
WAYNE STATE
UNIVERSITY
Welcome

Wayne State University
Institutional Review Board (IRB)

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

eProtocol Introduction

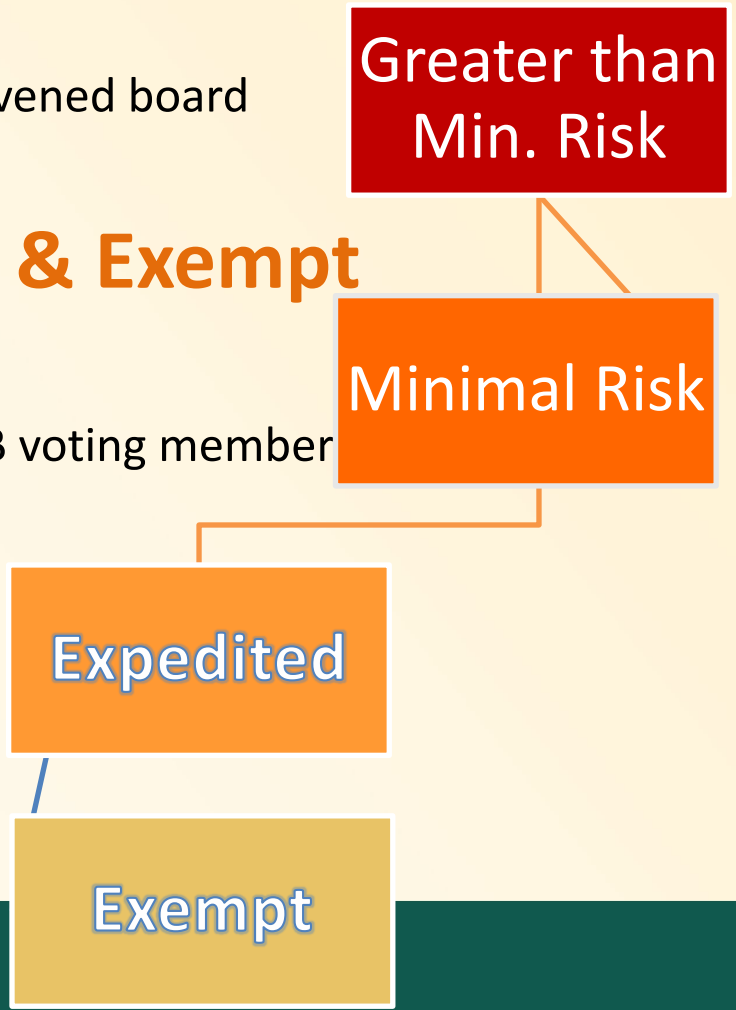
Institutional Review Board (IRB)

In accordance with ethical principles, applicable laws and regulations the Wayne State University's Institutional Review Board (IRB) is a federally mandated and accredited independent entity that must approve all research involving human participants, both biomedical and social science/behavioral, before research can begin at WSU or any of its affiliates (i.e. Karmanos Cancer, Detroit Medical Center, John D. Dingell VA).

IRB Review Types

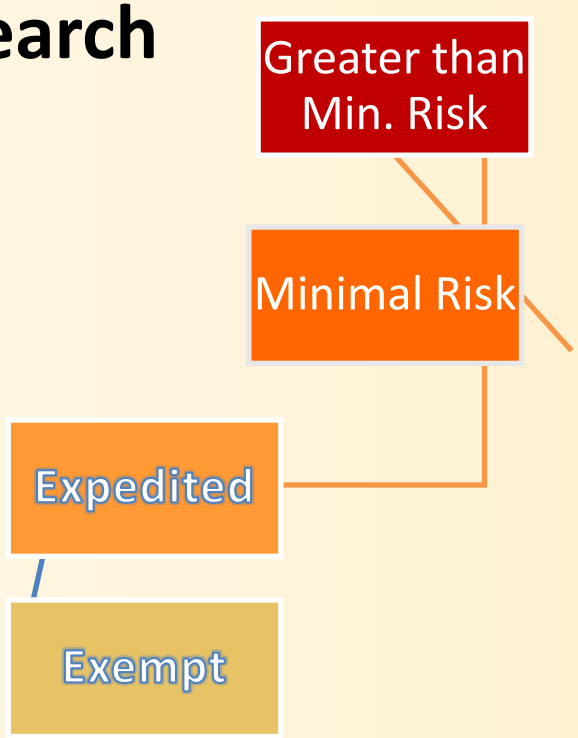
- **Greater than Minimal Risk: Full Board**
  - Research that puts participants at greater risk than they would encounter in their every day life.
  - Reviewed by and voted on by a full convened board

- **Minimal Risk: Expedited & Exempt**
  - Risks experienced as part of every day life
  - Review's conducted by one experienced IRB voting member
    - Expedited: Low risk
    - Exempt: Least risk



IRB Review Types

Not sure about type of IRB Review or if your project is human participant research



Complete the IRB's Human Participant Determination Tool

See Guidance Tools & Training Materials links provided

Preparing for IRB Submission

- Complete CITI Training Profile
- Complete Mandatory CITI Training
- Visit the IRB's Website (www.irb.wayne.edu)
  - Education page
  - IRB Forms and Submission page
  - Templates for Consents, Information Sheets, Assents
- Attend IRB trainings
- Completion of eProtocol Application
  - Guidance Tools Available on Education web page

Submissions Accepted via eProtocol

- New/Initial Studies including VA
  - Full Board, Expedited, & Exempt
- External IRB Submissions
- *Amendments’
- *Continuations
- *Unanticipated Problem (UP) Reports
- *Closures/Final Reports

*The initial submission must have been approved via eProtocol

eProtocol & IRB Submissions

Biomedical & Social, Behavioral, & Education (SBE)

NEW

Full Board (greater than minimal risk)

Expedited (minimal risk)

Exempt (minimal risk)

Previously approved submissions (before eProtocol) must use the paper-based forms available on the IRB's website.
irb.wayne.edu.
The paper-based submissions must be emailed to
eIRBmanager@wayne.edu

WAYNE STATE

External IRB Submissions

NEW

The reviewing IRB for a WSU or WSU affiliate site that is not WSU IRB, but rather another institutional IRB or a commercial IRB.

A Reliance Agreement must be in place between the External IRB and WSU IRB in order for this to occur. A local administrative review must be conducted.

