IRB eProtocol Checklist & Guidance Tool

☐ 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 WSUIRBIInfo@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:

<table>
<thead>
<tr>
<th>Required CITI Training Modules for IRB Submissions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>o Basic Course in Human Subjects Research: Biomedical or Social Behavioral Investigators (Refresher course is required every 3 years)</td>
</tr>
<tr>
<td>o Responsible Conduct of Research</td>
</tr>
<tr>
<td>o Health Information Privacy and Security (HIPS) Module (per research role)</td>
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<tr>
<th>Additional CITI Modules may be required based on Research Type:</th>
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</thead>
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<tr>
<td>• Children included as participants (CITI module: 152332 or 152335)</td>
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<tr>
<td>• Pregnant Women, Fetuses, Neonates as participants (CITI module: 152332 or 152335)</td>
</tr>
<tr>
<td>• Prisoners included as participants (CITI module: 152332 or 152336)</td>
</tr>
<tr>
<td>• Students included as participants (CITI module: 152334 or 152337)</td>
</tr>
<tr>
<td>• Internet Research (CITI module: 152338)</td>
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<tr>
<td>• International Research (CITI module: 153207)</td>
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</tbody>
</table>

☐ 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. Be sure to complete eProtocol addendums, if applicable.
   ○ The “Check for Completeness” function can be used to assist with completing the form.

updated 1/21/2019
If copying & pasting text into eProtocol, use Plain text. Copying & Pasting is not advised.

It is recommended that you complete all sections of the submission before starting the key personnel sign off process. See full board schedule on IRB website

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:

| Consent Information section: | Research Informed Consent, Parental Permission, Research Information Sheets, Request for Waiver or Alteration of Consent |
| Assent Information section: | Adolescent Assent, Oral Assent Script, Request for Waiver of Assent |
| Protocol Information-Attachment section | Protocol, Protocol Addendums, Research Proposal |
| CV/Resume | Data Collection Tools (Diaries, Questionnaires, Surveys, Assessments etc) |
| Investigator Brochure/Packag e Inserts | Recruitment Materials: Advertisements, Flyers, Scripts |
| Participant Materials | Other documents (i.e. FDA IND/IDE letters, Sponsor Letters |
| Department Approvals (i.e. PRMC, DMC, Radiation Safety, Psychiatry, etc) | PSF Appendices: D, F, G, and H (see below) |

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

Coordinating Center Application (attached under the Study Location section)

The Full Board Review Process

Submit based on the IRB Deadlines & Meeting Dates Schedule

IRB Chairperson assigns submission to the IRB reviewers

IRB Members/Reviewer may request revisions before the IRB meeting.

IRB Members/Reviewer 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 indicate that revisions have been made in the comments section. Addressing each comment.

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.

updated 1/21/2019
Expedited & Exempt Submissions

- Review IRB Expedited & Exempt Guidance Tools to identify appropriate submission type
- No deadline for Expedited or Exempt submission types
- Protocol information – Study Details select the Identified Submission Type: (Expedited or Exempt)
- Research Categories will populate based on selected Submission Type
- Complete all sections of the form (including addendums & appendices)

Supporting Documents:
  - Attach Consents/Information Sheets to the “Consent Information” section
  - Assents/Information Sheets attach to the “Assent Information” section
  - Protocol Information- Attachments: Protocol/Proposal, CV, Surveys/Questionnaires, Participant Docs etc.

Upon receipt of your submission in the IRB Office you will receive email notifications during the review process up until final approval (emails are sent to the WSU email address)

- IRB Reviewer is assigned
- IRB Reviewer Request Revisions
- IRB Administrator forwards revision request via eProtocol
- PI or Protocol Coordinator:
  - Make changes to the sections indicated per the revision request
  - Attach any revised documents to the applicable sections
    - Consent & Assent Information section
    - Attachments section
  - Corrections should be made to the sections indicated per the comments request.
  - Indicate that revisions have been made in the comments section. Addressing each comment.
  - Submit revisions back to IRB

- IRB Reviewer will review and approval or request additional revisions.
- Approval letters will be available in the Events History section
- Stamped documents are available in the Attachments sections. Labeled “IRB Approved Stamped Documents”

Note: Minimal Risk Studies: Status Update or Continuing Review
  - Status update or Expiration Date indicated on IRB Approval Memo
  - Follow instructions of approval memo for completion of the status update or continuation

Note: Studies requiring DMC Review (Full Board, Expedited, or Exempt)
  - Select Print View tab:
    - Select applicable sections of the eProtocol form
    - Save form as a PDF to provide for DMC Review
    - Consent & Assents and other participant documents will need to be saved separately and forward to DMC for review.

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