

The submission of an amendment/modification to an approved IBC protocol requires the creation of a subsequent **PACKAGE** project.

After an IBC application is approved, the project may require modifications during the course of the research. The Principal Investigator (PI) is responsible for submitting an amendment/modification application to the DU IBC for review to obtain approval for any changes that may be requested or required. An example of a change that would require an amendment could include adding new personnel

Step 3: [CREATE NEW PACKAGE](#)

To submit an Amendment Application you need to create a new PACKAGE , not a new project.

Step 4: [SELECT FORMS](#)

After clicking on 'Create New Package' you will be automatically directed to the [DESIGNER](#) screen where you can add documents for this package.

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The 'IBC Amendment Form' and other relevant section documents are available through the DU [IBC Library of Forms & Templates](#). Click on the blue '[Need Forms? Show Form Libraries](#)' link to view the document library.

Referencing the diagram below, select 'University of Denver (DU) | [BC](#), Denver, CO Documents for Res EMC /P 7,,chTshoc 0 Tw 65.9 2rRes EMC /P 7,



If you need to modify or change a document, utilize the following icons:



- x To remove a document from this package, click on the red [icon]
- x To revise document click on the pencil icon [icon]
- x To view the document click on the paper icon [icon]
- x To view and manage different versions of a document click on the icon [icon]

#### Step 6: LABEL FORMS

Once you have attached all the necessary documents to your study package, a list of your documents will be posted under Step 2: on the **DESIGNER** page. Select 'Amendment/Modification' to label your document.

If documents are not labeled, your application cannot be submitted.



#### Step 7: SIGN YOUR PACKAGE

When all the necessary documents are uploaded to the package, the Principal Investigator must sign the package electronically. If you are completed this package on behalf of the PI, send an email to the PI using the 'Send Project Mail' function and request that the PI sign the package. The Principal Investigator **MUST** sign the package before it is submitted.