Study previously Authorized before eProtocol?

submit modifications & UPs using the

- ***External IRB Modification Worksheet & Guide**
- ***Unanticipated Problem Event & Reporting Form**

available on the WSU IRB's external IRBs websites

- **NCI CIRB**
- **WCG**
- **All other External IRBs: Advarra, Academic IRBs**

***Follow submission instructions on the respective forms**

eProtocol System Requirements & Access

WAYNE STATE

How to Access eProtocol?

www.irb.wayne.edu

https://ksprodweb.ovpr.wayne.edu/

Log in using WSU Access ID & Password

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

System Requirements

- **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**

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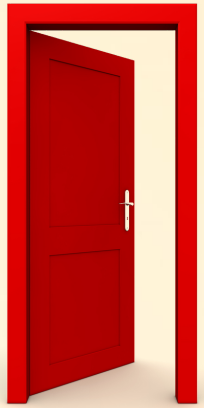
System Requirements

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

WAYNE STATE

System Requirements

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:

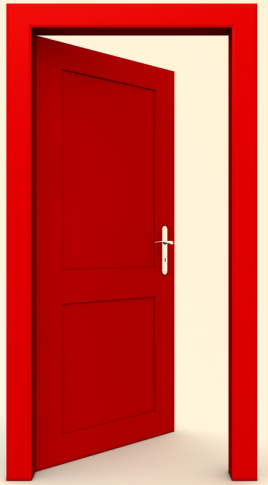
- **Other sites' Principal Investigators**
- **Key Personnel from other non-affiliate sites**
- **McLaren Personnel (they are listed for the McLaren authorization). The McLaren Authorization document is submitted with the eProtocol application.**

WSU Affiliates include:
Detroit Medical Center, Karmanos Cancer Institute, & John D. Dingell VA Medical Center

WSU Access ID Requirement

- If the submission will include individuals that are **not** WSU faculty, staff, or a students.

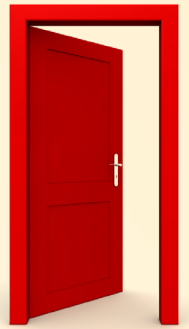
A guest WSU Access ID will need to be requested for the non WSU key personnel



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 CITI Profile
- 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

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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 Biomedical or Social Behavioral Investigators

(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)

***Prisoner research is not allowed for External IRB submissions**

Completing the IRB Form

eProtocol - WayneStateUniversity

https://ksprodweb.ovpr.wayne.edu

Search

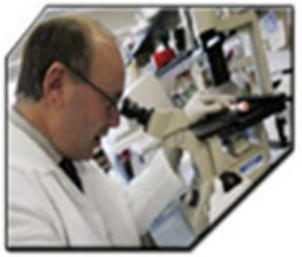
WAYNE STATE UNIVERSITY

KEY SOLUTIONS
Comprehensive IT for Research

version 2.5.63.5

ePROTOCOL

Welcome to the Wayne State University eProtocol system - a powerful and efficient way to submit, track and approve research protocols and Conflict of Interest disclosures.
Browser Requirements: **This site requires Firefox 12 and higher or Apple Safari.** Using older browsers, non-compatible browsers or disabling browser features, such as Javascript, cookies and SSL, will reduce site functionality.



