Weill Cornell Medicine

Weill Research Gateway

Comprehensive Job Aid

Overview

This document provides a detailed review of all transactions housed within the Weill Research Gateway (WRG). You can navigate to a specific section of the document using the table of contents below.

Table of Contents

The Weill Research Gateway

What is the Weill Research Gateway?

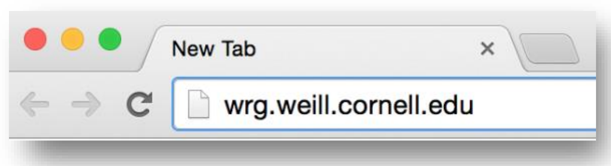
The Weill Research Gateway (WRG) will be used to consolidate research-related administrative tasks into one portal. Currently it is used for Conflicts of Interest and Sponsored Programs. Keep an eye out for expanded research functionality coming soon to WRG.

Logging In to WRG

WRG operates best using the following browsers:

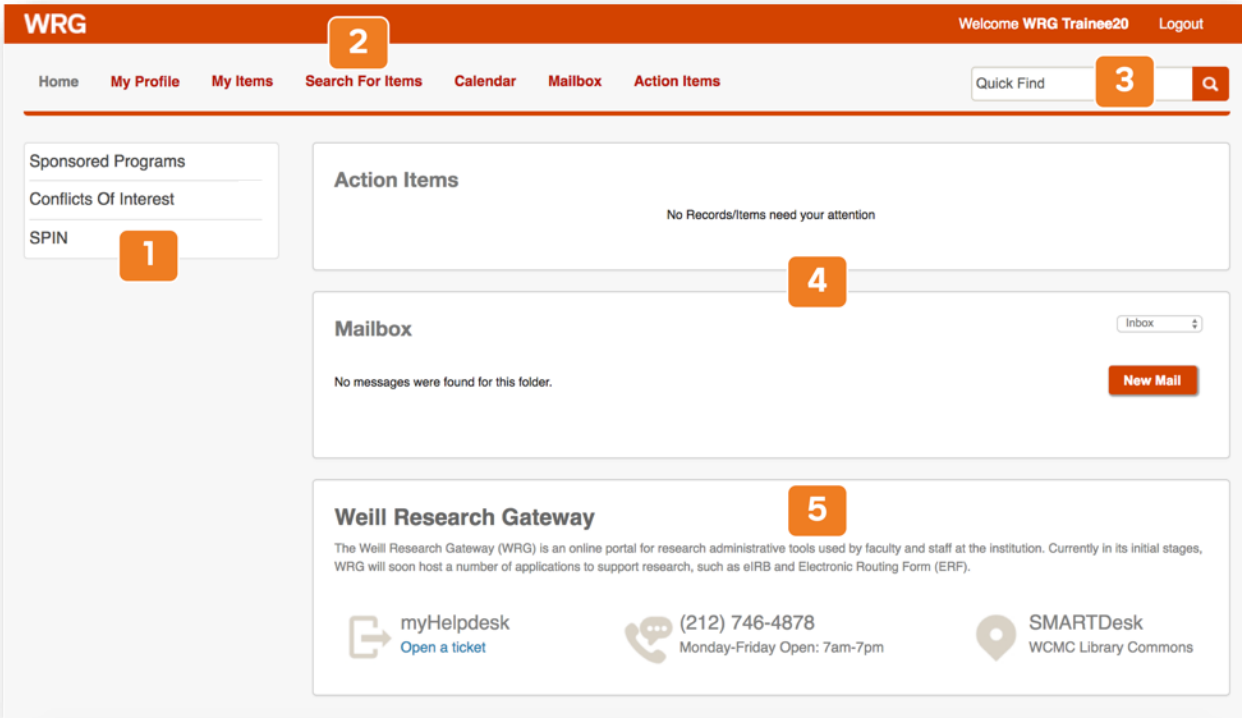
PC	Mac
Firefox	Safari
Chrome	Chrome
	Firefox

1) To log in, enter the URL below into your browser address bar:
    a. **http://wrg.weill.cornell.edu**
2) Select your institution from the list provided.
3) Enter your CWID and password on the next screen.
4) This should take you to the homepage of WRG.



Weill Cornell Medicine

The WRG Homepage



1) **Left Navigation Menu**: This is where you will find the different modules of the Weill Research Gateway. Currently, Conflicts of Interest is the only available module, but this is where you will access other modules as they become available.
    a. **Sponsored Programs**: The Sponsored Programs module is where you'll go to submit proposals in the system, including system-to-system grants.gov applications as well as other proposal types.
    b. **Conflicts of Interest**: The Conflicts of Interest (COI) module is you can find the transactions to report conflicts of interest, including the Annual Conflicts Survey, Travel Disclosures, and Study Specific Reports.
2) **Top Navigation Menu**: This provides a more administrative and broad set of navigation options within the Weill Research Gateway.
    a. **My Profile**: Allows you to edit certain settings in the Weill Research Gateway. There is not much functionality here that you can customize, but you can change the color of your WRG theme, as well as adjust the number of results displayed on a search.
    b. **My Items:** Will list the items you have submitted (ex: Proposal submission in Sponsored Programs)
    c. **Search for Items**: Similar to the Quick Find Search Bar, this allows you to search for items you have previously submitted.
    d. **Calendar**: An internal-to-WRG calendar you can update with particular events.

e. **Mailbox**: This is where you can go to see any system-generated notifications that were sent by the Weill Research Gateway. These should have additionally been emailed to your @med.cornell.edu email address.
f. **Action Items**: This section is where you will see any open action items you may have. In most cases you navigate directly to the transaction that requires your action.

3) **Quick Find**: You can search for entries or submissions you made in WRG. (Ex: You can search for a Proposal by its title or Proposal number.
4) **Content page**: This is where the content of your menu selection will open. By default, the Homepage contains your Action Items and Mailbox.
5) **Help + Support**: At the bottom of the homepage you'll find options for getting Help + Support with the Weill Research Gateway.

Sponsored Programs

What is the Sponsored Programs Module?

The Sponsored Programs module of WRG provides a single intake portal for all research-related documents to be routed to central offices, including grants, sponsored research agreements, data use agreements and other research related contracts. As you enter the system and begin answering questions, it will adapt to your needs and fit the document type you're routing for review.

Process Flow for Sponsored Programs

The Sponsored Program module is built to accommodate several different types of documents. The workflow may change a bit depending on the type of document or proposal you're submitting.

Additional Notes

1) You can continue to update sections of the Proposal Screen after submitting for Pre-Review. Note that you should not make any changes to the Budget tab after submitting for Pre-Review.
2) For contracts, there is no Pre-Review Route. After completing relevant questions and uploads, and if applicable a budget, you'll move straight to the Final Review for submission to the appropriate central office, OSRA or JCTO.
3) Each route also collects important departmental approvals before reaching Central Administration for review. Depending on whether you're submitting a grant or contract, either the Pre Review Route or Final Route stops with the financial approver and the department head or department chair. It will also send conditional notifications to collaborating department personnel, as well as central offices like EHS, IRB, and ITS.
4) For grants, the Final Route stops with the principal investigator and again with the Financial approver for a final thorough review before reaching OSRA.
5) Once OSRA has reviewed the proposal, they will submit the package the sponsor for approval.
6) You will be notified of the approval of your application or whether it was returned for edits via system notification and direct messaging from OSRA.

