### Items to Consider During Convened Continuing Review:

- Were any exception requests or deviations submitted in the last approval cycle?
- Were any adverse events reported? Are revisions necessary due to these events?
- Is the enrollment notably slow? If so, was adequate justification provided?
- Is there a notable rate of withdrawals? Are withdrawals adequately explained?
- If vulnerable populations are participating, does the study meet established criteria?
- Were any monitoring reports received?

### Does the study continue to meet the criteria for approval?

- Risks to subjects are minimized and reasonable in relation to anticipated benefits
- 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>Re-Approval</td>
<td>Greater than Minimal Risk</td>
<td>Convened Annual Renewal Required</td>
</tr>
<tr>
<td>Conditional Re-Approval</td>
<td>Minimal Risk</td>
<td>Convened Renewal Required Every 6 Months</td>
</tr>
<tr>
<td>(pending responses to the issues raised)</td>
<td></td>
<td>Expedited Annual Renewal via Category 9 Required</td>
</tr>
<tr>
<td>Tabled</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(to address the issues raised for which responses require convened review)</td>
<td></td>
<td></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.

### If you need further guidance while conducting your review:

- [Click for IRB guidance on reportable events](#)
- [Click for IRB continuing review submission requirements](#)
- [Click here for the IRB Member toolbox](#)