

Coordinating Center Application

DIRECTIONS FOR INITIAL SUBMISSION

Initial Submissions

- (a) Coordinating Center Application
 - **For eProtocol submissions attach a copy of this form to the Study Location section. Label the Form as Coordinating Center Application with date.**
- (b) IRB approval letter from additional sites or reliance agreement if WSU is the IRB of Record.
- (c) Any other documentation

VA Submissions include copy of Coordinating Center Application and email to eIRBManager@wayne.edu

Applications can be submitted to the IRB Administration Office at any time.

DIRECTIONS FOR AMENDMENT SUBMISSION

Full Board Amendment Submissions

- (a) Coordinating Center Application and the Amendment Submission Form
 - **For eProtocol submissions attach a copy of this form to the Study Location section. Label the Form as Coordinating Center Application with date of form.**
- (b) IRB approval letter from additional site; IRB approval memo must be within twelve months

All other Amendment Submissions

- (c) Coordinating Center Application and the Amendment Submission Form
- (d) IRB approval letter from additional site; IRB approval memo must be within twelve months

Applications can be submitted to the IRB Administration Office at any time, unless full board—refer to deadlines on website.

DIRECTIONS FOR CONTINUATION SUBMISSION

All Continuation Submissions

- (a) Coordinating Center Application and the Continuation Form
 - **For eProtocol submissions attach a copy of this form to the Study Location section. Label the Form as Coordinating Center Application with date of form.**

- (b) IRB approval letter from additional sites; IRB approval memo must be within twelve months

Please complete and submit this form **by the date indicated on the IRB protocol specific approval letter**. This date will be approximately six weeks before the expiration date of the protocol

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

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

For Non-eProtocol Submissions:

Place the Coordinating Center Form along with all other submission forms and supporting documents in a single zip file and email to: eIRBManager@wayne.edu

Email Subject Line should indicate the type of submission, PI's Name, and IRB Number



IRB Administration Office
 87 E. Canfield, Second Floor
 Telephone# (313) 577-1628
 Detroit, MI 48201
<http://irb.wayne.edu/index.php>

Coordinating Center Application

- This additional application form must be submitted to the IRB office for all projects where WSU/WSU affiliate is to serve as the Coordinating Center for a multicenter Research Project
- **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

IRB Number _____ **IRB Use ONLY**

Type of Submission: Initial Application Amendment Continuation

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

1.	Name of PD/PI		Department	
2.	PD/PI's Signature	Click on box to sign Open and save form using Adobe or software that allows for digital signature.		
3.	Address	Pager		
		*E-Mail		
		Telephone		
4.	Form Completed By		Date Form Completed	
	Telephone		*E-Mail	

Section B: Grant/Project Information

5.	IRB Number	
6.	Grant/Project Title	

7.	Expiration Date or Status Check-In Date <i>(IF NEW SUBMISSION LEAVE BLANK)</i>	
8.	Funding Source:	
	Contact Name:	
	Address:	
	Phone:	
9.	Status of Funds:	<input type="checkbox"/> Approved <input type="checkbox"/> Pending
10.	How many sites are anticipated to participate in this multicenter trial?	
11.	Is this an amendment to a current coordinating center application?	<input type="checkbox"/> No – go directly to Q#12 <input type="checkbox"/> Yes
	a. State what changes are being made to the coordinating center application:	

12.	Describe the process for the collection, analysis, and dissemination of data to all sites:
13.	Is this a research project that could pose potential risk to the participants?
<input type="checkbox"/> No – go directly to Q#16 <input type="checkbox"/> Yes	

14.	<p>Describe the organization, function, and membership of the committee used to monitor safety between the various sites and how often the committee meets. (Data safety and monitoring boards, or DSMB, are required for clinical trials involving interventions that could cause harm to participants.)</p>
-----	---

15.	<p>Describe the process for reporting adverse events/unexpected problems to participating sites and to the WSU IRB. All sites must be made aware of serious adverse events/unexpected problems that occur at each participating site (See the Unanticipated Problems and other Reportable Events policy)</p>
-----	--

