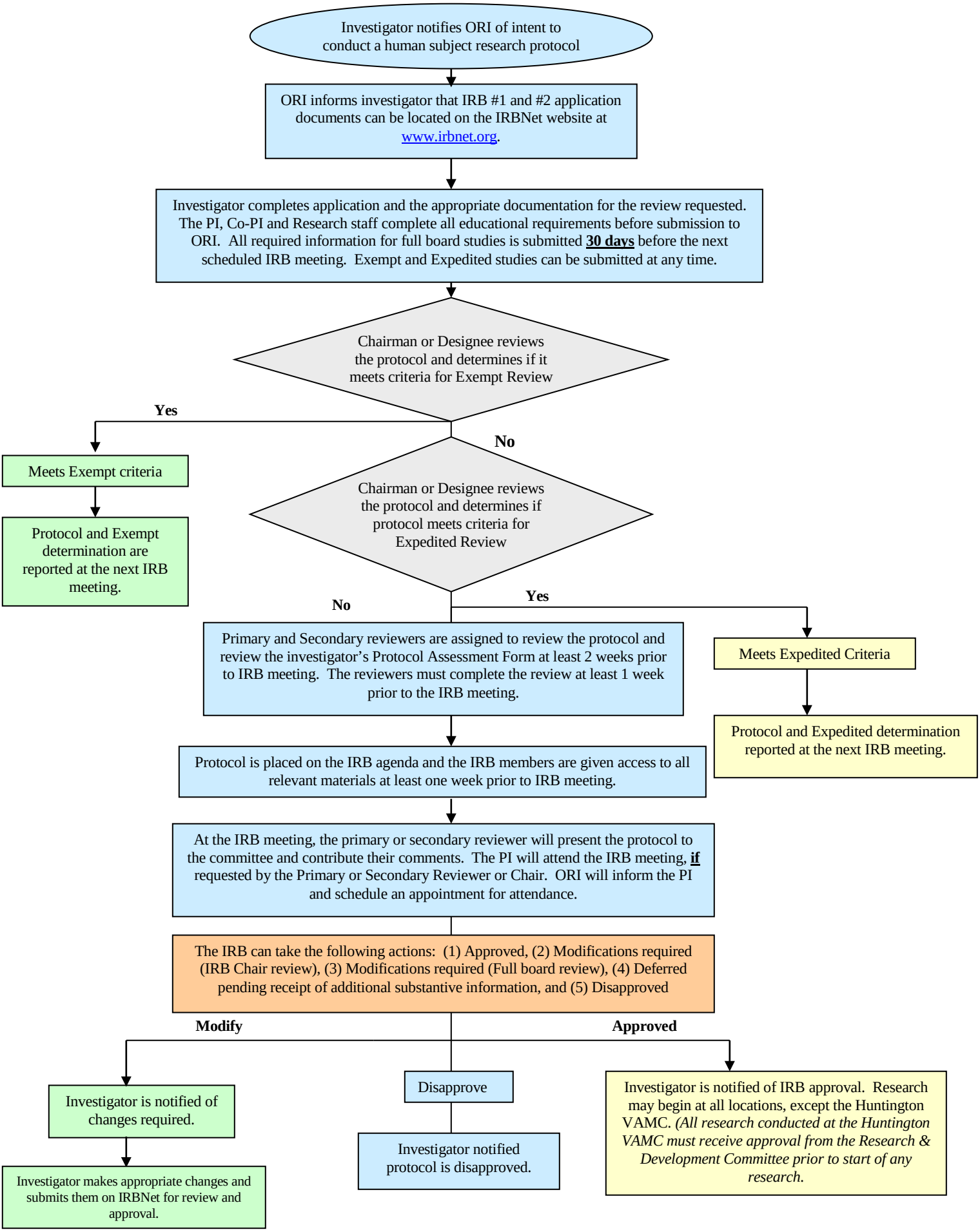
Investigator notifies ORI of intent to conduct a human subject research protocol
ORI informs investigator that IRB #1 and #2 application documents can be located on the IRBNet website at www.irbnet.org.
Investigator completes application and the appropriate documentation for the review requested. The PI, Co-PI and Research staff complete all educational requirements before submission to ORI. All required information for full board studies is submitted 30 days before the next scheduled IRB meeting. Exempt and Expedited studies can be submitted at any time.
Chairman or Designee reviews the protocol and determines if it meets criteria for Exempt Review
Yes
Meets Exempt criteria
Protocol and Exempt determination are reported at the 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 review the investigator's Protocol Assessment Form at least 2 weeks prior to IRB meeting. The reviewers must complete the review at least 1 week prior to the IRB meeting.
Yes
Meets Expedited Criteria
Protocol and Expedited determination reported at the next IRB meeting.
Protocol is placed on the IRB agenda and the IRB members are given access to 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 or Secondary Reviewer or Chair. ORI will inform the PI and schedule an appointment for attendance.
The IRB can take the following actions: (1) Approved, (2) Modifications required (IRB Chair review), (3) Modifications required (Full board review), (4) Deferred pending receipt of additional substantive information, and (5) Disapproved
Modify
Approved
Investigator is notified of changes required.
Investigator makes appropriate changes and submits them on IRBNet for review and approval.
Disapprove
Investigator notified protocol is disapproved.
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.