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

WSU Status Update Report for Minimal Risk Studies

Expedited & Exempt Submissions

In order to provide an appropriate level of oversight and adjust to the changes in the Revised Common Rule, the WSU IRB has implemented a status update process for the ongoing review of minimal risk research. The status update process is for minimal risk research in which continuing review is not required by the Common Rule in accordance with 45 CFR 46.104, 46.109, & 46.110 and for all studies have been granted a Concurrence of Exemption after January 21, 2019. It is the WSU IRB's responsibility to maintain oversight of minimal risk studies which includes confirming the currency of CITI training and Conflict of Interest (COI) disclosure, review of study modifications, and management of unanticipated problems.

If a study requires submission of a status update report, this will be noted on the initial approval/concurrence of exemption memorandum from the IRB. For more information regarding the status update report and/or continuing review requirements see the [WSU IRB Continuation/Renewal of a Protocol policy](#).

Status Update Report Submission Instructions

- ☐ **Exempt Studies Approved via eProtocol:**
  - ○ Complete the [Minimal Risk Status Update Form](#) available on the IRB's website
  - ○ Start an **Amendment** in eProtocol [(see eProtocol Amendment Submission Guidance](#))
  - ○ Select "Status Check-In" on the Amendment Form
  - ○ Attach the [Minimal Risk Status Update Form](#) for the Protocol Information-Attachment section with the label "Minimal Risk Status Update Form"
    - ▪ Note: If modifications to the study or study documents are being made the remainder of the amendment form will need to be completed and updates made to the appropriate eProtocol sections.
  - ○ Select "**Submit Form**"
  - ○ Upon completion of IRB review and approval, notification of an amendment approval will be sent to the Principal Investigator.

- ☐ **Expedited Studies Approved via eProtocol**
  - ○ Complete the [Minimal Risk Status Update Form](#) available on the IRB's website
  - ○ Start a **Continuation** in eProtocol.
  - ○ Select "Status Update Report" on the Continuation Form
  - ○ Attach the [Minimal Risk Status Update Form](#) at the end of the Continuation Form. **Do not** complete the remainder of the Continuation Form.
  - ○ Select "**Submit Form**"

- Upon completion of IRB review and approval, notification of approval will be sent to the Principal Investigator.
- Note: If modifications to the study or study documents need to be made an amendment form must be completed and submitted either before or after the review and approval of the status update submission.

Expedited & Exempt Studies Approved via the Paper-Based Process

- Complete the Minimal Risk Status Update Form available on the IRB's website
- Email the form to eirbmanager@wayne.edu

Mandatory CITI Training

All key personnel CITI training must remain current and is checked as part of the status check review process. The Basic Course in Human Subject Research (Biomedical or Social Behavioral Investigators) refresher course is required every 3 years. To complete required CITI training go to the CITI website: www.citiprogram.org.

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