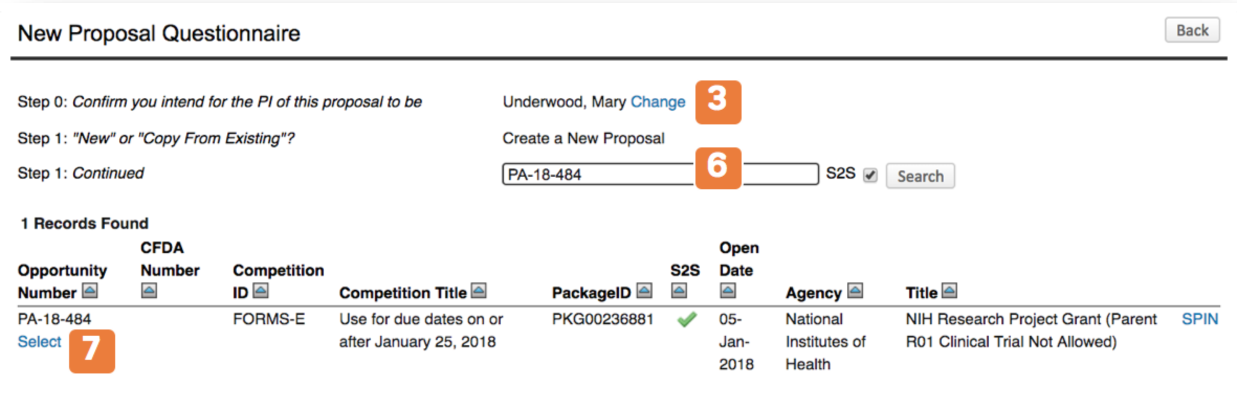
Creating a New Proposal

The following step-by-step instructions cover how to initiate a proposal in the Sponsored Programs module of WRG.

Initiating the Proposal

Don't forget! – You can access the Quick Reference Guide for this transaction from the Sponsored Programs - Guides page on the ITS website.

1. Click the **Sponsored Programs** tab on the left navigation menu of the WRG Homepage.
2. Click the **Create New Proposal** button from the menu.
   a. A new window will open with the New Proposal Questionnaire.



3. Confirm the PI (**Principal Investigator)** for this proposal.
   a. By default, your name will be selected. Click the blue Change button next to your name to update the PI.
4. Select whether you will **Create a New Proposal** or **Copy from an Existing Proposal** and click **Continue.**
5. Choose the opportunity source or manual proposal setup from the **dropdown** menu and click **Continue**.
   a. In this example, we'll continue with a Grants.gov opportunity.
   b. See the section **Manual Proposal Types** for more information on other types of submissions.
6. Enter the **Program Announcement (PA)** number in the entry field and click **Search**.
   a. Ex) PA-16-160
7. Note the results and click the blue **Select** button directly underneath to your choice.
8. Select a **Proposal Type** and click **Continue**.
9. Select a **sponsor** from the dropdown menu or full list and click **Continue**.
10. Enter the **Proposal's Title** and click **Continue**.
11. Enter the **From** and **To Dates** in the corresponding fields.
    a. Click the calendar icon to open up a quick way to select dates.
12. Confirm the number of **budget periods** that are automatically generated and click **Continue**.
13. Review the information you've submitted on the proposal.
    a. If you need to make any changes, you can click the **Step back through responses** button.
14. Click **Create Proposal**.

Answering Setup Questions

After answering a few basic questions, the Proposal Screen opens and is restricted to a few additional Setup Questions. These questions will inform the specific sections of the Proposal Screen you will fill out later in the transaction. Descriptions of each section of Setup Questions can be found below.

After answering all sections you'll click the blue Save and Continue button.

Grants.gov Submission Information: This pulls in information directly from the Grants.gov opportunity you selected earlier in the transaction. You can view information like the opportunity number and title, as well as R01 Validations. Beneath that, you can few the included forms which are marked with a green checkmark. You will fill these out later in the proposal and can additionally opt to add forms that may be relevant to your proposal.

Deadline Information: This should automatically populate based on the opportunity. You can adjust as necessary.

General Proposal Properties: This section contains a short list of questions that, depending on how you answer, will inform which additional sections of the proposal you will fill out later.

PHS/NIH: These additional questions are asked when you selected a PHS/NIH opportunity.

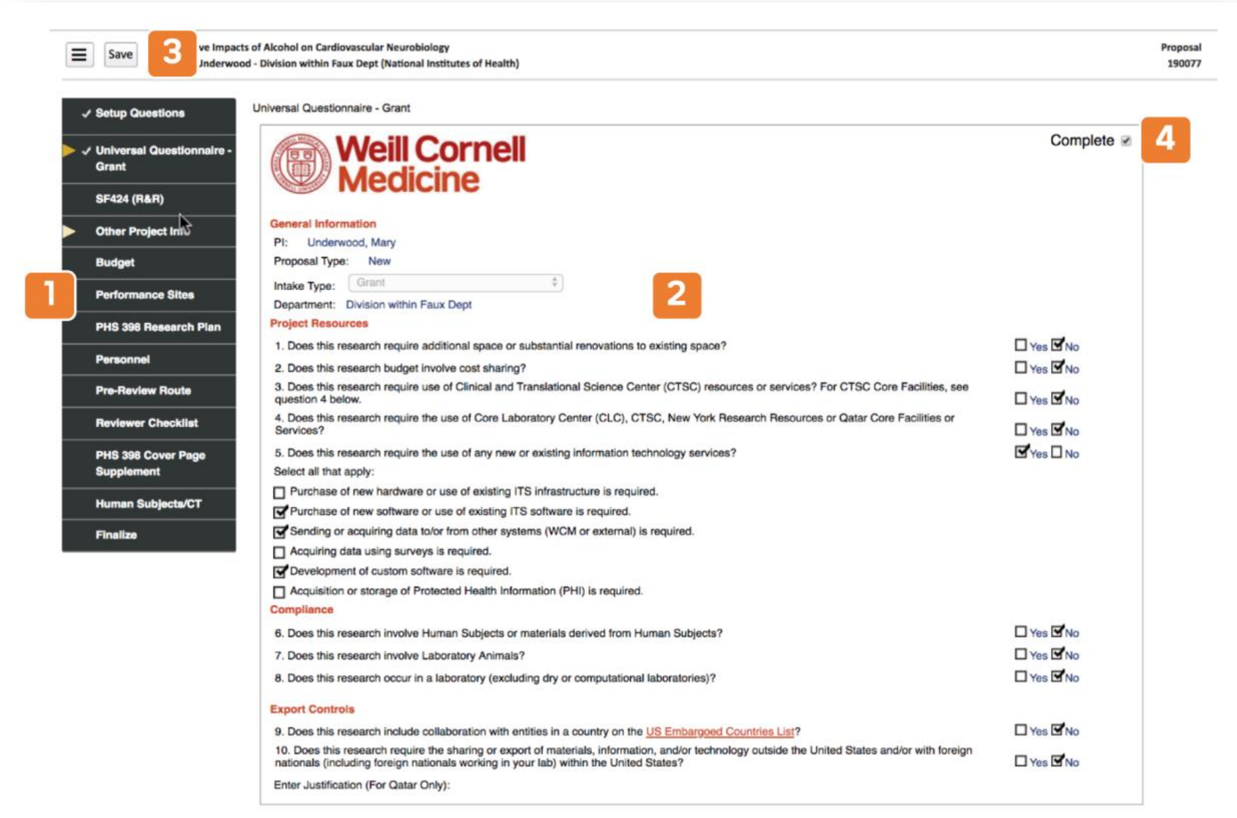
Budget Setup Information: This is where you'll choose the Program Type (ex: grant, contract, training, etc) as well as indicate where the majority of research will be conducted (either on or off campus.)

After answering all sections you'll click the blue **Save and Continue** button.

The Proposal Screen

The Proposal Screen is the primary location you will enter information for your submission. If applicable to your chosen type of submission, you must complete all sections above the Pre-Review Route before sending it off for that initial review. Otherwise, all sections must be completed before submitting to the Final Review Route (Finalize).

