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|  | **SUNY Downstate Medical Center****University Hospital of Brooklyn****College of Medicine****College of Health Related Professions****College of Nursing****School of Graduate Studies****Graduate Program in Public Health** | IRBNET™:IRB Application and Reporting System |
| For more information or training on the system, please contact Nakih Gonzales at 718-270-4372 or nakih.gonzales@downstate.edu |

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# Introduction

SUNY Downstate Medical Center (DMC) uses [IRBNet](http://www.irbnet.org) for the electronic submissions and management of its IRB activities. IRBNet provides electronic management of protocols and documents; on-line submissions; web-based protocol sharing and collaboration; automatic notifications; the furnishing of electronic signatures; event tracking; and other important electronic features. All protocols (including revisions and renewals), follow-up actions, and reportable events must be submitted electronically via IRBNet, and all review decision notifications are issued electronically via IRBNet. Follow the instructions in this document to submit an online IRB application and any required follow-up packages.

For additional help, please see “Guidance – Visual Snap Shot of IRBNet Submission Process (IRBNet Training Energizer).” This is a graphic presentation of the screens used in IRBNet.

If for any reason you do not want to continue with an IRB submission and would like to delete the package, please click on the **“Delete this Package**” button on the left menu.

If you need to make any changes after submitting an IRB package, please contact the IRB office at (718) 613- 8480 to unlock it.

Once a new project has been assigned an IRBNet ID, for example 44879-1, the project will keep the same main project number (44879) while the number after the dash will continue to increase through the life of the project. For example if the IRB requested changes to a project after it has been submitted, the number after the dash will change as you will create a new submission to address requested revisions - the new IRBNet ID will then be 44879-2. Also, the number after the dash will increase if you submit an Amendment or another package so the next IRBNet ID will be 44879-3 and so on.

You will not be able to submit a package for an existing study until the last package created has been submitted to the IRB. For example, if you previously submitted an Amendment for an existing study and have not submitted it to the IRB and you are now ready to create your Progress Report, that existing Amendment will have to be submitted to the IRB first.

# Obtaining an IRBNet User Name and Password

To create an IRBNet user name and password, do the following:

**Step 1: Create an IRBNet user account**

* Go to [www.irbnet.org](http://www.irbnet.org/) and click the “New User Registration” link.
* Follow the online instructions. Complete all items with red asterisk (\*).
* When asked to identify your “organization” type SUNY in the text box and then select “SUNY Downstate Medical Center, Brooklyn, NY”.
* Remember to click on the “Register” button in order to finalize your “New User Registration.”
* Press the “Continue” button on the “Registration is Complete” page and follow **“Step 2”** to activate your IRBNet user account.

**Step 2: Activate your IRBNet user account**

* After successful completion of **“Step 1,”** the User will receive an activation email to the registered email address.
* Sign-in to the email account that you entered into the system and click on the link within that email to activate your IRBNet account.
* You may begin using IRBNet as soon as activation is complete.

If you forget your password, navigate to <https://www.irbnet.org/release/public/login/hint.jsp> and follow the instructions on the website.

# Submitting New Projects

Submitting a new IRB application involves the following steps:

1. Creating a New Project in IRBNet
2. Using the **“Designer”** to attach all relevant forms and documents and create a Registration Form.
3. Sharing the submission with others.
4. Obtaining SRC review and approval.
5. Obtaining any necessary ancillary reviews and approvals.
6. Obtaining e-signatures
7. Submitting the package to the IRB.

Each step is described in more detail below.

## Creating a New Project

1. On the **“My Projects”** page, click on the **“Create New Project”** button on the left blue-shaded area to start creating your IRB submission. This will bring you to the **“Project Information”** page where you can begin inputting your information for your submission.
2. Please follow the online instructions as indicated.
3. The items with the red asterisk (\*) must be filled out
4. Click **“Continue”** to move to the next section of the submission, which brings you to the **“Designer”** page (see next section)

## Using the Designer Page

The “Designer” Page is where you will locate all the forms and templates to be used with your submission.