User ID

Password

Login

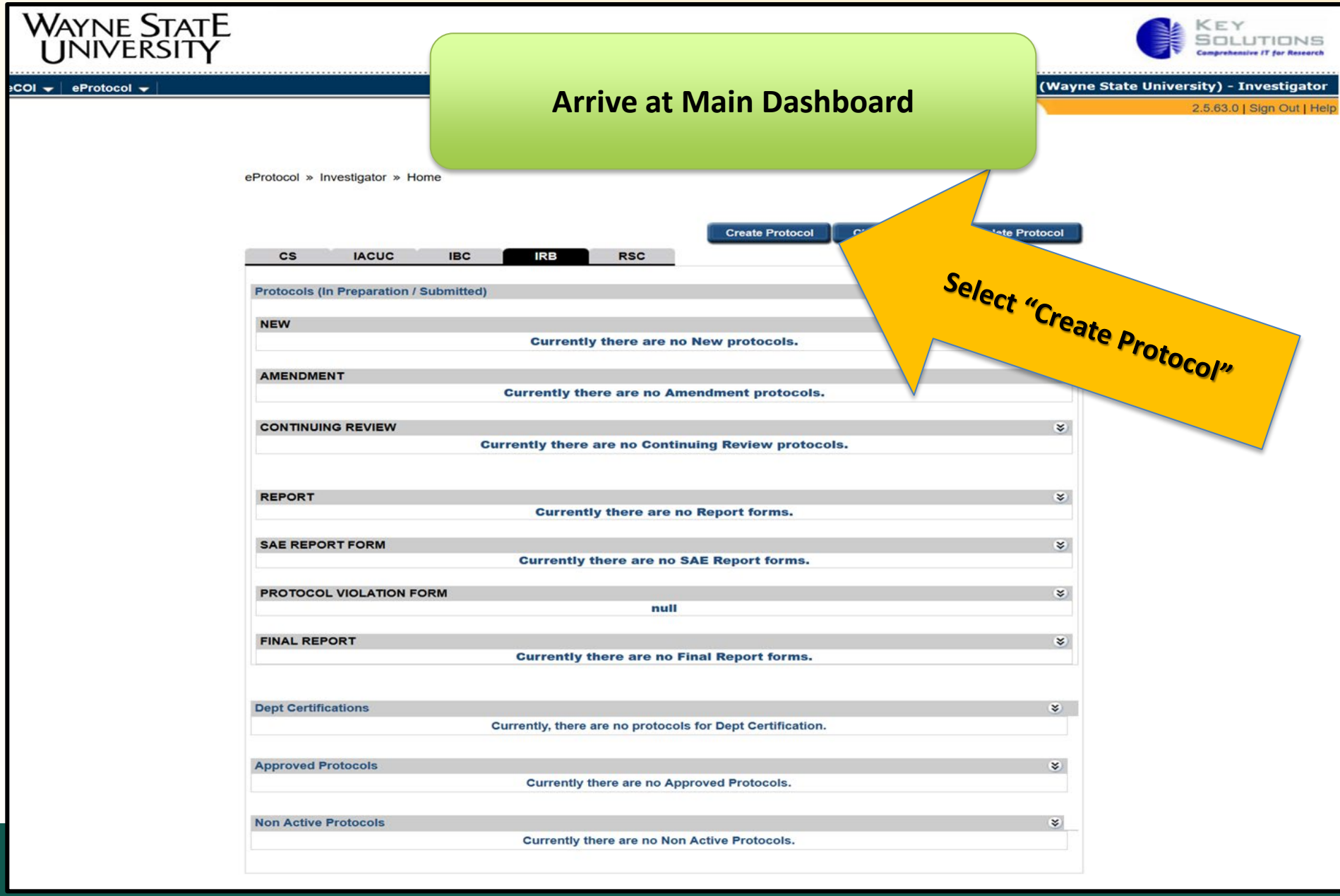
WAYNE STATE
— EST. 1868 —

Initial Submission Tips

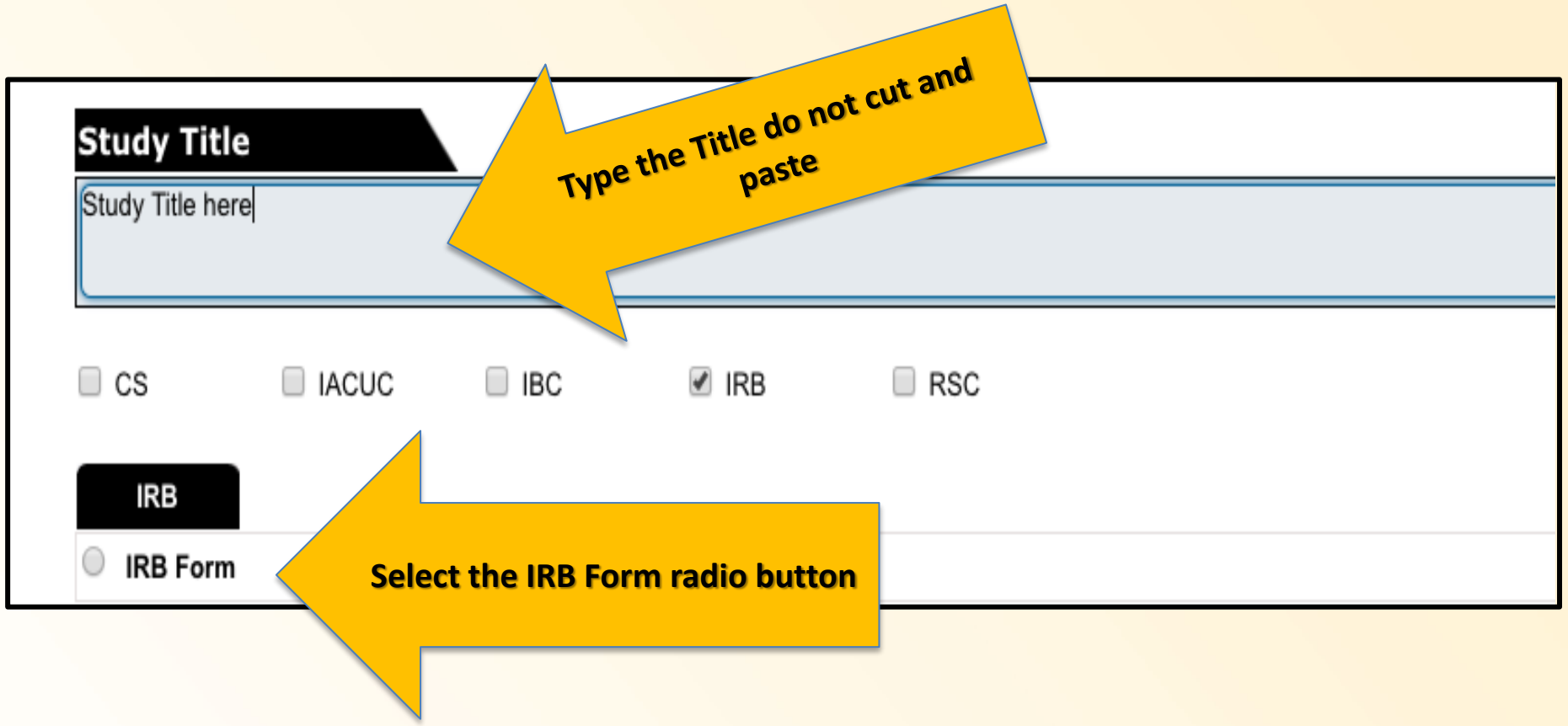
- **Individual that creates protocol is listed as the PI**
  - Coordinator can complete the submission and switch the PI
  - Complete this switch before requesting key personnel to sign off on submission
- **Key Personnel Sign Off**
  - PI or assigned/designee contacts key personnel to complete the 2 step sign-off process
  - IRB Office can provide assistance with CITI checks or use the eProtocol Training Checklist
- **Complete all sections of the form**
  - Attaching Consent & Assent documents to the Consent Information and Assent Information sections
  - Complete Addendums/Appendices ***(vulnerable population appendices are not required for exempt submissions)***
- **Submitter "Checks for Completeness" & CITI Training Validation**
  - Will show currently missing items for the application
  - Will indicate if CITI training modules are missing
  - Will not allow for submission to the authorized signatory until items are completed

