

## **Instructions for Creating a New Study in IRBNet**

1. Register with IRBNet if you have not already done so.
2. Go to [www.irbnet.org](http://www.irbnet.org) and Login.
3. In the navigation bar on the left side of the screen, select the 'Create New Study' button.
4. Type in the full Study Title (followed by title acronym if applicable), the Principal Investigator's Name, Degree(s), and the Study Sponsor\*. If there is no sponsor enter the name of your department. The keyword box is for your reference only and will assist you later if you need to search through your studies to find one pertaining to a specific topic. The Internal Reference Number is for your use only. A separate IRB number will be assigned to your study after it has been submitted. Click the 'Continue' button.

\*If this is an Industry Sponsored study, a \$2,000.00 IRB review fee will be charged.

5. The **Study Designer** page will open up. A message will be displayed indicating that no documents are attached to the study. From this page you can A) download forms and document templates or B) add a completed form or document to your study package. The Study Designer page can also be opened at any time from the navigation bar on the left side of the screen.

**A. Forms and Reference Library:** The list of MSM documents\* is available in the dropdown list. Highlight the one needed and select the Download button. The document will be saved in the desired location on your computer's hard drive or your flash drive. You can logout<sup>#</sup> of IRBNet at any time and fill out all the required forms and documents. When you log back in to IRBNet select the name of the study from the Study Manager page, then select Study Design.

\*These documents have been modified slightly from the previous versions. They no longer ask for signatures since IRBNet records electronic signatures. Also, a submission checklist must now also be completed. Please include it when submitting an initial application, continuation application, or amendment.

### **#Logging out**

You can leave the system at any time from any place within the system by selecting '**Logout**' from the top right hand corner of the page. All of your work and files that have been uploaded will be saved and can be accessed the next time you enter the system.

### **B. Add a document**

To add a completed document to your submission package, select the 'Add New Document' button.

Browse for the file on your computer or flash drive. Select the 'Document Type' from the drop-down menu, and include a Description if it is needed (ex., Revised Consent Form with changes highlighted). Select 'Attach' to upload the file. Repeat these steps until all documents for the study submission package are attached.

6. On the **Study Designer** page, a document that has already been uploaded can be A) **replaced** with a modified version of the document or B) **deleted** from the submission package.

Note: while the study submission is still in preparation and the study team is revising and modifying documents, a document that has been added to the project in the Study Designer can be updated and replaced with a new version. However, once the study has been submitted to the IRB, documents for this application package can no longer be updated, deleted or added.

1. To **replace** a document with a revised version, click the 'Update' button associated with that file.  
The **Attach Document** page will be displayed. Browse your hard drive or flash drive to locate the updated document. Select 'Update'. The new version of the document will replace the previous version.
  2. To **delete** a document from your submission package, click the 'Delete' button associated with that document. The document will be deleted from the submission package.
7. Your study can be **shared** with another investigator (Research Coordinator, Co-Investigator, Administrator, etc.). To share your study, click on the 'Share this Study' button in the navigation bar on the left side of the screen.
    - a. The **Share Study** page is displayed. Select the word "Share" in blue text.
    - b. "Morehouse School of Medicine" is automatically selected. If the person you want to share the study with is at MSM, click the 'Select Organization' button. If the person is at another institution, either scroll through the drop-down menu list or type in the organization in the Search field. The investigator must be at an institution that is using IRBNet in order to share files with that investigator. If the investigator's institution does not use IRBNet, you will have to send files and communicate with them via the standard email system.
    - c. Type in the name of the person you would like to share the study with. Select the type of access you would like them to have. Repeat this process to add each study team member. If a person that you want to share the study with is not listed, they are not registered in IRBNet. They need to create an IRBNet account and then you can share the study with them.

### **Definitions of Access Rights**

**Full**= user may add/delete/edit study documents, share the study with other users, and submit the study. Individuals with Full access to a study will receive auto-notification when an action has been taken regarding the study. You may have more than one person with Full access rights. It is recommended that students and non-affiliated PIs give this level of access to their Faculty Sponsors/Advisors.

**Write**= user may add/delete/edit study documents, but cannot share the study with other users or submit the study. Any changes a person with “write” access makes to a document using the Study Designer will automatically transfer across to the PI’s copy.

**Read**= user may only access a read-only PDF of the study. All other management features are disabled.

- d. Each user selected will automatically be sent an email notification that they have access to the study file. If you would like to include a message to be sent in the email, type it in the comment box. Click the ‘Save’ button.
  - e. A list of people that have access to the study, and the type of access that each has, will be displayed on the **Share Study** page as well as the **Study Overview** page.
8. To **Sign** your study, select the ‘Sign Study’ button from the navigation menu on the left side of the screen. The **Sign Study** page is displayed. The PI or the PI’s designee **MUST** sign the study before it is submitted. Sign your study by selecting your role on the study from the drop down menu and select the ‘Sign’ button.

The PI may have someone sign on their behalf. If another study team member signs on behalf of the PI, this acknowledges that the PI has read and approved all study materials to be submitted. To sign on behalf of the PI, click the ‘designee signer mode’ in blue text on the Sign Study page.

If work is to be conducted in the CRC, then a CRC official (Dr. Priscilla Johnson) **MUST** sign the study. If the study is sponsored by Institutional funds, the PI’s Department Chair **MUST** sign the study. The IRB office suggests that you complete the entire package, and then share it with the people who must sign it.

A confirmation note will be displayed to indicate that it has been signed.

9. 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 'New Study'. 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 study 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.
10. 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](mailto:josmith@msm.edu))

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

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