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.

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
Re-Approval	Greater than Minimal Risk	Convened Annual Renewal Required
Conditional Re-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.

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