Section C: Site Information

16. Select only One Option

Separate IRB Review and approval provided for each site

For individual sites serving as their own IRB please provide the IRB approval letters for the site. If the site's IRB approval letter has not yet been received select "Pending"

OR

Single IRB Review (WSU is the IRB of Record)

A reliance agreement is required for this option. Sites can be added as an amendment upon execution of agreements. If the reliance agreement is not complete select "Pending"

Total number of sites, including sites indicated for addendum pages:

Update this number as sites are deleted or added via an amendment

List all sites below:

a.	Name of Site:		
	OHRP/FWA Number		
	Name of PI		
	Address		
	Phone		PI's Email:
	IRB approval date: (attach copy) or <input type="checkbox"/> Pending	Reliance Agreement <input type="checkbox"/> Approved <input type="checkbox"/> Pending <input type="checkbox"/> Not Applicable	Reliance Agreement Type <input type="checkbox"/> Smart IRB <input type="checkbox"/> Other:
b.	Name of Site:		
	OHRP/FWA Number		
	Name of PI		
	Address		
	Phone		PI's Email:
	IRB approval date (attach copy) or <input type="checkbox"/> Pending	Reliance Agreement <input type="checkbox"/> Approved <input type="checkbox"/> Pending <input type="checkbox"/> Not Applicable	Reliance Agreement Type <input type="checkbox"/> Smart IRB <input type="checkbox"/> Other:

c.	Name of Site:		
	OHRP/FWA Number		
	Name of PI		
	Address		
	Phone		PI's Email:
	IRB approval date: (attach copy) or <input type="checkbox"/> Pending	Reliance Agreement <input type="checkbox"/> Approved <input type="checkbox"/> Pending <input type="checkbox"/> Not Applicable	Reliance Agreement Type <input type="checkbox"/> Smart IRB <input type="checkbox"/> Other:
d.	Name of Site:		
	OHRP/FWA Number		
	Name of PI		
	Address		
	Phone		PI's Email:
	IRB approval date: (attach copy) or <input type="checkbox"/> Pending	Reliance Agreement <input type="checkbox"/> Approved <input type="checkbox"/> Pending <input type="checkbox"/> Not Applicable	Reliance Agreement Type <input type="checkbox"/> Smart IRB <input type="checkbox"/> Other:
e.	Name of Site:		
	OHRP/FWA Number		
	Name of PI		
	Address		
	Phone		PI's Email:
	IRB approval date: (attach copy) or <input type="checkbox"/> Pending	Reliance Agreement <input type="checkbox"/> Approved <input type="checkbox"/> Pending <input type="checkbox"/> Not Applicable	Reliance Agreement Type <input type="checkbox"/> Smart IRB <input type="checkbox"/> Other:

f.	Name of Site:		
	OHRP/FWA Number		
	Name of PI		
	Address		
	Phone		PI's Email:
	IRB approval date: (attach copy) or <input type="checkbox"/> Pending	Reliance Agreement <input type="checkbox"/> Approved <input type="checkbox"/> Pending <input type="checkbox"/> Not Applicable	Reliance Agreement Type <input type="checkbox"/> Smart IRB <input type="checkbox"/> Other:
g.	Name of Site:		
	OHRP/FWA Number		
	Name of PI		
	Address		
	Phone		PI's Email:
	IRB approval date: (attach copy) or <input type="checkbox"/> Pending	Reliance Agreement <input type="checkbox"/> Approved <input type="checkbox"/> Pending <input type="checkbox"/> Not Applicable	Reliance Agreement Type <input type="checkbox"/> Smart IRB <input type="checkbox"/> Other:

Not enough spaces? Use and attach the Coordinating Center Additional Site Addendum

IRB Administration Office Note:

Note to IRB Reviewer: Please complete the IRB Coordinating Center Reviewer Checklist. Contact the IRB Administration Office for assistance or questions.