further instructions: <https://research.wayne.edu/irb/reliance-agreements>

If Not Applicable Select N/A and go to next section N/A

1.	Name of the IRB of Record:		
2.	List all collaborators of the project, their roles (i.e. Lead P.I, key personnel), and their location (i.e. WSU or Collaborating Site)		
	Name	Research Role	Location/Site
The following documentation must be provided:			
	II. <u>Authorization to use another IRB for Protocol Review Agreement</u> see: http://irb.wayne.edu/forms-requirements-categories.php		
	III. The non- WSU IRB approval letter. <i>If the non-WSU IRB approval letter is pending, please submit approval letter as an amendment when final approval is granted</i>		

Administrative Application Appendix B

If Not Applicable Select N/A and go to next section N/A

1. Please attach a summary of all individual research projects involving human participants covered by this grant. The summary must include all of the information:

a.	IRB Number	
	Protocol Title	
	Principal Investigator	
	Student	
	Student	
	Student	
	Student	
	Last IRB Approval Date	

b.	IRB Number	
	Protocol Title	
	Principal Investigator	
	Student	
	Student	
	Student	
	Student	
	Last IRB Approval Date	

c.	IRB Number	
	Protocol Title	
	Principal Investigator	
	Student	
	Student	
	Student	
	Student	
	Last IRB Approval Date	

Project Director/Principal Investigator's Signature and Attestation

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

Project Director/Principal Investigator's Name

Title

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

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

I certify that I have reviewed this application, including attachments and that all information contained herein is accurate to the best of my knowledge. I agree to report any substantive changes to the information contained in this application immediately to the WSU IRB. If applicable, the IRB will be notified when the project is complete by submitting a closure form.

Signature of Project Director/Principal Investigator

Date

Department Chair, Dean or Authorized Signatory Official FCOI

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

Name of the Dean/Chair/authorized signatory

Title

Name of College/Department/Institute/Center

Is CITI Training up-to-date? Yes No

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

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. I certify that:

(a) appropriate support will be provided

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

For Training Grants, Planning Grants, Just In Time, Program Project/Center Grants:

(c) all future research projects involving human participants will require individual IRB review

(d) IRB approval will be required prior to the initiation of the research

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

Date