See the Initial Submission Guidance Tool for instructions

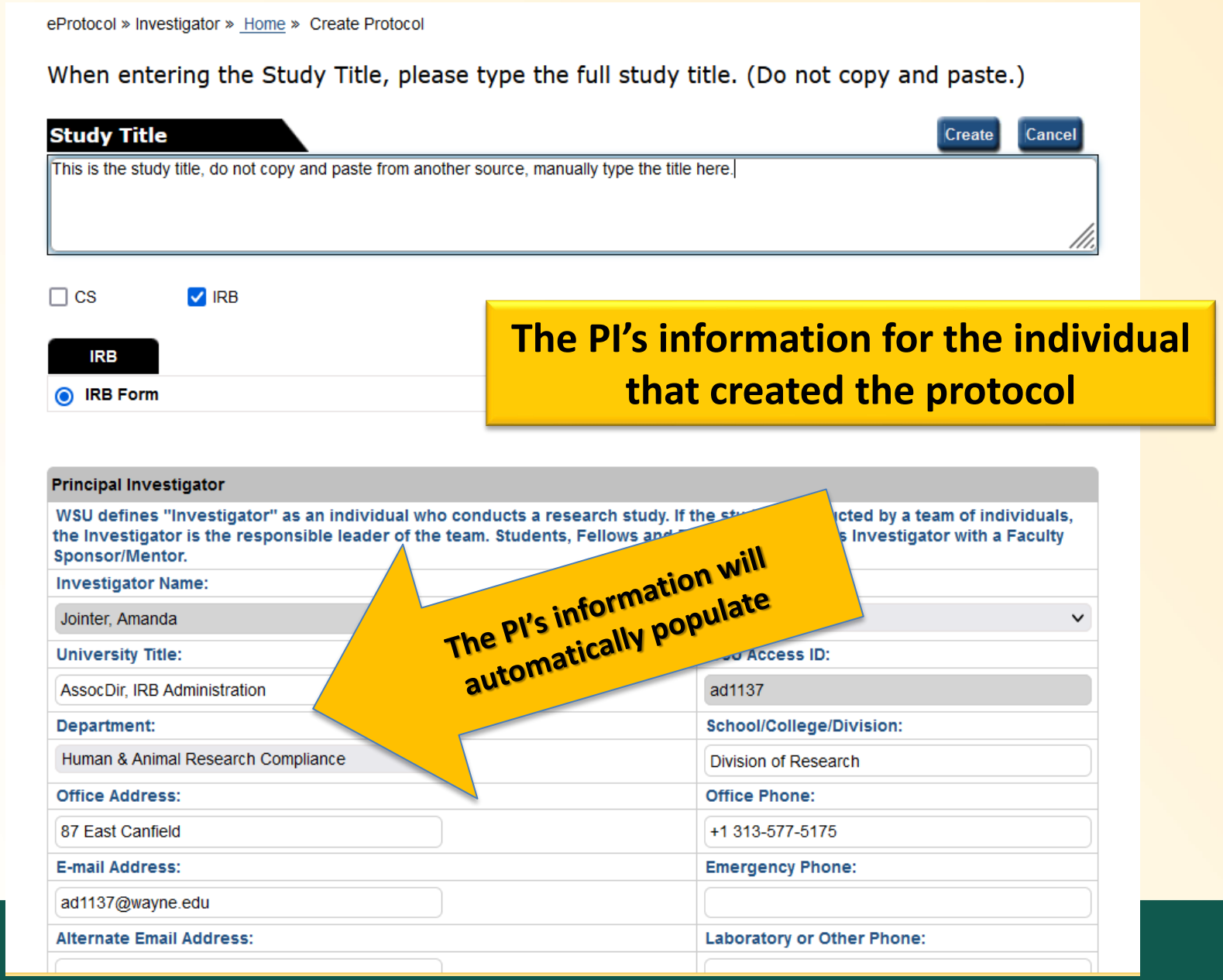
Creating an Initial Submission



Creating an Initial Submission

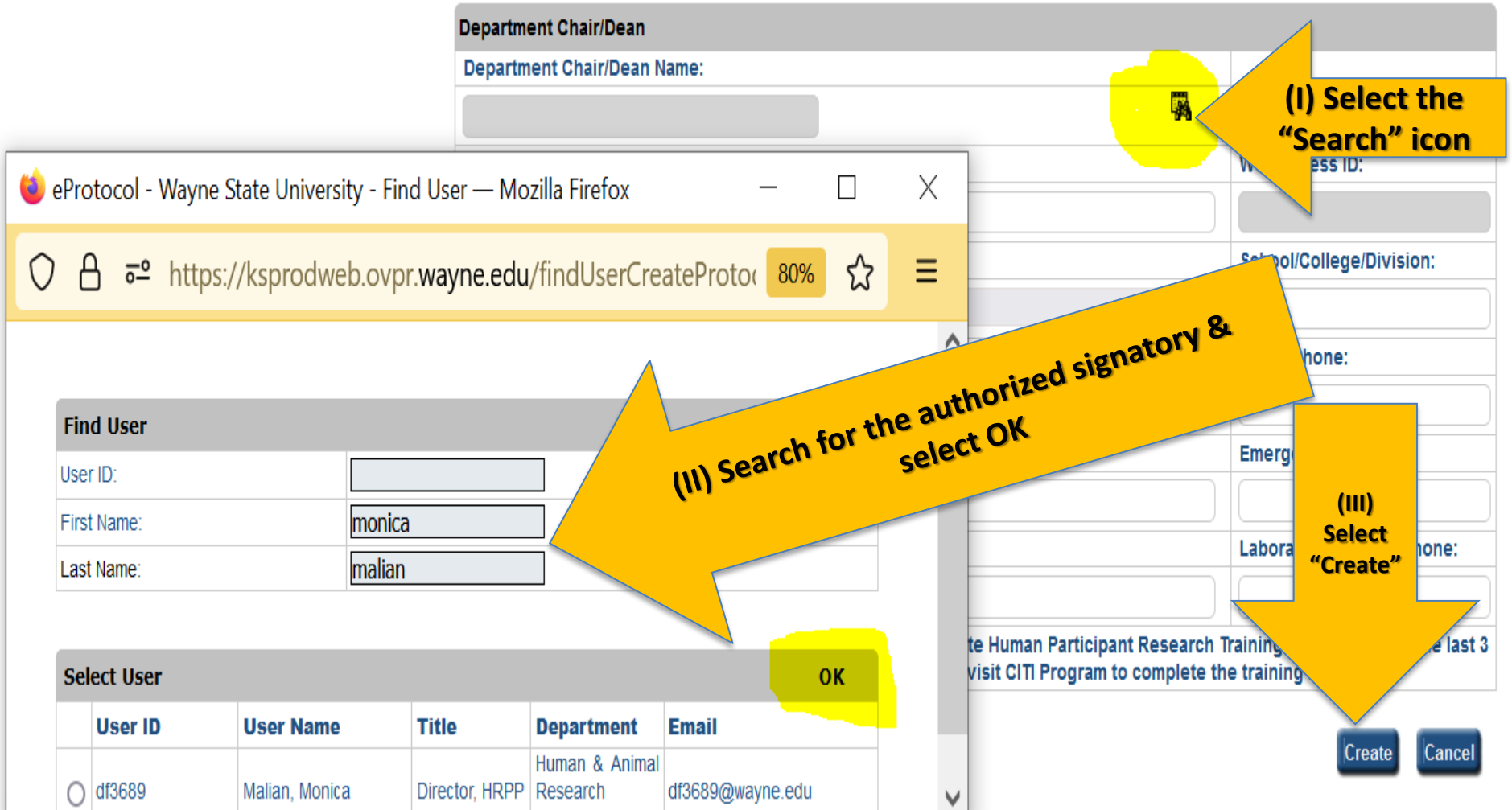


Creating an Initial Submission



Creating an Initial Submission

Selecting the Authorized Signatory



Creating an Initial Submission

After selecting "Create"

- **The IRB Form will populate**

&

- **IRB number/ID is assigned**

IRB - IRB Form **Protocol ID:** IRB-19-08-1240 (Jointer, Amanda)
Protocol Title: test

Save | Spell Check | Help | Close

Previous Next

- Personnel Information
- Participant Checklist
- Study Location
- VAMC Checklist
- Protocol Checklist
- Funding
- DoD Questionnaire
- Protocol Information
- Addendum: Children a...
- Addendum: Prisoners ...
- Addendum: Pregnant W...
- Addendum: Internatio...
- Addendum: Internet U...
- Addendum: NIH Genomi...
- Training Checklist
- Obligations
- COI Disclosure
- Check For Completeness
- Submit Form
- Print View
- Event History

Principal Investigator

WSU defines "Investigator" as an individual who conducts a research study. If the study is conducted by a team of individuals, the Investigator is the responsible leader of the team. Students, Fellows and Residents may act as Investigator with a Faculty Sponsor/Mentor.

