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.

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

*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