Navigating the Proposal Screen



- **1) Left Navigation Menu**: These are the sections of the proposal you must complete. More information about each section can be found below.
  - **Best Practice**: Always start by clicking the Budget tab and entering Personnel for this proposal. Salary will need to be released for personnel on the Budget, and starting here allows this process to occur while you fill in other parts of the proposal.
- **2) Section**: This is where the content or forms you must fill out will appear.
- **3) Save**: After completing each section you must click the Save button, followed by the Complete checkbox within the section.
  - There's also a callout box here where you can click **Done**, as well as access **Help** and **Support**.

- **4) Completed Checkbox**: Click this *after* clicking Save. This locks in the responses you made on this form. You will notice a blue checkmark next to sections on the Left Navigation Menu that have been completed.

The Sections of the Proposal Screen

Universal Questionnaire: This form contains additional questions pertaining to your application.

- Answer the questions on the form.
- Additional branching questions may appear based on how you answer.
- Click the blue Save button in the top left corner of the page, followed by the Complete checkbox in the top right corner of the form.
- Note a blue checkmark next to the Universal Questionnaire link in the left navigation column, indicating this section is now complete.

SF424: Much of this form comes preloaded with institutional info but there may be additional questions required, which will typically be highlighted in yellow.

- Answer the highlighted questions on the form.
- Click the Save button, followed by the Completed checkbox.
  - *You will see a prompt directing you to any missing information.*

Budget: The Budget tab is a complex transaction. Please view the Budget section of this document or the Budget Quick Reference Guide.

Personnel: This tab is where you'll list all personnel relevant to this proposal. It pulls in information you entered in the Budget tab, but you can add additional entries here (ex: Other Significant Contributors)

- Click the black Add Personnel tab if you need to add any additional personnel here.
- Review the personnel listed.
- Note whether or not their Conflicts of Interest survey has been completed (indicated with a green checkmark).
  - *You can hover over this field.*
- Upload the CV / Biosketch of Key personnel.
- Upload Current / Pending Support if necessary.
- Click the Save button, followed by the Completed checkbox.

Pre-Review Route: (System-to-System Grants only). The Pre-Review Route allows both your department and OSRA to review administrative information and the application budget.

- Ensure there is a blue checkmark for all tabs above the Pre-Review Route on the left navigation panel.
- Click the Thumbs Up icon on the form.
  - *A popup window will appear which goes over the process flow.*
- Click the Submit button.
  - *This will now be submitted through the workflow.*
  - *You will be notified via email once the Pre-Review Route is complete*
  - *You can continue the application even while the Pre-Review Route is underway*
  - *Please make sure not to un-complete or edit any tabs above the Pre-Review Route.*

Reviewer Checklist: The Reviewer Checklist is where you'll go to view feedback from the approvers on this proposal, however no action is needed by you on this tab.

Other Project Info: This form collects additional information about the project. It populates with some of the questions you answered previous and some additional ones you have to answer now.

- Note that Other Project Info now incorporates other sections/tabs from the left navigation menu that were previously listed separately in past iterations of the transactions, including:
  - Project Summary
  - Project Narrative
  - References Cited
  - Resources
  - Other Attachments
- Answer any blank questions on the form.
- Additional branching questions may appear based on how you answer.
- Click the Add Attachment button to upload any necessary documentation.
- Click the Save button, followed by the Completed checkbox.

PHS 398 Research Plan: Allows you to upload specific documentation that may be required for your proposal. You can also refer to the submission guides found on Grants.gov or the National Institutes of Health opportunity.

1) Click the blue Upload link that pertains to the document you need to upload
   a. *If you're not sure what you need to upload, you can click the Completed checkbox (an error message will display, specifying which documents are required)*
2) Click the Choose File button.
3) Locate the file on your computer.
4) Click the blue Upload link.
   a. You can view the Original or PDF versions of the document, or Remove it from the list.
5) Repeat this process for any additional documentation that must be attached.
6) Click the Save button, followed by the Completed checkbox.

Performance Sites: This outlines the sites where research will be conducted and is populated based on previous sections.

- Review the information on this page.
- Make any necessary changes.
- Click the Save button, followed by the Completed checkbox.

PHS 398 Cover Page Supplement: This form pre-fills information based on questions you've answered in other parts of the proposal.

- Answer any missing questions.
- Click the Save button, followed by the Completed checkbox.

Human Subjects / CT: The new Forms E package includes a new section you must fill out which pertains to Human Subjects and Clinical Trials. This new section will pull in your responses from the Setup Questions and Other Project Info sections you previously filled out.

- You would use this form if:
  - Your study includes human specimens or data
  - Your study includes human subjects
  - Your research plan includes delayed onset
  - Your study is a clinical trial
- For a detailed walkthrough, view this resource from the NIH: https://www.youtube.com/watch?v=nz9NWFhYOG8
- Validation Tool: For NIH submissions we have included a validation feature that allows you to test your package in the system before sending it to NIH. The system will recognize which pieces of your application may potentially be rejected by NIH, allowing you to make those changes before you officially submit.

Finalize: The Finalize tab is a final review route where OSRA and other groups will perform a final thorough review of the application, including the final science and all remaining sections, before final submission to the sponsor.

1) Ensure there are blue checkmarks all down the side of the left navigation panel.
2) Click the blue Build button under the Build PDF / Form Pages heading.
   a. Note that if you make any changes to the proposal after this step—even un-checking a Completed checkbox—you will have to rebuild these pages.
   b. It may take a minute to build the pages, depending on the type of proposal you're submitting.
   c. The table expands with additional information once this step is finished.
3) Click the Build Grants.gov Application button.
4) Click the Thumbs Up icon under the Submit for Internal Review heading.
5) Click the Submit button on the popup window, which outlines the process flow.

Next Steps:

- Once the final review of the proposal is completed, OSRA will notify the requester and send the package to the sponsor.
- For Grants.gov applications, the department and OSRA will be able to run Grants.gov validations prior to submission and view the final assembled package as it will later appear in the eRA Commons.
- If there are any required edits, OSRA will return the application for modification. Once complete, the department can resend for final review
- This process will also be available if the PI would like to make any changes following successful submission, as long as it's before the grant deadline.

The Budget

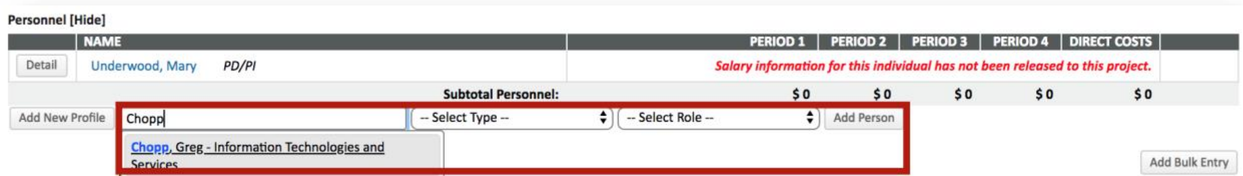
The Budget tab of the proposal allows you to build your budget right in WRG. You can enter Personnel, whose salary can be released to the budget, as well as their effort. You can also add Non-Personnel costs, Sub Awards, and Sub Projects.

The appearance of the Budget tab may change a bit, depending on the type of proposal you're submitting, but will contain the same general steps and information to enter.