Investigator Name:	Investigator Role:
Jointer, Amanda	Student/Resident/Fellow
University Title:	**WSU Access ID:**
IRB Operations Manager	ad1137
Department:	**School/College/Division:**
Human & Animal Research Compliance	Division of Research
Office Address:	**Office Phone:**
87 East Canfield	+1 313-577-5175
E-mail Address:	**Emergency Phone:**
ad1137@wayne.edu	
Alternate Email Address:	**Laboratory or Other Phone:**

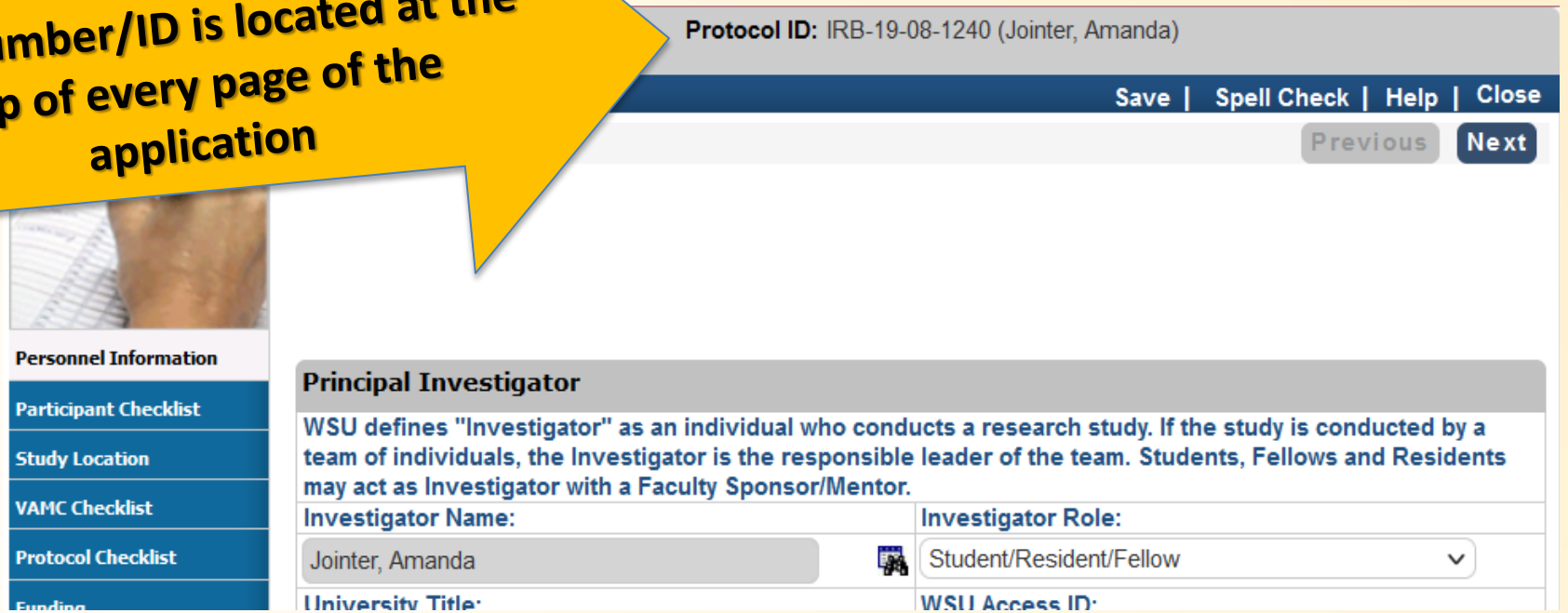
Training Details: All research personnel are required to complete Human Participant Research Training from CITI within the last 3 years prior to engaging in any research-related activity. Please visit CITI Program to complete the training if needed.

Training Details

Course ID	Course	Course Completion Date	Course Expiration Date
27086	Biomedical Investigators	2019-06-24 14:22:00	2022-06-23
27090	Biomedical Responsible Conduct of Research Course 1.	2008-05-22 11:11:00	
27177	CITI Health Information Privacy and Security (HIPS) for Clinical Investigators	2011-08-14 21:32:00	
27085	IRB Staff	2020-02-12 16:40:00	2023-02-11
153207	International Research (BIOMED & SBE)	2019-06-26 16:56:00	2022-06-25
152338	Internet-Based Research (BIOMED & SBE)	2021-09-02 17:08:00	2024-09-01

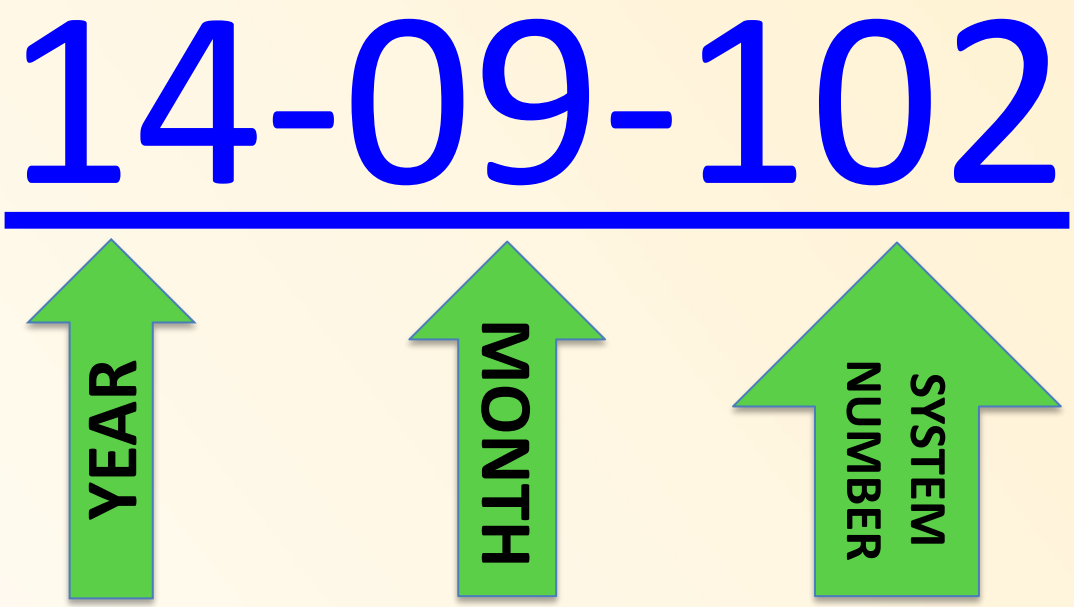
Creating an Initial Submission

IRB Number/ID is located at the top of every page of the application



Submission Numbering

- IRB Number (**eProtocol ID**)



Completing an Initial Submission

Complete the tabs in the Order

IRB - IRB Form **Protocol ID:** IRB-19-08-1240 (Jointer, Amanda)
Protocol Title: test

Save | Spell Check | Help | Close

Previous Next

- Personnel Information
- Participant Checklist
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Jointer, Amanda	Student/Resident/Fellow
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Completing the IRB Application

Be mindful of the boxes that are selected for the form.

