

WSU IRB Administration Office

87 East Canfield, Second Floor Detroit, MI, 48201 313-577-1628 irb.wayne.edu

IRB eProtocol

Overview







What is eProtocol?

Is a web-based system used to submit track, review, and approve research protocols in a paperless format.

WSU IRB Administration Office began implementing eProtocol

December 2017



Now Accepting

Full Board (greater than minimal risk)

Expedited (minimal risk)

Exempt (minimal risk)

External IRB-Reliance Agreements via eProtocol



Electronic Submission Features

- WSU Access ID & Password is required
- CITI Profile must include the WSU Access ID
- Electronic Checks of Mandatory CITI Training
- Required CITI Training completed before submitting to the authorized signatory
- Transparent listing of key personnel & CITI Training with access ID connecting training
- Alerts & Notifications of IRB Review via WSU email
- Spell check
- Revision tracking
- Immediate access to approval letters and stamped documents

Web Browser Requirements

Supported by Firefox 12 & Safari 7 web browsers









(please disable the pop-up blocker)
Do not use the "Back" or "Refresh" buttons



WSU Access ID & Password is required for log-in

If you do not have an access ID & Password please sign up for a guest WSU Access ID (note guest ID's require annual renewal)

- Completion of Mandatory CITI Training
- Update CITI Profile with WSU Access ID
 - Access ID Connects CITI training to eProtocol
 - Entry in lower case no extra characters or spaces
 - Must affiliate CITI profile with WSU
- Electronic Sign-Off by Key Personnel





X Does not require registration by users



Does require a WSU Access ID & Password

WSU Access ID's are assigned to:

- WSU Faculty
- Staff
- Students



A WSU Access ID & Password opens the door to eProtocol



Use the IRB's Key Personnel Guidance Tool to determine key personnel for your study

Only key personnel that will conduct research activities at WSU/WSU Affiliate should be included as key personnel for a submission

If it is an External IRB Submission (WSU IRB is not the IRB of Record)

DO NOT Include:

- Other sites' Principal Investigators
- Key Personnel from other non-affiliate sites
- McLaren Personnel (they are listed for the McLaren authorization). The McLaren Authorization document is submitted with the eProtocol application.



WSU Affiliates include:

Detroit Medical Center, Karmanos Cancer Institute, & John D.

Dingell VA Medical Center

WSU Guest Access ID Request

- Submit an e-mail request to irbstatus@wayne.edu
- Include in email guest users:
 - First Name, Middle Name, Last Name
 - Birthdate
 - Previous Access ID (if applicable)
 - Organization (affiliate institution)

Guest Access ID users will receive an email with ID activation instructions.

- Guest IDs are for 1 year and must be re-activated yearly
- Guest IDs include a WSU Academica account with email
- Guest users should add their WSU Access ID to their <u>CITI Profile</u>
- Guest users should forward their WSU email to their primary email accounts to receive eProtocol notifications
 - > Click here for instructions on forwarding the WSU email



- Electronic sign offs by <u>ALL</u> study key personnel (2 step process)
 - Completion of Obligations Statement Must use the WSU Access In
 - Maintain CITI training
 - Follow direction of PI to adhere to the study protocol, institutional policies, & research regulations
 - Conflict of Interest (COI) Statement

Dean/Chair/ Authorized Signatories (3 step process) also log in to eProtocol to:

- 1. Complete Obligations
- 2. COI disclosure
- 3. Complete Department/College certification (pre-approval)



Mandatory CITI Training

(3) Required CITI Training Modules for

ALL Key Personnel & Authorized Signatories

(I) Basic Course in Human Subjects Research: Biomedical or Social Behavioral Investigators (Refresher course is required every 3 years)

(II) Responsible Conduct of Research

(III) Health Information Privacy and Security (HIPS)

Module (per research role)



Mandatory CITI Training

Additional CITI Modules based on Research Type

- Children included as participants (CITI module: 152332 or 152335)
- Pregnant Women, Fetuses or Neonates included as participants (CITI module: 152332 or 152335)
- Prisoners included as participants (CITI module: 152333 or 152336)
- Students included as participants (CITI module: 152334 or 152337)
- Internet Research (CITI module: 152338)
- International Research (CITI module: 153207)



Tips & Tools

- Start Early
 - IRB Full Board Submission Deadline Dates
 - Schedule is Available on IRB's Website
 - No deadlines for Expedited & Exempt Reviews
- All Users must complete the Mandatory IRB CITI Training

(before submitting Dean/Chair Sign-Off)

All Users must add WSU Access ID to their CITI Profile

(6 character letter number combination, for example: aa1234)

- Work with your research personnel NOW to get this completed
- Make sure the correct individual is listed as PI*
- Use IRB Guidance Tools for Assistance (available on IRB website)
- Remember Administrative Approvals (DMC, CIC, PRMC, Psychiatry, Radiation)





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For assistance with submitting to eProtocol e-mail

irbstatus@wayne.edu

or call the IRB Office 313-577-1628

Stay Updated:

Sign up for the IRB listserv

Email: irbstatus@wayne.edu





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Guidance Tools available on the IRB's website: irb.wayne.edu

Full training manuals & videos available on your mobile device's app store



How to Access eProtocol?

www.irb.wayne.edu



or

https://ksqaweb2.ovpr.wayne.edu/

Log in using WSU Access ID & Password