1. Click on **“Designer”** on left menu.
2. Choosing **“Need Forms? Show Form Libraries”** will allow you to download blank forms, templates, or reference materials.
	1. **In the section “Select a Library,”** choose the location of the IRB which would be **“SUNY Downstate Medical Center, IRB Office, Brooklyn, NY”**
	2. The section labeled **“Select a Document”** is where all the most updated DMC/IRB forms and templates will be located.Please download all forms needed for your submission to your desktop so that you can begin editing as needed.
3. Save and edit your documents on your computer.
4. Click on **“Attach New Document”** page so you can begin to add the documents needed for your IRB submission:
* Choose the document type from the drop down menu.
* Clicking on the paper **** icon allows you to view your document
* Clicking on the pencil **** icon allows you to update your document by replacing it with a revised version
* Clicking on the red **** icon allows you to delete any document you have uploaded in error.
1. If you have any questions about which documents are needed for a particular study, please consult with the **Guidance – Submission Requirements for IRB Review** or call the IRB for help.
2. Follow IRBNet Registration Form instructions below to register the submission.

### IRB Forms and Templates

With the exception of the IRB Registration form (see section titled IRB Registration Form), all IRB Forms and Templates are available in IRBNet on the page labeled “**Forms and Templates**”. The instructions for using each form are contained within the form itself. A list of required documents based on the type of submission is provided in IRBNet in a document named “**Submission Requirements for IRB Review**”.

To view or download forms or templates from IRBNet, click on “**Forms and Templates**,” button on the left menu in the blue-shades area of IRBNet and navigate to the form or template of interest.

### IRBNet Registration Form

An IRBNet Registration form is required for each initial IRB Application submission. The registration form must also be amended when an amendment request involves changing information on the Registration Form.

The Registration Form can be accessed as follows:

#### New Submissions

Following the set of directions below, depending on whether or not you have already started the IRB application package in IRBNet.

##### If you have not yet started the IRB Application package in IRBNet, do the following:

1. Log into IRBNet.
2. On the “**My Projects**” page click on the “**Create New Project**” button on the left.
3. Follow the onscreen instructions.
4. On the “**Designer**” page select **“Start a Wizard”**
5. Select the **“SUNY Downstate Registration Form for DMC/IRB Review.”**
6. You will then be prompted to either *create a new wizard* from scratch or you *may clone an existing wizard*. Make a selection and choose “**Continue**.” With a new submission you will most likely wish to select *create a new wizard.*
7. Follow the instruction and click “Next” to move through the document.
8. At the end of the form, you must press the “Save and Exit” button.

##### If you have already started the IRB Application package in IRBNet, do the following:

* + 1. Log into IRBNet.
		2. On the “**My Projects**” page select the study.
		3. When the study opens click on **“Designer”** page.
		4. On the “Designer” page select **“Start a Wizard”**
		5. Select the **“SUNY Downstate Registration Form for DMC/IRB Review.”**
		6. You will then be prompted to either *create a new wizard* from scratch or you may *clone an existing wizard*. Make a selection and choose “**Continue**.” With an existing project you will most likely wish to select *clone an existing wizard.*
		7. Follow the instruction and click “Next” to move through the document.
		8. At the end of the form, you must press the “Save and Exit” button.

#### Editing a Registration Form

1. Log into IRBNet.
2. On the “My Projects” page select the study.
3. When the study opens click on **“Designer”** page.
4. Click on the pencil ****icon.
5. Using the drop down form, jump to the appropriate section that needs to be edited.
6. Once you are finished filling out the form, you must press the **“Save and Exit”** button.
7. This action will bring you back to the **“Designer”** page where you can begin to add as many documents as you require for this IRB submission.

## Sharing Access to a Study

In order for others to view a study, it must first be shared with them. This is required when requesting Scientific Review and Department Chair approval.