For Example:

- ✓ **If vulnerable Populations are included (i.e. Children, Pregnant Women). This must be selected for the Participant Checklist section.**
- ✓ **For External IRB Submissions: "Request to Rely on Another IRB-External IRB Submission" must be selected for the Protocol Checklist.**
- ✓ **If conducting research on the Internet, Internationally, the appropriate check boxes must be selected for the Protocol Checklist.**

Participant Checklist

	Check All That Apply :
☐	N/A (Please only select this option for Not Human Participant Research).
☑	Children Under 18
☑	Pregnant Women
☐	Fetuses / Neonates
☐	Prisoners (If using Prisoners, you must select Full Board Review in the Study Details)
☐	Military Personnel
☑	Adults

Protocol Checklist

☐ Planned Emergency Research - see Planned Emergency Research Policy at http://research.wayne.edu/irb/policies-human-research.php

☑ Request to Rely on Another IRB-External IRB Submission

Please attach the External IRB Worksheet for the Protocol Information Attachments section.

Select the External IRB.

Please select the applicable Ancillary Reviews below.

☑ Advarra External IRB Submission ☐ NCI CIRB External IRB Submission ☐ WCG IRB External IRB Submission

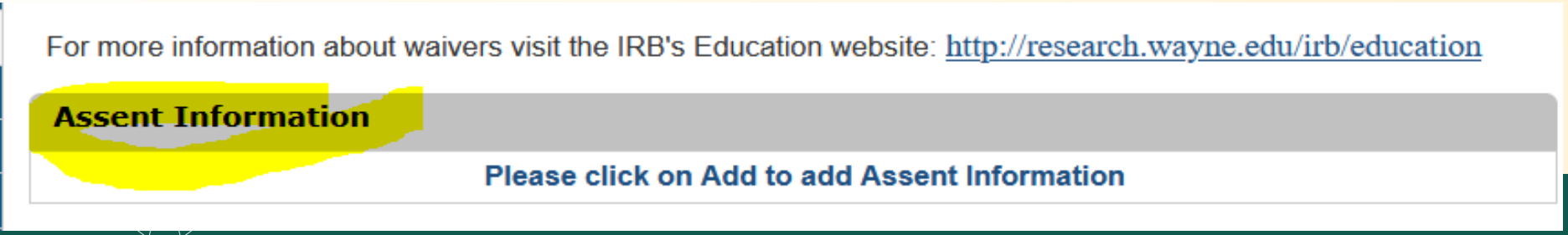
☐ Other External IRB Submission: Please state the name of the IRB:

Completing the IRB Application

Attach Consent & Assent Forms for the correction section

For Example:

- ✓ **Consent Documents including Research Information Sheets are attached for the Consent Information section**
- ✓ **Assent documents (i.e. Adolescent Assent Forms, Oral Assent Scripts) are attached for the Assent Information section.**
- ✓ **All other documents are attached for the Attachments section.**



Electronic Sign-Off

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Electronic Sign-Off Overview

- Principal Investigator (PI)
- Faculty Sponsor/Supervisor/Mentor
- Key Personnel (co-investigator, Study Regulatory, Other Personnel)
- Authorized Signatory (Dean or Chair)

=

All Key Personnel will log-in with the role of

"Investigator"

Only use supported web browsers: Firefox or Safari

Disable the pop-up blocker for your web browser

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eProtocol Electronic Sign-Off

➢ Principal Investigator (PI)

Log into eProtocol as Investigator (ksprodweb.ovpr.wayne.edu) complete the following:

- **Obligations (PI Responsibility Statements):**
  - Maintain CITI training
  - Submit Modifications to the IRB for review and approval
  - Provide participants informed consent, if applicable
  - Agree application is accurate
  - Responsible for management and conduct of the study
  - Submit Closure
- **Conflict of Interest (COI) Statement:**
  - »Disclosing any financial interest or non financial interest

The student Principal Investigator must select their role as: "Student/Resident/Fellow"

Only use supported web browsers: Firefox or Safari

eProtocol Electronic Sign-Off

➢ Faculty Sponsor/Mentor

Log into eProtocol as Investigator (ksprodweb.ovpr.wayne.edu) complete the following:

- **Review the submission for consistency per guidance and instructions provided to the student/resident.**
- **Obligations (Faculty Sponsor/Mentor Responsibility Statement):**
  - Faculty Sponsor will maintain CITI training
  - Faculty Sponsor has reviewed the research plan
  - Faculty Sponsor has approved the scientific and ethical aspects
  - Faculty Sponsor will supervise all compliance with IRB guidelines
- **IRB Conflict of Interest (COI) Statement:**
  - »Disclosing any financial interest or non financial interest

The PI must contact their Faculty Sponsor to sign off on the submission.

Only use supported web browsers: Firefox or Safari

eProtocol Electronic Sign-Off

➢ Key Personnel (coordinator, co-investigators, other personnel)

Log into eProtocol as investigator (ksprodweb.ovpr.wayne.edu) complete the following:

- **Obligations (Key Personnel Responsibility Statement):**
  - Maintain CITI training
  - Follow direction of the PI to adhere to the study protocol, institutional policies, and research regulations
- **IRB Conflict of Interest (COI) Statement:**
  - »Disclosing any financial interest or non financial interest

The PI or assigned coordinator must contact their key personnel to complete electronic sign-offs.
Only one person can log in at a time.

Only use supported web browsers: Firefox or Safari

Electronic Sign-Off

➢ Authorized Signatory (Dean or Chair role) (3 steps)

- ➢ ***After receiving email notification:***

Log into eProtocol as investigator (ksprodweb.ovpr.wayne.edu) complete the following:

- **(Step 1) Obligations (Authorized Signatory Responsibility Statements):**
  - Maintain CITI training
  - Scientific Review (elements of sound research design)
  - Provide appropriate support and adequate facilities and staff
- **(Step 2) Conflict of Interest (COI) Statement:**
  - »Disclosing any financial interest or non financial interest
- **(Step 3) Department Certification (pre-approval)**

The listed Authorized signatory is notified of sign off when the PI or assigned coordinator selects "Submit Form" the first time

