

Investigator notifies ORI of intent to conduct a human subject research protocol

ORI informs investigator that IRB #1 and #2 application documents can be located on the website at [www.marshall.edu/research/ori](http://www.marshall.edu/research/ori).

Investigator completes application and the appropriate documentation for the review requested. The PI, Co-PI and Research staff complete all educational requirements before submission to ORI. All required information is submitted **30 days** before the next scheduled IRB meeting.

Chairman or Designee reviews the protocol and determines if it meets criteria for Exempt Review

Yes

Meets Exempt criteria

Protocol and Exempt Checklist are reported as meeting Exempt criteria at next IRB meeting.

No

Chairman or Designee reviews the protocol and determines if protocol meets criteria for Expedited Review

No

Primary and Secondary reviewers are assigned to review the protocol and are given a copy of the investigator's Protocol Assessment Checklist at least 2 weeks prior to IRB meeting. The reviewers must complete and return the completed checklist at least 1 week prior to the IRB meeting.

Protocol is placed on the IRB agenda and the IRB members receive copies of all relevant materials at least one week prior to IRB meeting

At the IRB meeting, the primary or secondary reviewer will present the protocol to the committee and contribute their comments. The PI will attend the IRB meeting, if requested by the Primary and/or Secondary Reviewer or Chair. ORI will inform the PI and schedule an appointment for attendance.

IRB Approves, Modifies, or Disapproves

Modify

Investigator notified of changes required.

Investigator makes appropriate changes and submits them to ORI review and approval by the IRB Chair or designee.

Disapprove

Investigator notified protocol is disapproved.

Approved

Investigator is notified of IRB approval. Research may begin at all locations, except the Huntington VAMC. *(All research conducted at the Huntington VAMC must receive approval from the Research & Development Committee prior to start of any research.*

Meets Expedited Criteria

Protocol and Expedited Checklist are reviewed and reported as meeting Expedited criteria at next IRB meeting.