eIRB is a great tool for showing changes when protocol amendments must be submitted, so reviewers are able to identify changes easily and efficiently. One caveat, however, is that coordinators/investigators are copying and pasting whole new sections (e.g., study procedures, inclusion/exclusion criteria, risks), even when only a small number of changes in a section have been made. This makes it very difficult and time-consuming for reviewers to locate the changes and make decisions as to whether or not the risk profile of the study has changed. Therefore, when amendments are submitted, each change needs to be specific. In other words, for example, if only three words in one sentence change, then only delete and replace those three words.

We realize this requires a bit more effort on the part of the person submitting the amendment. However, if it is not done like this, the amount of time our volunteer reviewers have to spend to make a decision on the amendment goes way up. In addition, contingencies may be applied to an amendment simply because the reviewer cannot isolate the changes in the SLU documents. As a result, amendments in which entire sections are copied and pasted will be sent back, with comments to submit specifically-identified changes only.

For further tips or instruction, please see the eIRB user guides and quick sheets on the IRB web site.