Adding Personnel to the Budget
Entering Personnel Effort (Details)
Entering Sub Awards Manually
Importing a Sub Award

Adding Personnel to the Budget

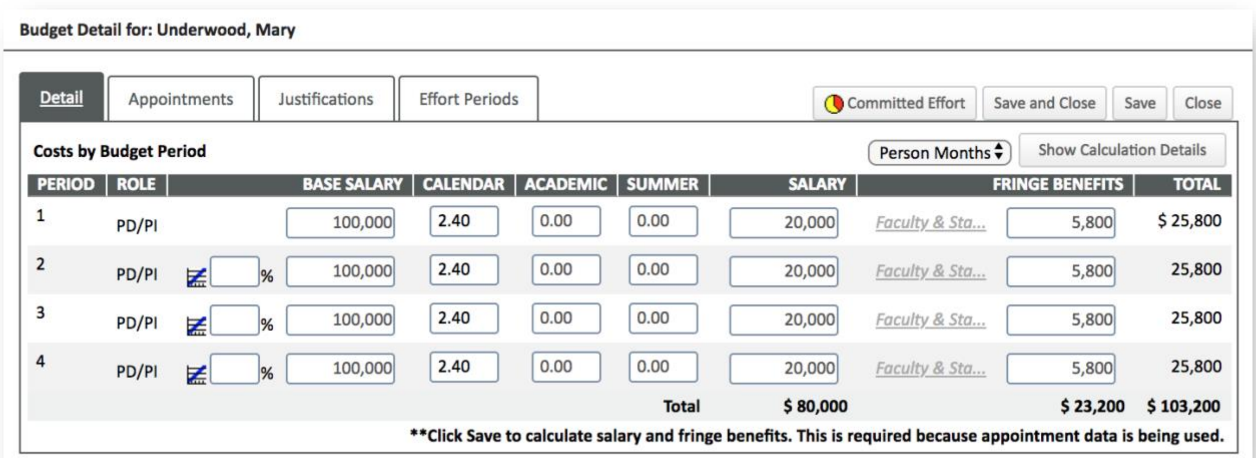
It's considered best practice to Immediately add Personnel to the Budget, which will allow more time for the salary releases to be completed. Complete



1) **Begin typing the name** of the colleague you want to add to the Budget.
   a. **IMPORTANT**: You must select them from the list that populates below the text entry field.
   b. If you need to add personnel to the Budget who are TBD, you can select the **Add New Profile** button to the left of the text entry field and type in their First and Last name, ensuring Temporary Profile is selected.
2) Select the **Type dropdown** and choose either Key or Non-Key.
3) Select the **Role dropdown** and choose from the list that populates.
4) Click **Add Person**.

Entering Personnel Effort (Details)

The next step will be to enter Personnel Details (effort, salary, fringe, etc).



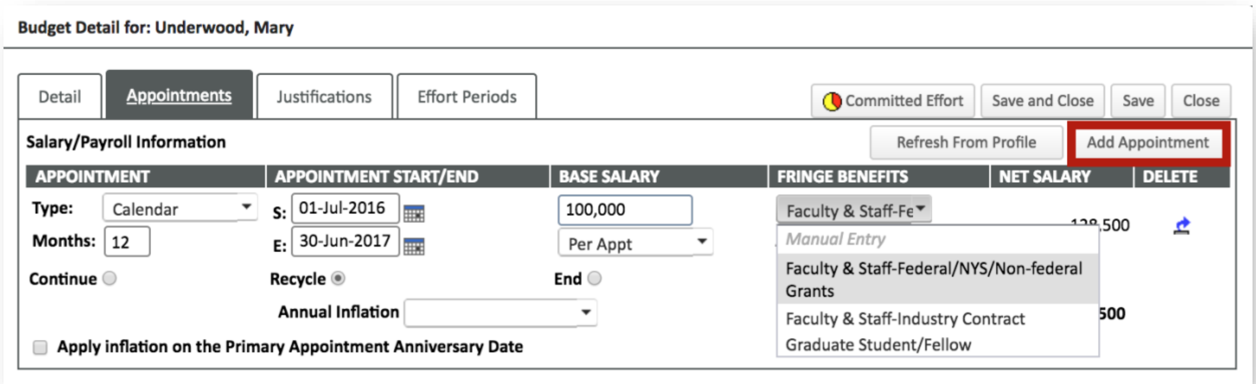
1) Click the **Detail** button to the left of the name of the Personnel.

a. You may see a note about **Salary Release** populate. If you have the ability to Release the salary there will be a link to do so, otherwise you must wait for the salary to be release by appropriate department personnel.

2) On the Detail tab, enter the effort in the **Calendar** column for Period 1. (Ex: 2.4)
   a. Effort will automatically populate for subsequent periods based on your entry.
3) Click **Save**.

The Personnel Appointments Tab

This is where you can enter Personnel Appointment information, including Salary. You can also select Fringe Benefits on this tab.



1) Click the **Appointments** tab, ensuring you clicked **Save** to lock in any previous changes.
   a. For most WCM personnel, Appointment information should come in pre-filled.
   b. If this is the case, you can skip ahead to Step 5 and select the Fringe Benefits dropdown.
   c. If no information populates here (ex: TBD Personnel) you can click the Add Appointment button on the right side of the box.
2) **BEST PRACTICE**: Work from left to right to fill out information on the Appointments tab.
3) **Appointment column**: Ensure Calendar is selected from the Type dropdown menu, and enter 12 in the Months entry field.
4) **Appointment Start/End**: The specific dates here aren't necessarily important, just so long as they equal out to one year. It is considered best practice to enter the employee's appointment dates, if known, or simply the fiscal year (ex: July 1, 2017 – June 30, 2018).
5) **Base Salary**: Enter the personnel's base salary in the entry field.
6) **Fringe Benefits**: Make a selection from the dropdown menu. In most cases (except for Manual Entry), an amount will automatically populate in the entry field.
7) Click **Save**.
8) Other features on this page:
   a. **Continue / Recycle / End**: Pertains to action after the end date of the appointment. It is considered best practice to leave this as Recycle.
   b. **Annual Inflation**: You can select this dropdown if you want to opt to include standard inflation between periods.
   c. **Apply Inflation on the Primary Appointment Anniversary Date**: You can check off this box to apply inflation based on the appointment dates entered. This will allow for inflation in the first year should the appointment cycle in the period.

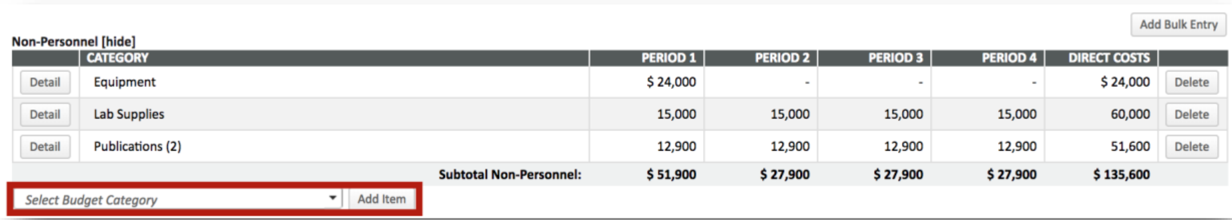
d. **Delete**: Click the Delete icon to delete the appointment from the Budget Details record.

Other Notes About Entering Personnel

1) Don't forget that you can't enter effort for Weill Cornell personnel you add to the Budget until their salary has been released.

Entering Non-Personnel Costs (Line by Line)

The Non-Personnel costs table is where you'll enter your expenses that don't pertain to Personnel costs (ex: Equipment, Travel, Publications, etc). You can also click the Add Bulk Entry button to add five expenses at a time.