The study can also be shared with IRB Office staff or IRB Members if you would like them to review the submission for feedback before it is submitted to the IRB. If you would like the IRB or another individual to do a pre-review before the package is officially submitted, you may Share the package with an IRB Member or IRB Staff and request they do this.

To share access to a study package, do the following:

1. Click on “**My Projects”** and click on the project title
2. Click on “**Share this Project**” on the left menu bar, then click “**Share**”
3. Select SUNY Downstate Medical Center
4. Search for user, select type of access, then enter a comment to the user, for example, to request e-signature.

**NOTE**: If a particular user’s name does not come up, contact that user. It is possible they have not yet registered with IRBNet or they did not complete the registration process for IRBNet.

## Obtaining Scientific Review Committee review and approval

The Scientific Review Committee must submit their review in the following manner:

1. Log into IRBNet at [www.irbnet.org](http://www.irbnet.org) with the Username and Password
2. Click on **“My Projects”** in the blue-shaded area on the left-hand side of the webpage and click on the project title
3. When the project opens, click on Designer on the left menu
4. Choosing **“Need Forms? Show Form Libraries”** will allow you to download blank forms, templates, or reference materials.
5. In the section **“Select a Library,”** choose the location of the IRB which would be **“SUNY Downstate Medical Center, IRB Office, Brooklyn, NY”**
6. The section labeled **“Select a Document”** is where all the most updated DMC/IRB forms and templates will be located.Please download the SRC Reviewer Form to your desktop so that you can begin editing as needed.
7. Attach the completed form by returning to the **“Designer”** page and clicking **“Attach New Document”** and upload the document.

1. Contact the study team if revisions are needed, before e-signing the submission.

1. If revisions are not required, see section below on “Electronic Signatures” for instructions on how to e-sign the submission.

## Electronic Signatures

The package should be electronically signed, preferably in the following order, before submitting the package to the IRB:

1. E-signed by the PI
2. E-signed by the Scientific Review Committee Reviewer
3. E-signed by the Department Chair

The Scientific Review Committee or Department Chair must require modifications to the protocol if it does not meet their expectations. Do not submit the IRB application to the IRB until both have approved the study. Incomplete submissions will not be reviewed and the package will be unlocked for the required e-signatures.

*NOTE: The IRB may return the IRB application to study team, Department Chair, and Scientific Reviewer, if the study is not scientifically sound.*

## Obtaining any necessary ancillary reviews and approvals.

Follow instructions in the IRB Application to obtain any other necessary ancillary review and approval.

## Submitting the IRB Submission

Click on the **“Submit this Package”** button to the left and follow the instructions. Once the IRB Application package is submitted it is locked.

# Retrieving IRB Documents

Click on the title of your study which will bring you to the **“Reviews”** page.

Under the section labeled **“Board Documents”** please click on the paper **** icon to review / retrieve the documents from the IRB.

# Responding to IRB Reviews

The IRB process is iterative in nature. The IRB may unlock a package for minor revisions or may require the submission of a revised package if major modifications are required.

## Revising a Package that is Unlocked by the IRB

If the IRB provides the study team with a notice that a package has been unlocked, revisions are required by the study team by the deadline stated in the message to the investigator, otherwise the study will be administratively withdrawn. The package must be re-locked by clicking “**Mark Revisions Complete**” when the required information in IRBNet.

To submit the revisions to the unlocked package and re-lock the package, a new package must be created. Please create and submit a new package within the existing project as follows:

1. Log into IRBNet.
2. Click on “**My Projects”** and click on the project title to open the project

1. Click on **"Designer"**
	1. If the Registration Form needs to be modified, click on the "**pencil image**" to edit the previously submitted SUNY Downstate - Registration Form for DMC/IRB Review. You can use the “**jump**” or “**next**” buttons to get to the page that needs to be edited. Click "**Save & Exit**" to save all of your changes.
	2. If any other form needs revisions, revise the document, saved to your PC and then upload it to the Designer page in place of the existing document
	3. Add any additional documents to the Designer page, as requested by the IRB.
2. Lock the package when complete, by clicking the link for **“Mark Revisions Complete”** at the top of the Designer page. You will be prompted to write a note to the IRB, when locking the study.

