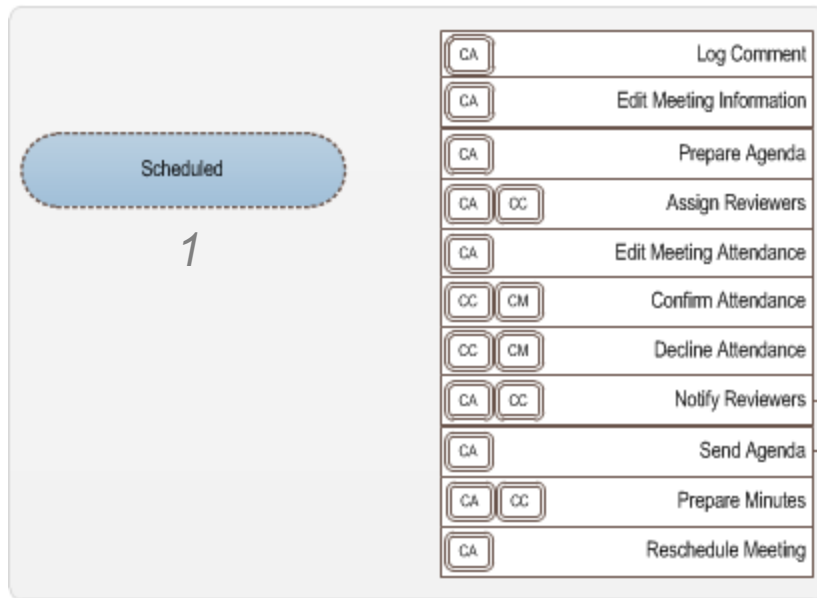
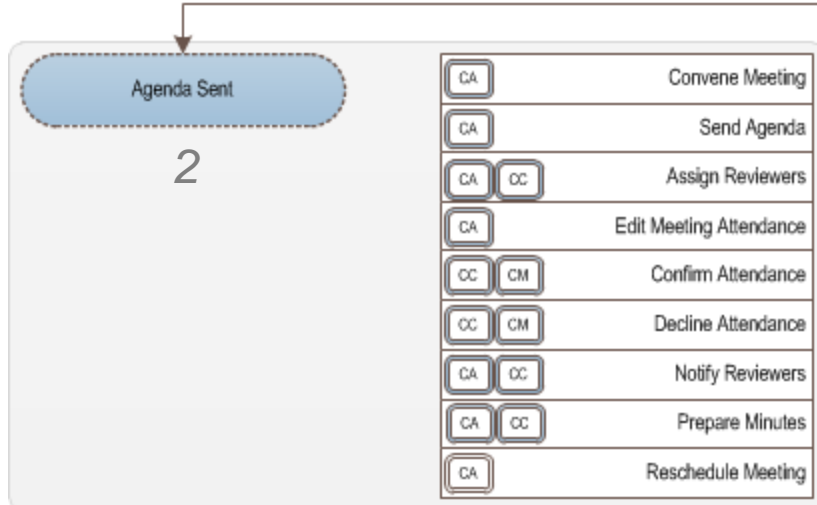


