UWM IRB Review Process for New Submissions

Is it Human Subjects Research?
- No
  - Complete "determination" form and you may submit to IRB Office for decision
  - No IRB Submission needed
- Yes
  - No
  - Don't know
  - Complete "determination" form and you may submit to IRB Office for decision
  - Prepare a New Study Submission for the IRB to review
  - Submit new study x-form

IRB Office completes a preliminary review of the submission
- 1. Determine if all necessary documents have been submitted
- 2. Determine a review category (consult with other IRB members as needed). PI may be asked for clarifications prior to determining review category

Exempt from the Common Rule
- IRB Staff conducts review to ensure participant rights are being respected. PI may be asked to clarify areas that are unclear
- Exempt Approval

Exempt from the Common Rule
- Expedited Review
  - Sent to 1-2 IRB members for review
  - PI/SPI will receive a list of the revisions and clarifications requested by the reviewers
  - Average review time is two weeks
  - New study x-form sent back to person who created it
  - PI/SPI revises documents, creates cover memo addressing requested revisions
  - Attach cover memo and revised documents to original new study x-form and resubmit
  - SPI and/or PI submits revisions back to IRB
  - Revisions reviewed and follow-up with PI as needed
  - Study is approved

Full Board Review
- Reviewed by all IRB members at next scheduled meeting (submission must be received two weeks prior to meeting date)
- Vote to table the study until next meeting
- Revisions reviewed at next full IRB meeting
- Vote to approve study
- Approval issued
- SPI and/or PI submits revised documents
- Revisions sent to PI
- Approval issued

Note: After approval for expedited and full board approvals:
- Amendment request will be needed if changes to the study procedure or data collection instruments occur
- Continuing reviews are not required, although you will be contacted in 36 months to determine if the study is still active

- Any changes to the study need to be approved through an amendment request
- Continuing reviews are required at least every 12 months. Be aware of your expiration date
- Conducting activities on an expired study is considered non-compliance and notification to funder may be required