## Items to Consider During Convened Modification Review:

- ✓ Does the amendment alter the risk/benefit ratio for subjects?
- ✓ Are the requested changes evident in all appropriate study materials?
- ✓ Could the proposed changes affect an active subject's decision to continue participation in the study?
- ✓ Was the informed consent form updated appropriately? Was an appropriate re-consent plan provided?
- ✓ Does the current modification request to enroll vulnerable populations? If so, does the study meet the criteria for enrollment of these populations?

## Does the study continue to meet the criteria for approval with the proposed changes?

- ✓ Risks to subjects are minimized and reasonable
- ✓ Selection of subjects is equitable
- ✓ Informed consent will be sought and properly documented
- ✓ The research plan makes adequate provision for monitoring data to ensure safety
- ✓ There are adequate provisions to protect subject privacy and confidentiality of data

## Recommendation Options:

**This is a 3 part decision to be made when the board has completed the review of an action item.**

| Part 1: Choose one overall decision for the agenda item: | Part 2: Choose the appropriate risk level | Part 3: Choose the appropriate frequency for renewal |
|---|---|---|
| Approval | Greater than Minimal Risk | Convened Annual Renewal Required |
| Withheld Approval (pending responses to the issues raised) | Minimal Risk | Convened Renewal Required Every 6 Months |
| Tabled (to address the issues raised for which responses require convened review) | | Expedited Annual Renewal via Category 9 Required |

*Review frequency and risk level might not be determined with a Tabled decision since the convened board must review the responses.

## Additional Resources for Modification Reviewers

Click here to review the IRB Modification Submission Requirements
Click here to access the IRB Member Toolbox