Full-Committee - Administrative Process Workflow

One of three

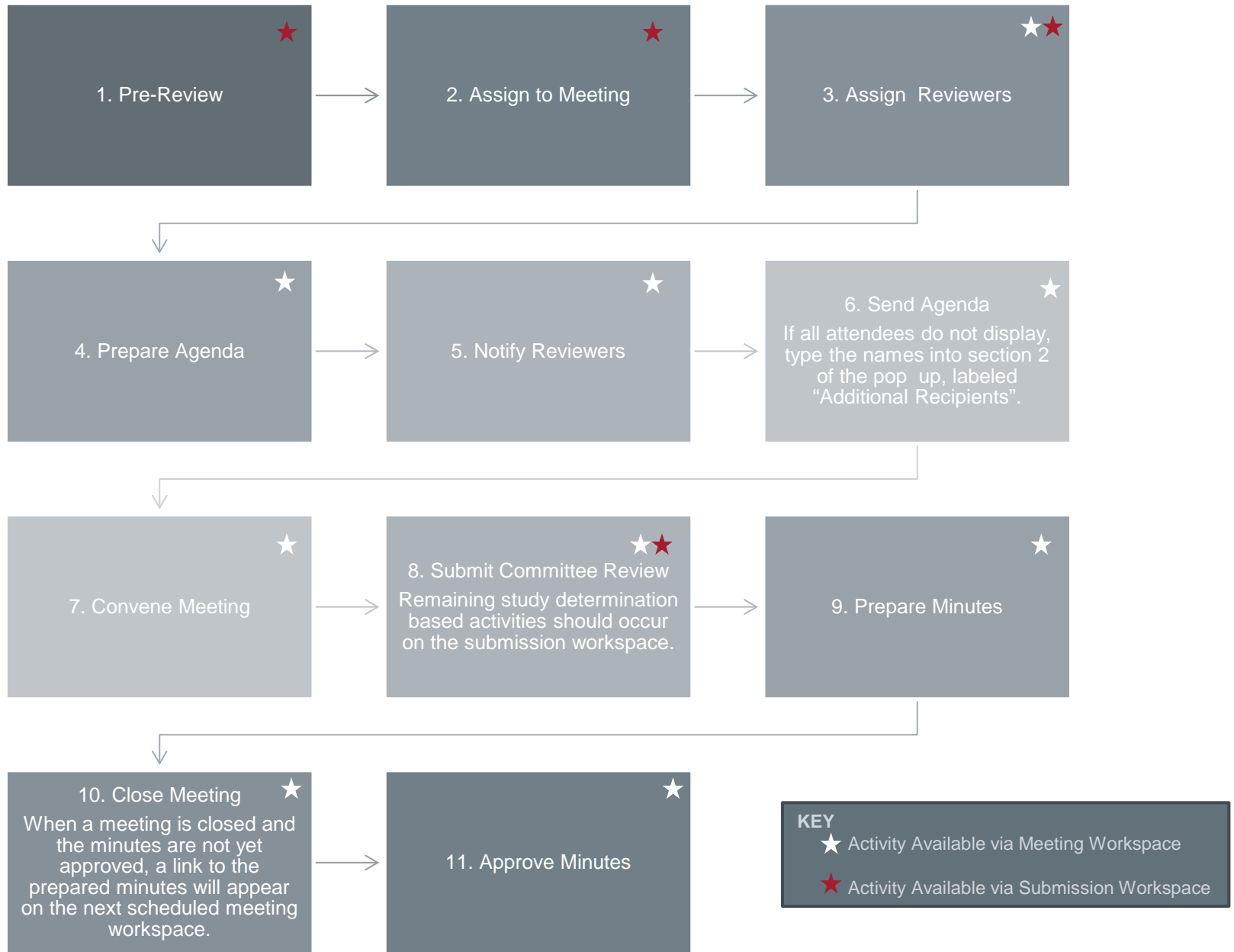


1. Meeting is scheduled
2. Specific reviewers are notified
Edit Meeting Attendance can be completed also
3. Agenda is sent to the Committee
4. Meeting is convened
5. Actions are recorded, minutes prepared and approved
6. Meeting is closed



Full-Committee - Process Activity Order

Two of Three



Full-Committee - Administrative Process Details

Three of Three

1. Pre-Review

- Initial high-level review conducted by the IRB Contact
- IRB Contact will complete the Pre-Review activity, and indicate the special populations, determinations, & waivers
- IRB Contact will assign Submission to Designated Reviewer to complete the review

2. Assign to a Meeting

- Completed after conducting pre-review and determining that a submission requires full-committee review

3. Assign Reviewers

- Reviewers can be assigned from either the Study Workspace or from the Meeting Workspace.
- Reviewers will only be notified when specified or when the Agenda is sent out.
- Meeting attendance can be updated

4. Update & Send Agenda

- From the Meeting Workspace, a draft agenda is generated and updated as necessary
- The "Notify Reviewers" activity is completed to email the reviewers, letting them know of their assignments.
- Send agenda is completed to send the agenda to all attendees
Workaround: If all attendees do not display, type the names into section 2 of the pop up, labeled "Additional Recipients"

5. Members Complete Review

- Reviewers can access information via the meeting workspace or navigate to their InBox to find their assignments.
- Reference Checklist can be viewed within the Pre-review activity
- Questions or concerns are sent direct to the IRB contact or noted outside the system to share during the meeting.

6. Conduct Meeting

- It is advised to take meeting notes in the draft meeting minutes document, by executing the "Prepare Minutes" activity
- Once the meeting is complete, execute the "Convene Meeting" activity - this activity locks the meeting, preventing new submissions being added, and allows the IRB to finalize the meeting minutes.

7. Record Decision

- From the Meeting Workspace, The IRB Contact can click on the "Record Meeting Decision" for each submission, and record the votes, determination and other relevant information. This will allow the IRB to continue the submission through the process, transitioning the submission to the "Post Review" state.

8. Finalize Minutes

- Once the meeting minutes are written, the Meeting Admin will upload the draft final version via "Prepare Minutes".
- Assign the Minutes to the next meeting for committee review.
- When committee has accepted the minutes, Meeting Admin executes "Close Meeting" (minutes can no longer be edited) & "Approve Meeting Minutes".