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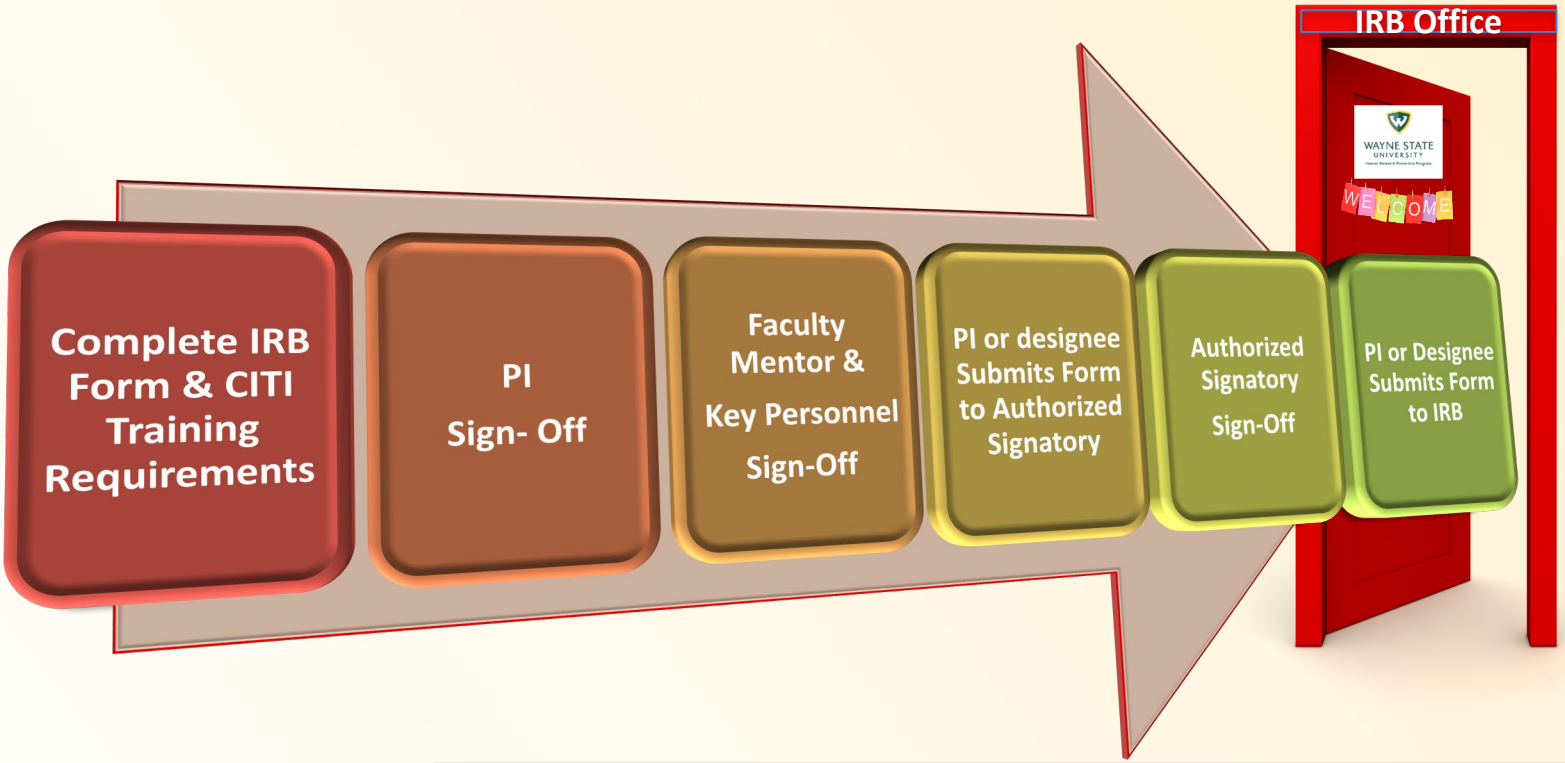
Only use supported web browsers: Firefox or Safari

Submission & Review Process

Submission Process Overview



Completed in this Order
See the Initial Submission Guidance Tool for instructions

*Coordinators (PI designee) please complete the PI assignment before key personnel sign offs began

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Submission Process

IRB Intake

- Check for Protocol/Proposal
- PI CV/Resume
- Correct Authorized Signatory
- Affiliate scientific Review
- Completion of Vulnerable Population Addendums

- Assign to IRB Committee
- Assign to IRB Reviewer

- Review Conducted
- Revisions Requested

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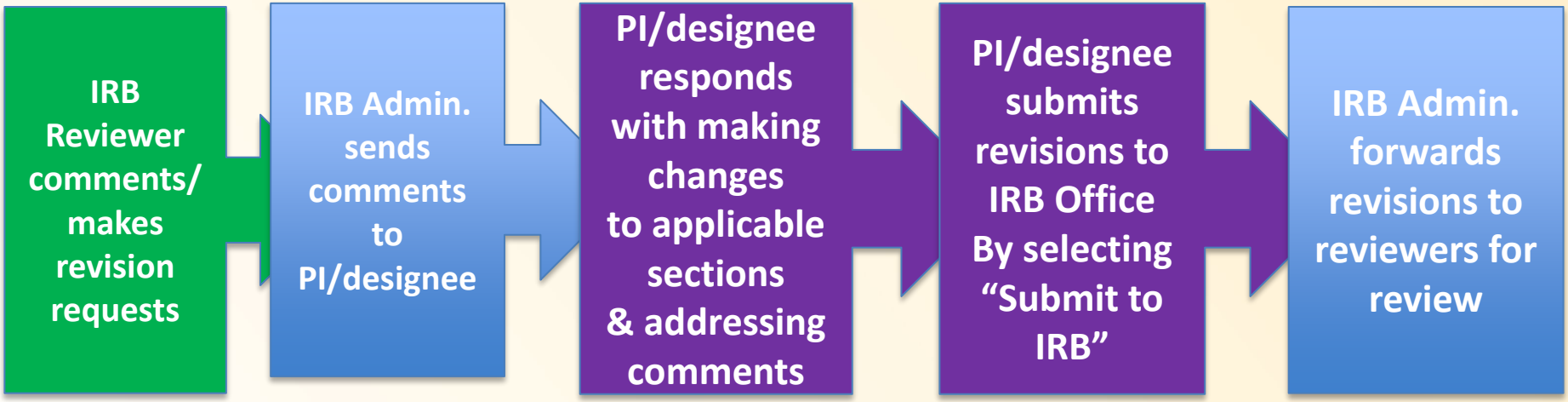
Review Process

*Review Cycles

A review cycle consists of the IRB primary reviewer submitting comment to the IRB Administrator to forward on to the PI or designee to make revisions to the Protocol



Carefully read and respond to the revision requests.
The Cycle repeats if the IRB reviewer request additional revisions.
Cycles are numbered and labeled accordingly (i.e. cycle 1, cycle 2)

The IRB reviewer may also send revision requests via email directly to PI.
However the revisions still must be completed in eProtocol.
***Full Board reviews are conducted based on the meeting date**

IRB Review & Turn Around Times

Give yourself plenty of time to:

- Complete the IRB submission
- Complete Key Personnel electronic signatures
- Authorized Signatory to sign-off

Give the IRB time to:

- Conduct an appropriate and thorough review
- Request revisions or clarification from the PI/study team, if needed
- Complete approval final checks
- Generate approval documents and stamp documents, if applicable

Current IRB Review Times:

Full Board: 30-60 days*
Expedited & Exempt: initial review average is 2 weeks to 21 business days*

*Exact timing of turn around is dependent upon volume of submissions, revision response time, reviewer scheduling, and/or if a study has met the reviewing criteria.