## Responding to a “Request for Modification” or a “Conditional Approval” Letter

If the IRB provides the study team with a “Request for Modification” or a “Conditional Approval” letter, a response is required by the study team by the deadline stated in the letter to the investigator, otherwise the study will be administratively withdrawn.

To submit the response, a new package must be created. Please **create and submit a new package** within the existing project as follows:

1. Log into IRBNet.
2. Click on “**My Projects”** and click on the project title to open the project
3. Click on the **“Project History”** link.
4. Click on the **“Create New Package”** button
5. Click on the **“New Document Package”** link which brings you to the **“Designer”** page.
6. **Please note:** As you are now creating a new package to respond to IRB changes, the number after the dash will increase while the main number before the dash will remain the same.
7. Once on the **“Designer”** page, you will be able to see all the documents you have submitted previously in the section labeled, **“Documents from Previous Packages that you can Revise”**
8. If the IRB is requesting changes to any of your previous documents, before you make any changes, please click on the paper **** icon in this section to download that document to your computer. Please save that document to your computer.
9. Open that saved document and make all necessary IRB requested changes (turn “tracked-changes” on, if possible).
10. Once you have revised and saved that document to your computer in both a tracked changes version (if applicable) and a clean version.
11. Upload the revised documents to the Designer page in place of the existing document
12. If the IRB requested change involves submitting a new document, please click on the **“Add New Document”** button and follow the directions
13. **Submit a cover letter answering point by point the issues raised in the Conditional Approval Letter or Modifications letter.**
14. Click on the **“Sign this Package”** button to the left and follow the instructions
15. Click on the **“Submit this Package”** button to the left and follow the instructions
16. **Please Note:** When prompted to list the **“Submission Type”** for this package, from the drop down menu click **“Revision”**
17. You may add any comments if applicable then click on the **“Submit”** button.
18. The response has to be submitted by the deadline required by the IRB, otherwise the study will be administratively withdrawn.
19. If the IRB requires re-review by the SRC or the Department Chair, request new e-signatures, as applicable.

# Post IRB Approval Packages

All activities subsequent to IRB approval are submitted to the IRB in IRBNet by creating a new package within a previously approved study using the instructions provided below. In general the same steps are needed for each type of submission:

## Overview of Steps for Submitting a Package to an IRB Approved Study:

* 1. **Log into IRBNet**
	2. Once you log into IRBNet, you will be on the **“My Projects”** page where you will find all the studies you have created as well as those that have been shared with you
	3. Locate the study that needs a new package submitted and click on the study title.
	4. Once you are in the study, click on the **“Create New Package”** button to the left of the page.
	5. Clickthe **“Designer”** page to download, complete and attach the applicable “**Application for Progress Report**” Form and any other materials**.** See instructions for **“Using the Designer”** above (page 4).

* 1. Modify the “**IRBNet Registration Form**,” if needed (e.g., if you are also submitting an Amendment). See instructions for above (page 5)

* 1. Share the project with the PI (see page 7 above) and request e-signature. Once the e-signature is obtained, please submit it to the IRB (see page 8 above).

