Weill Cornell Medicine
Research Integrity
Human Research Compliance

Researcher Checklist
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Single IRB Submission Checklist – Reliance on an External IRB

The purpose of this information is to assist WCM faculty, staff and students who are conducting a study for which an **external IRB will serve as the Reviewing IRB (IRB of record)**. Please read this information carefully to avoid noncompliance with Institutional policies.

If you have a question that is not answered below, please visit the IRB website at WCM IRB or contact our WCM Reliance Team at singleirb@med.cornell.edu .

Step 1: Complete Reliance Request Form

- ☐ Submit a reliance request by completing the WCM Reliance Request Form.
  - Reliance is applicable if two or more US sites are engaged in non-exempt human research.
  - See OHRP's policy and guidance on Engagement of Institutions in human research.

---- DO NOT PROCEED TO STEP 2 UNTIL Reliance is established and A MEMO FROM WCM SINGLE IRB CONFIRMING RELIANCE IS RECEIVED -----

Step 2: Confirm approved protocol and accompanying documents from the Reviewing IRB are available. These include but are not limited to:

- ☐ Protocol
- ☐ Recruitment materials (if applicable)
- ☐ Informed consent form(s) (if applicable)
- ☐ Any other relevant study materials

Step 3: Submit a Non-WCM Intake & Initial Submission

- ☐ **Submit the Non-WCM Intake Form** in WRG-HS
  - Select "Non-WCM Review and Approval (Central IRB or Single IRB)" for your application type.
  - See the ITS Knowledge Base (KB) article: HowTo: Submit an Intake Form (Study Activation)
  - Please note, the intake form will identify any additional ancillary reviews that may apply to your study based on proposed activities. Follow system provided guidance to initiate these applicable reviews.
- ☐ **Submit to PRMC:** After the intake form is submitted, you will need to submit to the Protocol Review and Monitoring Committee (PRMC).
  - The PRMC will review your protocol for scientific 'soundness', and its approval should ideally be obtained **before** submitting the Non-WCM initial application to the IRB.
  - Please allow 24 hours for the record number to be transferred over to Oncore
  - See the ITS Knowledge Base (KB) article: HowTo: Submit Your Protocol to the PRMC in WRG Clinical Trials (ePRMS)

*****If the study relates to cancer research, Disease Management Team (DMT) approval is also required, preferably before PRMC submission*****

- ☐ **Submit the Non-WCM Initial Application:** After receiving PRMC approval, proceed with the completion of the non-WCM initial application for local context review and acknowledgement.
  - Ensure to include all approved study material such as:
    - Reviewing IRB's approval notice (WCM added as a site)
    - Protocol
    - Consent form(s)
    - Recruitment material(s)
    - Questionnaires/assessments
    - Other study material documents
    - Reliance agreement document/memo
    - Any local context form(s). If not provided from Reviewing IRB we will include as part of our local WCM IRB review.
  - See the ITS Knowledge Base (KB) article: HowTo: Submit Your Initial IRB Application & New Submission Types

Step 4: Make sure all WCM key personnel on your application:

- ☐ Certifies the application. This is confirmation of their agreement to be part of the study.
  - See the ITS Knowledge Base (KB) article: HowTo: Certify on an IRB Application or Other Submission Type
- ☐ Have completed CITI training as required.
  - See the requirements on the IRB website: Research Team Training and Education Requirements
- ☐ Have completed their annual Conflicts of Interest (COI) survey.
  - For information on how to submit your Conflicts Survey, see the ITS Knowledge Base (KB) article: HowTo: Submit your Annual Conflicts Survey

WCM IRB Acknowledgement:

- Submission to the WCM IRB is not completed until the WCM IRB acknowledges the Non-WCM submission and provides an acknowledgment letter in WRG-HS.
- All research conducted under sIRB reliance arrangements must be conducted in compliance with all relevant WCM research policies and procedures. Actualization these protocols constitutes acknowledgement by the investigator that the research will comply with WCM policies and procedure.
- Non-WCM submission in WRG-HS will be set to expire on expiration date issued by the Reviewing IRB (IRB of record).

Progress reports, Amendments, Unanticipated Problems (UPs) & Closure:

- To gain re-approval, you must follow the reviewing IRBs annual reporting requirements. This may include submitting a Progress Report to the reviewing IRB prior to the expiration of the study. Once approved, submit a Continuing Review (CR) or Post Approval Monitoring Report (PAMR) to the WCM IRB for re- acknowledgement. The WRG-HS system will generate an email notification 90-60-30 days prior to the expiration of this study's approval. However, it is your responsibility to ensure that a CR or PAMR is

submitted in a timely fashion following reviewing IRB approval. (Please note that research activities may continue uninterrupted unless directed otherwise by the Reviewing IRB.)

- A change in PI must be submitted to both the WCM IRB via WRG-HS as well as to the Reviewing IRB.
- Any other changes in study personnel must be submitted to the WCM IRB via an Amendment in WRG-HS only.
- Any additional changes proposed for this protocol must be submitted to the Reviewing IRB, for review and approval prior to implementation, unless such a change is necessary to avoid immediate harm to the participants.
- Outside of personnel changes detailed above, only amendments impacting study related risk or warranting new local context considerations from WCM require prompt submission to the WCM IRB. All other changes can be collected and reported during the annual CR or PAMR submission as a list.
- Unanticipated problems that involve non privacy related risks to subjects must be reported to the Reviewing IRB in accordance with their reporting process. The WCM IRB must also be notified of such reports and be provided with any resulting the Reviewing IRB determination reports.
- Any Unanticipated problems that involve privacy related risks or breaches of patient protected information must be submitted in parallel to the Reviewing IRB and the WCM IRB.

Using SASP:

The Study Activation Status Page (SASP) is a dashboard where you can monitor a set of tasks and required activities which need to be completed for each of your study protocols. Depending on the specifics of the research, some requirements are not necessary, while others are always required (i.e., PRMC)

Please note that WCM final acknowledgment **does not** represent institutional approval. Please check the Study Activation Status Page (SASP) in WRG-HS and/or ensure that all ancillary approvals are received before commencing research.

Resources

Reliance and Single IRB Submission Process:
https://hrp.weill.cornell.edu/sites/default/files/103.1_reliance_process_and_sirb_.pdf

Questions/Concerns?

For Single IRB/Reliance questions/concerns, please reach out to our WCM Reliance Team at singleIRB@med.cornell.edu

or

set up an IRB consult: https://weillcornell.az1.qualtrics.com/jfe/form/SV_8B8nCOcC8q7pUN0