System Alerts & Notifications

- Alerts Dean/Department Chair for sign off (certification/approval)
  - Confirm appropriate dean/chair/authorized signatory before submitting for sign off.
    - This will eliminate pitfalls of incorrect routing and resetting the pre-approval by the IRB Office.
- Alerts IRB of Submission
- Alerts PI/Designated Key Personnel of IRB Committee & IRB reviewer Assignments
- Alerts IRB of Response and edits to application
- Completion of IRB review notification
- IRB Determination Notifications
  - (contingent-SMR requests, Tabled, Disapproved)
- IRB Renewal Reminders

Guest Access ID Users:
Email Alerts are sent to the WSU email account. The IRB recommends forwarding your WSU email to an preferred email account.

IRB Approval

- **Email is sent notifying PI /Key Personnel of IRB approval**
  - No paper approval documents are mailed or e-mailed
- **Approval letters are located in eProtocol "Events History" Tab**
  - Thoroughly Review the IRB Approval letter
  - Make note of your expiration date indicated on the approval letter
  - Courtesy reminders are generated 90 days, 60 days, 30 days before expiration
- **IRB Stamped Documents**
  - **Protocol Information – Attachments Tab**
  - **The IRB stamp or approval letter is not to be duplicated, deleted, or tampered with in any way (This is considered SERIOUS NON-COMPLIANCE)**
  - **If revisions are needed contact the IRB Office**

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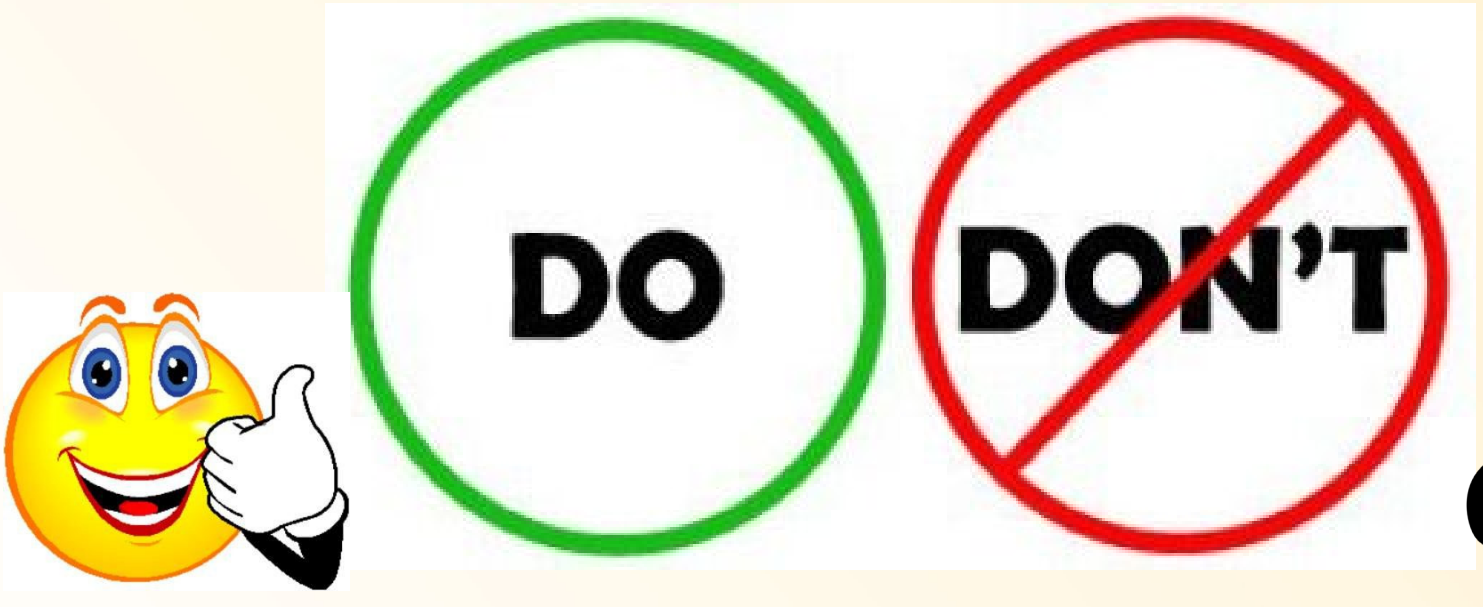
IRB Submission
Do's & Don'ts



Do's

- **Start Early**
  - IRB Full Board Submission Deadline Dates (Schedule is Available at irb.wayne.edu)
  - No deadlines for Expedited & Exempt Reviews
- **Complete the Mandatory IRB CITI Training**
- **Add your WSU Access ID to your CITI Profile**

  (6 character letter number combination, for example: ad1137)
  - Work with your research personnel NOW to get this completed
- **Make sure the correct individual is listed as Principal Investigator (PI) for eProtocol**
- **Read & answer the submission application questions**
- **Use IRB Guidance Tools & Education resources for assistance**
- **Remember Administrative Approvals** (DMC, PRMC, VA CIC, Psychiatry, Radiation, etc.)

WAYNE STATE

Ask the IRB for HELP!

Don't

- Wait until the last minute to submit.
- Provide incomplete responses or no response to IRB submission questions.
- Assume that your project does not need IRB review.
- Conduct human participant research without IRB approval/IRB concurrence (this includes modifications to the research).
- Don’t use the email: eprotocol@wayne.edu *(this email box is not to the WSU IRB Office).*
- Don’t hesitate to contact the IRB for help.

WAYNE STATE

Wayne State University
Institutional Review Board (IRB)

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

Need IRB Assistance or Information?

- **Visit the IRB's Education Website:**
  http://research.wayne.edu/irb/education
- **E-mail the IRB:** irbstatus@wayne.edu or IRBQuestions@wayne.edu
- **Call the IRB Office: 313-577-1628**
- **Sign-up for the IRB list serv:** email **irbstatus@wayne.edu**
- **Attend the monthly webinar:** **Every 4th Tuesday (various topics discussed)**
- **Visit Virtual Office Hour:** **Every Tuesday 1:00 pm– 2:00 pm**

WSU IRB Assistance

eProtocol IRB Virtual Training

Virtual Office Hours via Zoom

eProtocol real time assistance

No registration required

Tuesdays

1:00 pm – 2:00 pm

- ✓ Need Key Personnel CITI checks assistance?
- ✓ Key Personnel & Authorized Signatory questions?
- ✓ How to respond to revision requests?
- ✓ Where to find approval letters and IRB stamped documents?

Zoom Meeting Link
Zoom Meeting ID: 953 4534 4223
Passcode: 577514
Please make sure your name is stated on your Zoom profile.
Attendees are placed in the waiting room until their turn.

zoom

Need group or individual training? Need an Introduction to eProtocol session?
Email: WSUIRBInfo@wayne.edu

[Zoom Link & Credentials]

Meeting ID: 953 4534 4223

Passcode: 577514

Questions?