Investigator submits Intake Form to WRG-HS

IRB Manager (IM) receives the protocol and checks for gross inaccuracies, incomplete questions, or other major issues.

IM sends submission to appropriate IRB Analyst (IA) for pre-review within 2 business days of receipt.

IA conducts pre-review within 5-10 days of assignment by IM, or receipt from PI.

*IA may return the protocol to the PI if revisions are necessary.

PI completes responses and returns protocol to the IA.

The MR reviews the protocol and confirms that the protocol is compliant with federal regulations and ethical guidelines.

Reviews the risk level and Expedited/Exempt assignment and has the option to return the protocol for Full Board.

Protocol is assigned to an Expedited or Exempt Board member reviewer (MR) for formal review.

IA confirms whether the submissions meets the criteria for "Greater than minimal risk" or "Minimal Risk".

Protocol returned for additional information, or response to questions by PI.

Protocol is sent for review by IRB Member Reviewer (MR) and assigned to the next available Full Board meeting.

PI completes responses and returns protocol to the IA.

All Board members attending the meeting have access to the protocol. The MR is responsible for presenting the protocol and any recommendations.

During the meeting, the Board reviews the Full Board checklist as a group and the IA records the research summary, controverted issues, resolutions, and vote on a determination. The MR can recommend the following determinations for a vote: Approve (the protocol requires no revisions), Prescriptive Modifications Required (the protocol requires revisions to secure approval), Substantive Modifications Required (the protocol warrants Full Board review).

The MR makes one of three determinations: Approve (protocol requires no revisions), Prescriptive Modifications Required (the protocol requires revisions to secure approval), Substantive Modifications Required (the protocol warrants Full Board review).

Once all revisions are complete, the IA finalizes the protocol with an approval date and the protocol is marked as “Approved” in WRG-HS.

Substantive Modifications Required, Disapproved

Disapproved protocols cannot be resubmitted. Substantive Mods protocols must be resubmitted for a future IRB meeting.

Protocol is sent for COI review after the submission is assigned to a meeting agenda.

Approved, Prescriptive Modifications Required

Full Board

Expedited/Exempt

Incomplete Submission