Add Bulk Entry

Non-Personnel [hide]

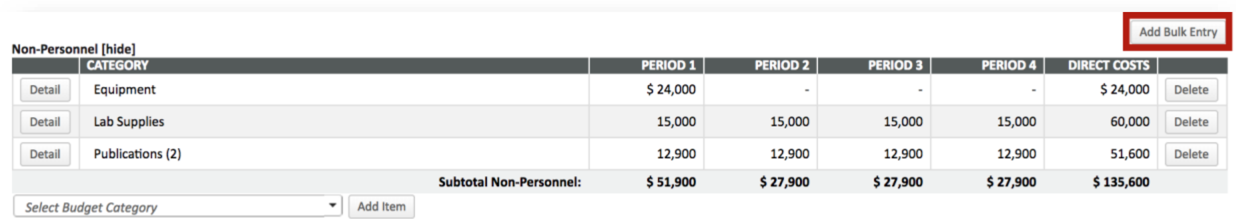
	CATEGORY	PERIOD 1	PERIOD 2	PERIOD 3	PERIOD 4	DIRECT COSTS	
Detail	Equipment	$ 24,000	-	-	-	$ 24,000	Delete
Detail	Lab Supplies	15,000	15,000	15,000	15,000	60,000	Delete
Detail	Publications (2)	12,900	12,900	12,900	12,900	51,600	Delete
	Subtotal Non-Personnel:	$ 51,900	$ 27,900	$ 27,900	$ 27,900	$ 135,600	

Select Budget Category | Add Item

1) Select the **Budget Category dropdown** at the bottom of the Non-Personnel table and make a selection from the list that populates.
2) Click the **Add Item** button.
3) Enter an amount in the **Total column** for Period 1. Note that it will populate that amount in each corresponding period, so make sure to adjust accordingly if it's a one-time cost.
4) **Optional**: You can update the name of the expense in the text entry field above the Totals column. However, note that the name of the category is what will appear on the Budget.
5) **Optional**: You can adjust for standard annual inflation by selecting Standard from the Annual Inflation dropdown menu, or you can manually enter inflation in the % field.
6) Click **Save and Close** when you're finished.

Entering Non-Personnel Costs (Bulk Entry)

Clicking the Add Bulk Entry button allows you to enter up to five expenses at a time, and may be a quicker way to add multiple expenses to the Budget.



Add Bulk Entry

Non-Personnel [hide]

	CATEGORY	PERIOD 1	PERIOD 2	PERIOD 3	PERIOD 4	DIRECT COSTS	
Detail	Equipment	$ 24,000	-	-	-	$ 24,000	Delete
Detail	Lab Supplies	15,000	15,000	15,000	15,000	60,000	Delete
Detail	Publications (2)	12,900	12,900	12,900	12,900	51,600	Delete
	Subtotal Non-Personnel:	$ 51,900	$ 27,900	$ 27,900	$ 27,900	$ 135,600	

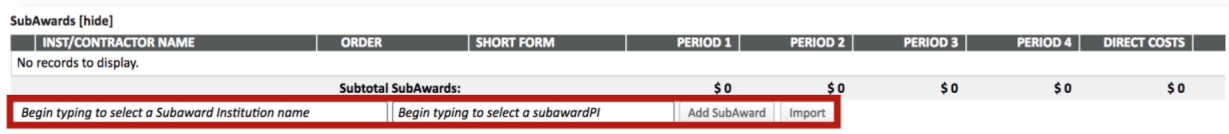
Select Budget Category | Add Item

- Click the **Add Bulk Entry** button in the top right corner of the table.
- Select the **Budget Category dropdown** menu and make a selection from the list that populates.

- **Optional**: You can update the name of the expense in the text entry field above the dropdown. However, note that the name of the category is what will appear on the Budget.
- Enter the **amount** of the expense in the Period 1 box, noting that it will populate that amount in each corresponding period, so make sure to adjust accordingly if it's a one-time cost.
- Click the **Add** button in the top right corner of the window.

Entering Sub Awards Manually

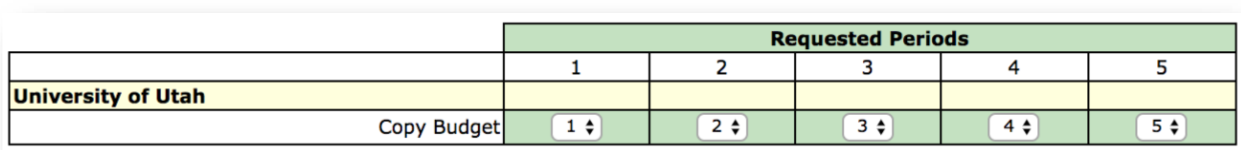
Sub Awards are initiated when a prime site plans to have a sub-recipient carry out a portion of the work on a grant or contract. A Sub Award must include a clearly defined, intellectually significant scope of work to be performed by the sub-recipient. If you have the Research & Related Budget form, you can opt to Import your Sub Award, which is a much easier way to add it to the Budget.



1) You may have to click **[show]** next to the SubAwards header.
2) Begin typing the **SubAward Institution Name** in the corresponding text entry field.
   a. **Important**: You must select from the list that populates beneath the text entry field.
3) Type the name of the **SubAward PI i**s listed in the corresponding **text entry field**.
4) Click the **Add SubAward** button.
5) The system automatically generates a SubAward number and title. You do not have to change this. You can simply click **Save**.
6) Click the **Detail** button next to Inst/Contractor Name.
7) A new window will pop up where you can **manually enter Personnel and Non-Personnel Costs, and F&A** in the corresponding tables.
   a. Consult the instructions above for entering Personnel and Non-Personnel Costs.
8) Click the **Budget** link in the left navigation menu to return to your Budget.

Importing a Sub Award

A far quicker way to add a Sub Award to your Budget is to Import it using the Research and Related Budget form.



- You may have to click **[show]** next to the SubAwards header.

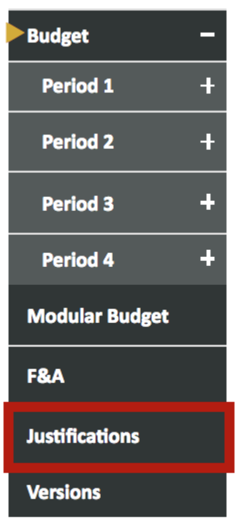
- Begin typing the **SubAward Institution Name** in the corresponding text entry field.
  - **Important**: You must select from the list that populates beneath the text entry field.
- Click the **Import** button.
- Click the **Choose File** button and locate the PDF form for the SubAward.
- Click the **Upload** button.
- Select the dropdown menus in the **Copy Budget row** to select the Periods you'd like to copy to the Budget. An example of all Periods copied to the Budget can be seen in the image above.
- If the SubAward personnel already exist in WRG-SP, please match up personnel on this page. If not, leave as "New Personnel."
- Click the Process button in the top right corner of the window.

Sub Projects

Sub Projects are an infrequently used feature of the Budget tab. Please consult with your OSRA Grants and Contracts Specialist for more information on this transaction.

Uploading Budget Justifications

While you can certainly enter line-by-line Budget Justifications in the Personnel and Non-Personnel sections of the Budget, it is probably far easier to include these Justifications on a single Word document for upload in the Justifications tab on the left navigation menu.



