

Modification Pro-Tips

Did you know that amendments or modifications (“MODs”) and renewals make up more than 70% of the REBs file volume? Amendments can also be as complex as the initial study application, so making sure your MOD submission is as clear will facilitate its review.

There are some things that you can do to help ensure the REB can review your MOD submission efficiently:

DO: Please provide a detailed, yet concise summary of the AME/MOD submission. The REB reviewers must understand what has been changed and why. Providing a description and rationale for changes help them to do this and facilitates review. REB reviewers have access to the protocol amendment summary, please do not cut and paste the full details into your modification request nor just refer to “attached documents” for your MOD description.

DO: Please update the applicable sections within the full application to reflect the changes made in the protocol amendment. The ethics application reflects what you are approved to do at any given time. Making sure all the revised details are reflected in your application will result in fewer delays to approval of the MOD.

DO: Please provide tracked changes AND clean versions of updated documents. Being able to readily identify what has changed is essential to reviewing a modification expediently and saves REB reviewers a lot of time.

DO: Please ensure that your MOD submissions are complete. Wherever possible, submit all revised elements for the study in one submission. While mistakes happen and sometimes documents are missed, multiple submissions create extra work for both study teams and for the REB.