

Instructions for Submitting an Amendment/Modification Application in IRBNet

1. Click on the **Study Manager** in the navigation bar on the left side of the screen. Select the title of the study that is undergoing continuing review.
2. Under the **Study Administration** in the navigation bar on the left, select 'Study History'.
 - a. A list of all "packages" that have been submitted as part of the study will be displayed. Your original submission package will be listed as package number 1, and any modifications, amendments or unanticipated adverse events will each be listed as separate "packages."
 - b. The information provided in the Study History page includes the type of package submitted, the date of submission, and the status of each submitted package (approved, pending review, etc.).
3. Select the **Create New Package** button at the bottom of the Study History page. A new package will be added to your Study History page, named "new document package." The status of this package will be shown as "work in progress." The "work in progress" status will be displayed in the status column until the Amendment/Modification package is submitted.
4. Click on the blue 'New Document Package' text. Use the dropdown menu to download the appropriate forms. After the forms are completed, upload each form required for your study's Amendment/Modification application (amendment/modification application, consent form, revised consent form, revised protocol, new advertisements, etc.).
5. Select the 'Sign Study' button from the navigation menu on the left side of the screen. The PI or the PI's designee **MUST** sign the study before it is submitted.
6. Once you have attached all the required documents and signed the study, it can be **submitted** to the IRB Office. Select 'Submit this Study' from the navigation panel on the left side of the screen.
 - a. MSM automatically is selected in the drop down list. Select 'Continue'.
 - b. Under 'Submission Type' use the drop down menu to select 'Amendment/Modification'. If you have any comments for the IRB office to accompany the submission, include them in the comment box. Select the 'Submit' button.
 - c. You will receive a confirmation message that your amendment/modification package has been submitted. An email message will be sent to you when there is activity required on your part or a decision letter has been issued.

7. You can **exit** out of the system when you are finished. Select 'Logout' from the top right hand corner of the screen. All of your work, and files that have been uploaded, will be saved and can be accessed the next time you enter the system.

If you have questions or need further assistance please contact the MSM IRB office:

John Smith, IRB Director- 404-752-1973 (josmith@msm.edu)

Pat Winfield, IRB Administrative Assistant, 404-752-1102, (pwinfield@msm.edu)

Brenda Klement, IRB Chair, 404-752-1637, (bklement@msm.edu)