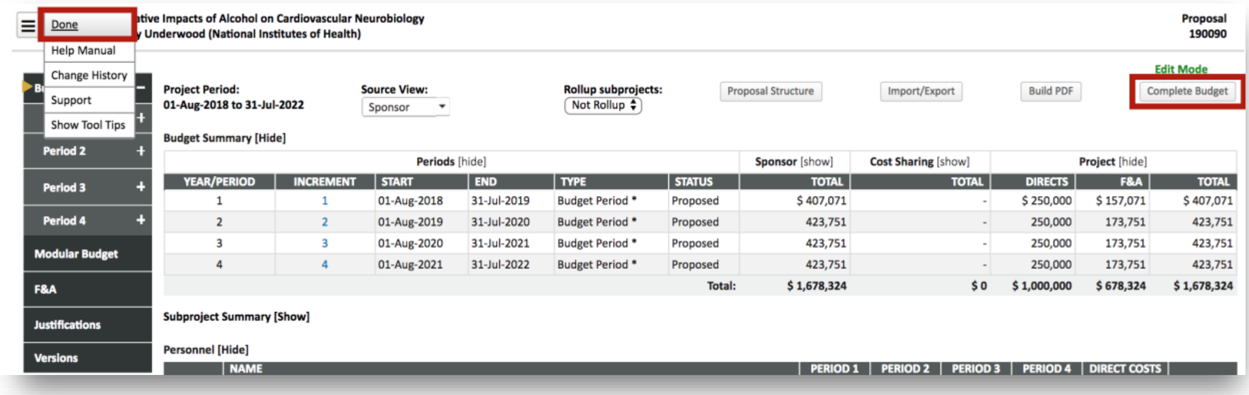
1) Click the **Justifications** link in the left navigation menu.
2) Click the **Choose File** button on the corresponding type of Justification and locate the file on your computer.
3) Click the **Upload** icon
4) You can confirm the upload was completed because you'll see the following options appear to the right of the Upload section:

5) These buttons allow you to view a PDF version of your upload, see the number of pages of the document, and give you the option to Remove the document if you choose.

Completing the Budget

Before Completing Your Budget, Make Sure…

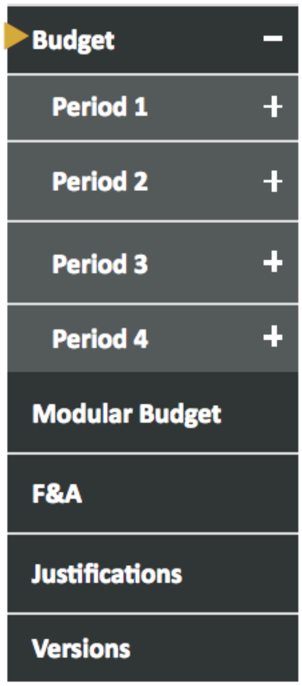
- You review the Budget Summary ensuring the numbers match up.
- Salary for all Personnel has been released.
- Effort has been added for all Personnel listed on the Budget
- Justifications for Personnel and Non-Personnel costs have been uploaded either line-by-line or using the Justifications link on the left navigation menu.



1) Click the **Complete Budget** button in the top right corner of the window.
    a. You'll notice the button will change to read Un-Complete Budget and a red notification will read 'You are in view only mode due to budget being completed.'
2) **Important**: Make sure to click **Done** in the top left corner to close the Budget window. If you don't click Done you run the risk of locking the Budget, preventing others from viewing it.
3) After clicking Done, you will be taken back to the **Proposal Screen** and will notice a blue checkmark next to Budget, indicating it has been completed.

Other Notes About Completing the Budget

- You do have the option to click the Save button in the top left corner of the budget tab if you need to come back to the Budget later.
- Make sure you click the Done button in the top left corner when you're finished with the Budget, otherwise you risk the Budget being locked.
- You can export the Budget to Excel by clicking the **Import/Export** button.
- You can export the Budget to PDF by clicking the **Build PDF** icon.



- You can restrict the view of your Budget to Period by Period if you choose.
- **Modular Budget**: On this screen you can view the modular budget, view the Gap between what you've entered on the budget and the module amount, as well as update the number of modules.
- **F&A**: On this screen you can review the F&A rate applied to the budget. For most research grants, the standard federally negotiation rate will apply. Manual entry is available for submissions to agencies with a published rate lower than WCM's negotiated rate, i.e. the American Heart Association or the Gates Foundation.
- **Budget Justifications**: While you do have the option to enter line-by-line justifications for Personnel and Non Personnel Costs in each of those sections (you'd simply enter them in the Justifications tab), it is probably far easier to compile these justifications on a single document and upload them using the Justifications link on the left navigation menu.
- **Versions**: You can upload different versions of the Budget here. This allows you to view the impact of adding or changing different segments of the Budget without impacting the information you entered.

Manual Proposal Types

Non System-to-System Grant: Financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity that are submitted as a manual proposal.

Sponsored Research Agreement: A Sponsored Research Agreement (SRA) is a contract between WCM and a non-federal sponsor for the purposes of funding and conducting research at WCM. The SRA governs the scope of work, deliverables, funding and intellectual property terms and conditions of basic and applied research and product development. The SRA can either be sponsor-initiated or investigator-initiated and is generally prepared to reflect the mutual interests of and benefits to the sponsor and WCM.

Incoming Material Transfer Agreement: The MTA delineates the individual rights of the provider and WCM with respect to the materials and any derivatives during the performance of research. Frequently transferred materials include biological materials, reagents, cell lines, plasmids, vectors, chemical compounds and mice.

Data Use Agreement: A Data Use Agreement (DUA) is a contract that governs the transfer of data outside the context of a Sponsored Research Agreement (SRA) or other agreement. When

WCM enters into a DUA, it shares, receives or transfers de-identified data, limited data sets or fully identifiable data.

Confidentiality Agreement: A Confidentiality Agreement (CDA), also known as a Non-Disclosure Agreement (NDA), is a contract governing the obligations of the parties who receive and/or disclose confidential information. For example, a sponsor may wish to disclose to a WCM faculty member information related to a research project in order to determine if the faculty member will be a suitable PI for the project.

Service Agreement: A Service Agreement is a contract used when WCM is hired to perform, or is hiring an outside party to perform, a service that is not covered by a Sponsored Research Agreement (SRA) or other agreement. A Service Agreement may be used to provide for specialized or professional services or to complete a specific scope of work in a certain field or technique. Depending on the type of work involved, the relationship may be regarded as a Consulting Arrangement. OSRA is responsible for Consulting Agreements where WCM hires a consultant paid from a Sponsored Research Grant or Agreement.

BioPharma Alliance Agreement: To proactively market, generate and structure new opportunities for business development and translational research alliances with industry in order to maximize the participation of WCMC faculty in research collaborations with the life science and biopharma sector in connection with investigator-initiated and investigator-led, pre-clinical, innovation-driven, discovery-oriented research projects with translational potential, around which either (1) IP already exists (aka, background IP); and/or (2) which may give rise to new IP (aka, foreground IP).

Approving Salary Releases

Approving Salary Releases by Email

When a Weill Cornell employee is added to a Budget, a salary release request will be initiated and emailed to that employee. Depending on how a department is structured, this salary release may be sent, additionally, to departmental administration who can release the salary on behalf of the employee.

Salary Release Requested - Proposal 170513, Submitted by Dr. PI...

W

Monday, March 13, 2017 at 3:54 PM

To:

You are listed on a proposal budget in the Weill Research Gateway (WRG). Salary approval is required in order to finalize the submission. For submissions going through WRG, this action replaces the ERF approval requirement.

Approval of this request will populate your base salary on the below referenced application's budget. Please proceed if you approve of your participation on this proposal. Note for NIH applications applicable salaries will be capped as per NIH guidelines.

Principal Investigator: Dr. Miranda Clarke
Sponsor: American Heart Association
Proposal Title: The Impact of Alcohol on Cardiovascular Neurobiology
Proposal Number: 170513

Click ***Open Information Release Screen*** below to complete this request.

Instructions for completing this process are available: [insert URL to training documentation].

For assistance or inquiries, contact the appropriate central research administration office:

Office of Sponsored Research Administration (OSRA): grantsandcontracts@med.cornell.edu
Joint Clinical Trials Office (JCTO): JCTOContracts@med.cornell.edu
Qatar Research Office (RO): dmw2005@qatar-med.cornell.edu

For technical assistance, contact ITS: WRG-Support@med.cornell.edu

Open Information Release Screen

1) Click the Open Information Release Screen link at the bottom of your email request.
2) Enter your CWID and password on the screen that opens to log in.
3) Note the salary in the bottom box, and select the radio button stating that you either authorize or do not authorize the release of the salary to the proposal.
    a. Note that for NIH applications, the salary cap will feed to the budget if the current base salary is over the cap.
4) Click the Submit button in the top right corner of the screen.