* 1. When submitting the package, please be sure to indicate the package type. The following options are provided in the drop down menu:
* Adverse Event (non-UP)
* Amendment/Modification
* Closure/Final Report
* Continuing Review/Progress Report
* Funding Grant
* New Project
* Other
* Other Reportable Event
* Protocol Deviation/Violation
* Publication
* Response/Follow-Up
* Revision
* Unanticipated Problem (UP)

## Continuing Review (Progress Reports)

In step 5 outlined above, please include the following materials:

* As applicable, please include one of the following documents:
	+ Application For Progress Report
	+ Application For Progress Report for HUD for Clinical Use Only
	+ Application For Progress Report with External IRB Oversight

## Reportable Events

In step 5 outlined above, please include the following materials:

* Application for Reportable Event Form

## Amendments

In step 5 outlined above, please include the following materials:

* Application for Amendment Form
* Include modified Word Documents using red-lined tracked changes
* Include any required materials as described in the Application for Amendment Form

## Acknowledgement Requests and Other Considerations

In step 5 outlined above, please include the following materials:

* Cover memo outlining the request
* Include any applicable materials

## Administrative Corrections

In step 5 outlined above, please include the following materials:

* Cover memo outlining the request
* Include any applicable materials

## Study Closure (Final Report)

In step 5 outlined above, please include the following materials:

* Application for Final Report

## Request to Re-activate (Re-Open) a Study

In step 5 outlined above, please include the following materials:

* Submit a cover memo explaining the reason for the lapse occurred and how it will be prevented from happening again.
* Include items listed for Progress Report (see above)

# Guidance For IRB Committee Members

## Logging Into IRBNet

1. Log into IRBNet.
2. If you don’t have an IRBNet account, please follow the directions under, “**Obtaining an IRBNet User Name and Password”** on pages 3 and 4 in this document.

## Pre-Review - IRBNet Review Basics

1. After logging in, you will be taken to the **“Submission Manager”** page where you will find the Agenda, Minutes and studies assigned to you for review. This will be your main page when working within IRBNet. You can find an additional link to the Agenda and Minutes by scrolling to the bottom of the page.
2. To show all items assigned to you, click on the drop down menu next to the “**Agenda**” icon and choose “**All submissions**”. Please be sure to *uncheck the boxes directly below the Agenda* drop down box so that all items will be shown. You can check and uncheck items to be shown as needed and based on agenda date.
* **Please note:** Once a new project has been assigned IRBNet ID for example ***44879-1*, t**he project will keep the same main project number while the number after the dash will increase.For example if the IRB requests changes to a the new project example above, the number after the dash will change as you will create a new submission within that project to address requested revisions - so the next IRBNet ID will be ***44879-2.*** Then if your next submission will be an Amendment etc. for that same project, the next # for that package would be ***44879-3*.**
* Whenever a study is assigned to you, an email will be sent to you. To view Agenda and Minutes, sign-in to IRBNet and click on the “**Agendas and Minutes**” link to the left of the screen that is blue shaded. You can also view all forms and templates if you click on the “Form and Templates” link to the left of the screen.
* The item with a star indicates that you are the **Primary Reviewer**.
* The item with a check  mark indicates that you have already *completed a review* for that item.
1. To access documents in the study submission, click on the title of the study which will bring you to the **“Submission Detail”** page. **Please note that only Committee Members and IRB Staff have access to this page. Researchers do not.** All details regarding a given study package will be located in this section.
* At the left hand blue-shaded side of the screen, click on the link **“My Reminders”** to view all emails sent to you. Other IRBNet users do not see your personal reminders. This is a good way for you to track your work.
	+ - The **“Message and Alerts”** link lists all communication that has been posted for a given project.
		- The link marked **“Committee Messages,”** towards the bottom of the white-shaded area next to the  bell, will contain internal Committee communications for the submission.
		- The link marked **“Send email message to Committee Members and Administrators,”** at the bottom of the page next to the ![C:\Users\DLewis03\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\H8DWZRKB\Closed-Envelope-9483-large[1].png]() envelope, is usedto send an internal committee communication to Committee Members and Administrators.
		- The red flagnext to your email alerts can be turned on or silenced by clicking on it. This will not affect other IRBNet users.
		- **Please note that messages can only be shared with the individuals who are listed as having access to a given study package. Please try to use the IRBNet messaging system for all review related communications for a specific study.**
* Under the heading, **“This submission is currently shared with the following Committee Members and Administrators:”** you will see this submission has been shared with.
* Under the heading **“New and Revised Documents”** items requiring extra attention will be flagged by the IRB in red in the “Last Modified” column. All items to be reviewed for a given study package will be listed here.
* Under the heading, **“Add** commentsand reviewer documents to this submission:**”** you will find the reviews from other Committee Members and Administrators regarding that study package. Click on the **“View”** link to see their comments.

