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 Continuation Submissions

## ☐ EXPEDITED Continuation

- No participants have been enrolled
- Enrollment is permanently closed *and* all participants have completed all research-related interventions
- The only research activity remaining is data analysis
- The research remains active only for the long-term follow-up of participants, *and*
- No additional risks or increase in existing risks have been identified which justified a full board amendment during the approval period under review
- Has not undergone a full board amendment review during the approval period under review.

## ☐ FULL BOARD Continuation

- A full board study that:
  - Has accrued participants in the current approval period.
  - Has not yet accrued participants in the current approval period; however, an amendment identifying a new risk and/or increased risk to participants was reviewed by the full board in the current approval period.
  - Continues to complete research-related intervention.
  - Has undergone a full board review of an amendment during the approval period under review.
  - A Humanitarian Use Device

## Submission Instructions:

- ☐ The eProtocol Continuation Form is available for use 90 days before the date of expiration.
- ☐ Continuation Reminders are sent at **90 days, 60 days, 30 days before the expiration date**.
- ☐ It is the Principal Investigator's responsibility to make sure continuations are submitted in a timely manner to the IRB before expiration or the study is closed by submitting an eProtocol Final Report.
  - Submit continuations at minimum at least **6 weeks before expiration.**
  - *Single IRB Submissions* (WSU is the IRB of record and coordinating center for multiple sites): Submit the continuation **at least 8 to 10 weeks before the date of expiration.**
  - Please include time to secure any administrative approvals (if applicable) (i.e. PRMC, CIC review) before submitting to the IRB.
- ☐ Full Board continuation submissions please be mindful of the deadline dates for the designated IRB. IRB submissions deadlines and meeting dates are available at irb.wayne.edu
- ☐ Attach **clean** copies of documents (i.e. consents, assents, scripts, recruitment materials, participant materials, etc.) that require re-stamping by the IRB at the end of the Continuation Form. Note, Data Collection Instruments and tools do not need to be re-stamped.
- ☐ The Dean/Chair/Authorized Signatory must complete sign-off on the continuation.
  - First time "Submit Form" is to the Dean/Chair/Authorized Signatory.
  - Second time "Submit Form" is to the IRB Office.

- Continuations that are submitted after expiration or IRB continuation approval is not granted before expiration: *all research activities must stop, unless activity is necessary for the safety of the participant. You must notify the IRB of any research activities that occurred during the period of non-approval.*

- Continuations submitted **60 days after expiration are not allowed** (a new study will be required).

## Mandatory CITI Training:

- CITI training modules for key personnel must be current. The Biomedical Investigator's or Social Behavioral Investigator's course expires every 3 years. The refresher course must be completed before CITI training expiration.
- Key Personnel must add their WSU Access ID to CITI Profile
- CITI is confirmed for each type of eProtocol submission (i.e. continuation & amendment)
- **If key personnel have not completed all required modules (including refresher course) the system will not allow submission of the continuation**.
- All modules including vulnerable populations & Specialty Modules (internet & international research)

**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)
- Pregnant Women, Fetuses, Neonates 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)

## An Amendment cannot be submitted at the same time of continuation

- The continuation must be approved before another submission type is completed. However, modifications can be made at the point of continuation.

## Modifications:

- Modifications are allowed during continuation submission, but not recommended.
- If modifications are made a summary of those modifications must be provided.
- Modifications should be made to the appropriate sections of the eProtocol Form and modified documents attached to the appropriate sections.
  - If revising consents, assents, participant materials a highlighted and clean copy must be attached.
  - If revising the Protocol or Package Inserts a highlighted copy must be provided.

# Reminders

- Use a supported web browser (Firefox 12, Safari 7)
- Make sure the Pop-Up Blocker is turned off
- Do not use the "Back button" or "Refresh" in the system
- It is not recommended that text is copied and pasted into eProtocol.