Approving Salary Releases in WRG

In addition to approving through email, you do have the option to approve salary releases in WRG through the Action Items menu.

5) On the homepage of WRG there will be a table containing Action Items for releasing salary releases, select the Action Item for releasing your salary.
    a. Alternatively, if you do not see it, you can click the Action Items or Mailbox link in the top navigation menu to locate your salary release.
6) Note the salary in the bottom box, and select the radio button stating that you either authorize or do not authorize the release of the salary to the proposal.

    a. Note that for NIH applications, the salary cap will feed to the budget if the current base salary is over the cap.
7) Click the Submit button in the top right corner of the screen.

Approving Proposals in the Reviewer Dashboard

Depending on where your role sits in the Process Flow for Sponsored Programs, you will receive proposals for review. You can either approve them to the next stage in the Process Flow or return them to the requester for edits.

The approval process is triggered by an email sent to your inbox. You can also see these right in WRG, in your Mailbox and Action Items tabs.

1) In your email, click the Reviewer Dashboard link.
    a. The Reviewer Dashboard will populate in a new window.
2) Click the Review tab on the left side of the screen.
3) Click the links under Form/Document to review the proposal information.
4) Click the Review Status dropdown and make a selection.
    a. Un-Reviewed means you have not looked at the form or document at all.
    b. Reviewed means you have reviewed the form or document.
    c. Not Applicable means the form or document does not apply to you (ex: Reviewer Checklist, which is specific to OSRA reviewers)
5) Click Save in the top right corner after reviewing the proposal form / documents.
6) Enter Comments in the corresponding boxes.
7) Click the My Decision Is dropdown and make a selection.
    a. Approved will move the proposal to the next stage in the approval process.
    b. Return for Edits will send the proposal back to the requester to make your suggested changes.
8) Click Save in the top right corner of the screen.
9) Click OK to confirm.
    a. After clicking Save, and OK to confirm, you'll see parts of the screen will be grayed out. You can click the Route tab on the left side of the screen to view where the proposal has gone on the route (either to the next stage of approval, or back to the requester to make changes).

Human Subjects

What is the Human Subjects Module?

The Human Subjects module of WRG is where you'll submit IRB applications, amendments, continuing reviews, and other study lifecycle events for research involving human subjects. This module utilizes the Study Activation Status Page, or SASP, to manage the plethora of tasks you need to complete in order to activate your study.

Submitting your Intake Form

Once it's been determined that you'll be conducting a research study with human subjects, you'll need to complete the Intake form in WRG.

1) Click the **Human Subjects** link in the left navigation menu.
2) Click the **Create New Protocol** button.
3) Select the **Intake radio button**, click **Continue**.
4) Copy from Existing Protocol should be marked to **No**, click **Continue**.
5) Enter a **Title** for this protocol and click Continue.
    a. The Title should match the name of your study.
6) Select the **PI** and click **Continue**
    a. Note that the PI will default to your name.
7) Click the **Intake form** (orange link)
8) Answer all the questions on the form. As you run through the form, note the following:
    a. Questions are dynamic. Additional questions may populate based on how you answer.
    b. Definitions for certain questions may appear once an option is selected.
    c. If you forgot to answer a required question, an Incomplete Mandatory Fields box will appear. You can click the question in that box to jump right to it on the form.
    d. Don't forget to check out the next steps at the bottom of the form!
9) When you've answered all questions, click the **Save + Complete buttons** at the top of the page.
10) Back on Submission Package, you'll note the Status column reads as completed.
11) Click the **Submit** button.
12) Note the protocol's Record Number in the top left corner of the screen. You'll need this to navigate through the process of study activation.

Review Activities on the Study Activation Status Page (SASP)

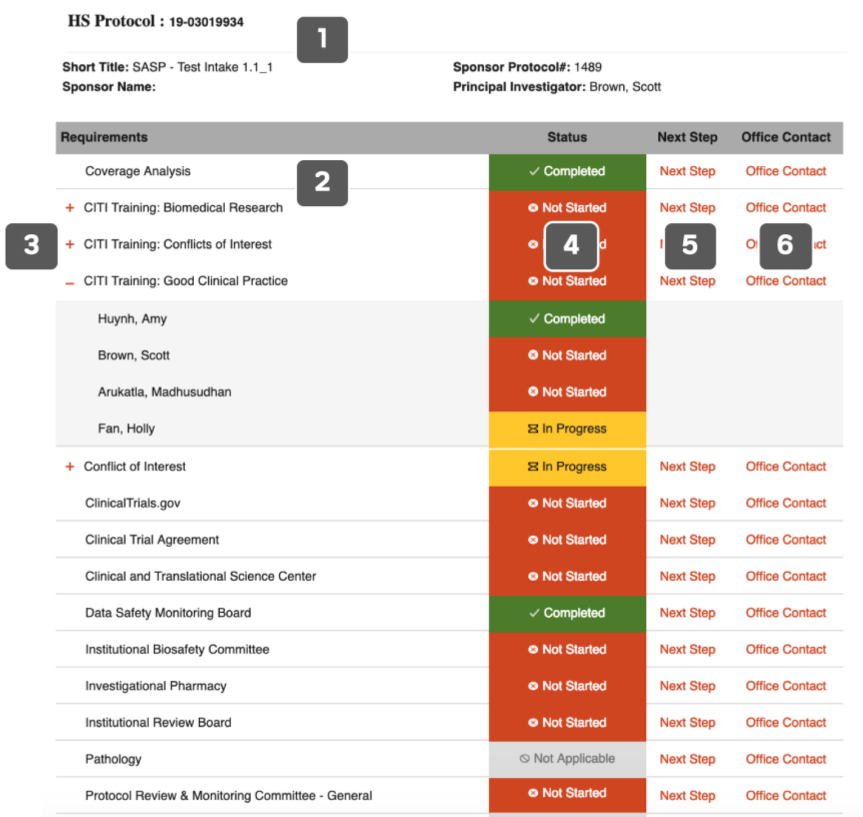
The Study Activation Status Page (SASP) is a dashboard where you can monitor your study protocols which were triggered by submitting the Intake Form.

Navigate to SASP

- **Log in** to the Weill Research Gateway with your CWID and password.
    - http://wrg.weill.cornell.edu
- Click the **SASP** link in the top navigation menu.

Search For and Add Protocols to your SASP Dashboard

- Type your **Protocol Record Number** in the entry field and click the orange Search button.
    - Results will display underneath the entry field.
- Click the **Add** button to add this protocol to your **Favorites** menu.
    - The Favorites menu is where your manually tracked protocols will appear.
    - You can click the **Remove** link to remove protocols from this list.
- Click the **Protocol Record Number** (orange link) to navigate to the SASP dashboard.



View Tasks on the SASP Dashboard

1. **Protocol Information**: Basic information about your protocol will appear in this section, including the Record Number, Title, Sponsor information, and PI.
2. **Requirements**: This is a list of potential tasks you may be required to complete (reference the Status column indicators to know whether or not that particular requirement applies to your study).
3. **[+] [-]**: These expand and collapse options will allow you to see whether action needs to be taken for any key personnel added to the study.
4. **Status**: This column indicates the status of a particular requirement.
   a. **Gray – Not Applicable**: This requirement is not applicable to your protocol and does not need to be completed. No action is required.
   b. **Red – Not Started**: This trigger means you must complete this requirement, and that it has not yet been started.
   c. **Yellow – In Progress**: This requirement has been started, but not yet completed.
   d. **Green – Completed**: This requirement has been completed.
5. **Next Steps**: This link will point you to specific instructions and guides about how to complete that particular requirement.
6. **Office Contact**: This is where you can find contact information for the central offices who handle that requirement.

