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

IRB eProtocol Checklist & Reminders

- ☐ Use a supported web browser (recommended browsers: Firefox 12, Safari 7)
- ☐ Make sure the Pop-Up Blocker is turned off
- ☐ Do not use the "Back button" in the system
- ☐ All Key Personnel must have a WSU Access ID & Password

  (*email WSUIRBInfo@wayne.edu if you do not have one*)
- ☐ All Key personnel should update their CITI profile to include their WSU Access ID (*including the Dean/Authorized Signatory*)

  (**see attached instructions**)
- ☐ All Key Personnel including the Dean/Chair/ Authorized Signatory must complete IRB required training modules:

Required CITI Training Modules for IRB Submissions:

- Basic Course in Human Subjects Research: Biomedical or Social Behavioral Investigators (Refresher course is required every 3 years)
- Responsible Conduct of Research
- Health Information Privacy and Security (HIPS) Module (per research role)

Additional CITI Modules may be required based on Research Type:

- Children 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)

- ☐ The role for **All** Key Personnel in eProtocol is identified as "**Investigator**"
- ☐ All Key Personnel must log-in to eProtocol and complete the Obligations & COI sections (**see instructions provided**)
- ☐ Only **"ONE"** individual can log in at a time to complete the Obligations & COI.
  - For studies with many key personnel it is recommended that a designee is assigned to coordinate key personnel sign off
  - Key personnel should log out of the system after completing their Obligations & COI
  - If an individual has a COI, their management plan must be attached to the Protocol Information-Attachments (section)
- ☐ Identify appropriate Dean/Chair/Authorized Signatory.

  (**Dean/Chair/Authorized Signatory will need to log into system with their WSU Access ID & Password**)
- ☐ Complete the eProtocol form section by section (in order), be sure to complete all applicable sections.
  - The "Check for Completeness" function can be used to assist with completing the form.

- It is recommended that you complete all sections of the submission before starting the key personnel sign off process. ***Please note IRB Deadline dates have not changed.***
- The first time "**Submit Form**" is selected it is routed to the Dean/Chair/Authorized Signatory.
- The Dean/Chair/Authorized Signatory is the **last** individual to complete Obligations, COI, & Department Certification before submitting to the IRB. This is a two-step process (**see Dean/Chair instructions**).
- After Department Certification is completed the **PI or designee** should "**Submit Form**" to the IRB.

- Please refer to the "Labeling Attachments in eProtocol" reference sheet

Attach all applicable documents in the appropriate sections:

  - Protocol, Protocol Addendums, Investigator Brochure/Package Inserts
  - Consents/Assents/Participant Materials/Recruitment Scripts/Letters
  - Data Collection Tools (Diaries, Questionnaires, Surveys, Assessments etc)
  - Department Approvals (i.e. PRMC, DMC, Radiation Safety, Psychiatry, etc) other approvals (i.e. FDA IND/IDE letters, Sponsor Letters)
  - CV/Resume, FCOI Plan, Letters of Support, External IRB Approvals etc.
- If copying & pasting text into eProtocol, use Plain text. Copying & Pasting is not advised.

If applicable the following Protocol Summary Form appendices must be uploaded and attached to the submission for the Protocol Information-Attachments section (appendices available on the IRB's website**):**

- PSF Appendix H: The Use of Biological Specimens
- PSF Appendix G: Imaging/Diagnostic Radiation Procedure
- PSF Appendix D: Cognitively Impaired Mentally Disabled Participants
- PSF Appendix F: Use of Drugs, Biologic Agents, or Devices
- Coordinating Center Application

The Review Process

- IIRB Members may request revisions **before** the IRB meeting.
- IRB Members will provide comments to the IRB Administration Office.
- The IRB Administration Office will forward comments on to the PI/Designee to make corrections.
  - Email notifications are sent to the WSU email alerting of IRB review activities.
- Corrections should be made to the sections indicated per the comments request.
- Please also address that revisions have been made in the comments section.
- Please complete revisions in the system **before** the IRB meeting date.
- Please "**Submit to IRB**" in order for revisions to be reviewed before the IRB meeting date.
- **After the Meeting**: An email alert is sent notifying the PI/Designee of the IRB's Determination.
- Please follow the instructions indicated on the e-mail. All Approval letters are available in the eProtocol Events History section.

Need eProtocol Training or Assistance, please email:
WSUIRBInfo@wayne.edu or contact the IRB Administration Office at 313 577-1628.

updated 2/25/2019