## How to Review a Project in IRBNet

1. To begin your review of an assigned submission, click on the **“Submission Manager”** link. To access details of the study, click on the title of the study which will bring you to the **“Submission Detail”** page. Under the heading **“New and Revised Documents”,** you may click on each document to be reviewed and *save it to your desktop*. Once the document has been saved to your desktop, you may open it and begin reviewing that document. At this point, you may choose to use the tracked changes if applicable and/or write your comments in a separate Microsoft word document or IRB checklist.
* **Please Note: The buttons to the left of the screen gives you a view of the project as the researcher sees it.** (**As a reminder, the researcher will not see any of these comments)**
* The button marked, **“Project Overview”** gives you an overview of a given project as the researcher sees it. You can also click on the **“Review Details”** link to view the status of an item assigned to a given agenda. You can also view the contents of a previous package submission
* The button marked, **“Designer”** allows you to view all documents submitted within the project, current and past. Click on the paper icon  to view current documents; click the stack of paper icon  to view past documents where applicable.
* The button marked **“Project History,”** gives you a summary of all the packages created for a given project.
1. Click the **“Back to Submission Details”** button to resume your review**.**
2. Once you are ready to add your reviewer comments:
* Click on the word **“Add…”** in the **“Add** comments and reviewer documents to this submission:**”** linkwhich will bring you to a text box so you may begin to write or copy and paste any comments you may have.
* If you have documents to attach to the written review, please note that you will not be able to attach any documents until you have pressed the **“Save”** button.You will then be prompted to add documents as needed.Click on the **“Add New Document”** button which will bring you to the document upload page. The items with the red asterisk (\*) must be filled out. You may repeat these steps to add as many documents as needed.
1. Next to “Recommendation,” please click on the drop down menu and select the appropriate recommendation such as: Approve, Modifications Required, Defer to Full Board, etc.
2. Once you have finished adding the necessary attachments, please check the box label, **“Mark my personal review as complete.”** You must complete this step in order for the IRB Office to be informed that you have completed your review.
3. You may now click the **“Save and Exit”** button. In the next page, you will see your comments listed under thesection labeled **“Update** your comments and reviewer documents*:***”**Please note that prior to submitting your review, the heading for this section was listed as “**Add** comments and reviewer documents to this submission:” However, once you submitted your review, the heading was change to **Update** your comments and reviewer documents*:***”**
4. Click on the **“Committee Messages”** link. The “**Committee Messages”** page will show you all the emails associated with the submission under review. Messages sent with a red flag next to them will also appear in your **“My Reminders”** page. Click on the red flag to silence that message once you have completed your review. This will also remove this message from the **“My Reminder”** page. This is a good way for you to keep track of your workload. If there are no reminders left then you have completed all reviews for that agenda

# References

* [IRBNet](https://www.irbnet.org/release/index.html)
* IRB Policy IRB-01

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# Review and Approval History

Original Issue Date: 11.04.2016

Revision Date: 2.10.2017

Replaces previous documents:

* IRB Application Guidance (updated and combined with this guidance on 12/27/2016)

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| --- | --- | --- |
| **Date** **Reviewed & Approved** | **Revision Required** | **Responsible Staff Name and Title** |
| Yes | No |
| 11.04.2016 |  |  X | Kevin Nellis, Executive Director Human Research Protections and Quality Assurance |
| 12.27.2016 | X |  | Kevin Nellis, Executive Director Human Research Protections and Quality Assurance |
| **02.10.2017** | **X** |  | Kevin Nellis, Executive Director Human Research Protections and Quality Assurance |
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