Submit your Protocol to the PRMC in WRG-Clinical Trials

If either of the ‘Protocol Review & Monitoring Committee’ requirements have a red, ‘Not Started’ status indicator in SASP, you must submit your protocol to the Protocol Review and Monitoring Committee (PRMC) in WRG – Clinical Trials.

Note the PRMC has formerly been known as the CSEC or Clinical Study Evaluation Committee.

1) From the WRG Homepage, click the **Clinical Trials** module from the left navigation menu.
    a. This will bring you to our Clinical Trials Management System also known as OnCore.
    b. You may be prompted again to enter your CWID and password.
2) Click the **Menu** from the top navigation menu.
3) Hover over **ePRMS**.
4) Click the **Submission Console**.
    a. Note that you can save this console as a Favorite by clicking the star. The Submission Console will appear in the top navigation menu, making it more easily accessible in the future.
5) Enter your **protocol numbe**r in the entry field in the left navigation menu and hit Enter on your keyboard. Results will display to the right.
    a. Note that you may also see your protocol listed in the Incomplete Table.
6) Click the **Submission Number**, which will appear as a blue link, to enter your PRMS application.
7) The following screen will contain information that carries over from your Intake form. You’ll want to ensure it’s accurate and up to date.
    a. The Protocol and Investigator’s Brochure (if applicable) that were uploaded at Intake are stored in the documents section of the PC Console.
8) To open the form for editing, scroll to the bottom of the page and click the **Update** button.
9) Update any information on the form as necessary.
10) There are two sections on this form where you will have to input information:
    a. **Competing Protocols**: If you have any competing protocols, you’ll either need to enter the **Protocol No** in the corresponding field, or click the **No Competing Protocol? checkbox**.
    b. **Documents**: This is where you will upload relevant documents for the PRMC to review. Examples of documents are the informed consent template, budget, ancillary forms, algorithm, and score sheet.
        i. Click the **Add** button in this section to add multiple documents for PRMC review.
11) Once your information is entered, click the **Save** button at the bottom of the page.
12) Finally, you’ll click the **Send** button to send for the PRMC to review.

Next Steps: After PRMC reviews and approves the study, the ‘Protocol Review & Monitoring Committee’ requirement on SASP will be flipped to a green, Completed status.

See a video demonstration of ePRMS here: http://bit.ly/2FwgaNI

Submit your Initial IRB Application

If the 'Institutional Review Board' requirement on SASP has a red, Not Started status indicator, you must complete an Initial IRB Application in WRG – Human Subjects.

Search For your Protocol in WRG

- **Quick Find**
  - If you have the Protocol Record Number, you can type it in the Quick Find entry field in the top navigation menu.
  - In the Results list, hover over the Record Number, hover over Edit, click Master Record.
- **My Items**
  - Click My Items in the top navigation menu.
  - A general listing of all your WRG items will appear.
  - Hover over the Record Number, hover over Edit, click Master Record.
- **Search for Items**
  - Click Search for Items in the top navigation menu.
  - Click the Human Subjects checkbox.
  - Select one or multiple of the Available fields to search by.
  - A search field will populate to the right depending on what you've chosen, enter your criteria and click the orange Search link.
  - In the Results list, hover over the Record Number, hover over Edit, click Master Record.

Add an Initial IRB Application to your Submission Package

- After searching for your record you'll be taken to your Submission Package Summary.
- Click the orange **Submissions** link toward the top of the form.
- Click the dropdown menu toward the right side of the form, and select **Initial**.
- Click the **Add** button.

Fill Out and Submit your Initial IRB Application

- Click the orange **IRB Application** link from the Documents/Form column.
- Answer all the questions on the form. As you run through the form, note the following:
  - Questions are dynamic. Additional questions may populate based on how you answer.
  - Definitions for certain questions may appear once an option is selected.
  - If you forgot to answer a required question, an Incomplete Mandatory Fields box will appear. You can click the question in that box to jump right to it on the form.
- When you've answered all questions, click the **Save + Complete buttons** at the top of the page.
- Back on the Submission Package you'll note the Status column reads as **Completed**.
- Click the orange **Submit** button.

- Optional: Click the **Show Route** button to see the review cycle for this application.

General Example: IRB Application Review Cycle

Next Steps: The Initial IRB Application will go through a review cycle. Once approval is granted, the application will move to an Initial IRB Approval status, at which point the 'Institutional Review Board' requirement on SASP will be flipped to a green, Completed status.

Note that you may also receive this application back from the IRB with Modifications Required. At which point you'll make the suggested changes and submit through the cycle again.

See a video demonstration of the Initial IRB Application process here: http://bit.ly/2U0tPET

Approve + Certify on an IRB Application

Once an Initial IRB Application is submitted, the first step is for any key personnel on that application to certify and approve their participation in the study. You will be notified of this necessary step a couple of different ways:

- You'll receive an **Action Item** in WRG.
- You'll receive an **email notification** in your regular email pointing you to that Action Item.

1) **Log in** to the Weill Research Gateway with your CWID and password.
    a. http://wrg.weill.cornell.edu
2) The Action Items section will appear in the middle of the page.
3) Click the associated **Action Item**, which will appear as an orange link.
4) The screen that pops up is called the **Reviewer Dashboard**.
    a. The Reviewer Dashboard opens up on the **Help** tab which provides you general instructions on how to review and approve your Action Item.
    b. The **Review** tab is where you'll be able to access the application for review, and make your final decision.
    c. The **Route** tab will show you where this application is in the review cycle.
5) Click the **Review** tab.
6) Click the **IRB Application** link. The application will open in a new window.
    a. Note you can also view this as a PDF by clicking that link as well.
7) Review the application.
8) If you want to add any clarifying comments, flip back to the Reviewer Dashboard and add it in the appropriate comments field.
9) Click the **Close** button to close the application once you're finished reviewing.
10) Click the **Review Status dropdown** and select **Reviewed**.
11) Click the **Approved** or **Disapproved** button below.
    a. Approved will move the application forward in the route.
    b. Disapproved will send the application back to the submitter.
12) **Important**: A popup will appear where you will acknowledge you are serving in the role indicated in the IRB application and certify the information is accurate.
13) Click the **Accept** button.

See a video demonstration of this process here: http://bit.ly/2uqiuPV

Complete Items on your Task List in WRG

There are a few Requirements listed on SASP which could require you to log into WRG – Clinical Trials to complete tasks, including:

- Coverage Analysis
- Investigational Pharmacy
- Pathology
- ClinicalTrials.gov
- DSMB

The steps you'll take in the system for each of these requirements is relatively similar. For this work instruction, we'll use the Investigational Pharmacy as an example.

1) From the WRG Homepage, click the **Clinicial Trials** module.
    a. This will bring you to our Clinical Trials Management System also known as OnCore.
    b. You may be prompted again to enter your CWID and password.
2) Click **Menu** from the top navigation menu.
3) Hover over **Protocols**.
4) Select **PC Console**.
    a. Note that you can save this console as a Favorite by clicking the star. The PC Console will appear in the top navigation menu, making it more easily accessible in the future.
5) Enter your **Protocol Record Number** in the entry field in the left navigation menu, and select it from the list that populates.
6) Click the **Status** link from the left navigation menu.
7) Click the **Task Lists** tab.
    a. The Task Lists required for this protocol will be displayed.
8) Click the **Task List** you want to complete.
9) Note the task line item and complete each one.
    a. Note that the target dates have been pre-populated. The date is 90 days post the submission of intake. Tasks can be completed prior to the target date. The responsible person/role is also listed for each task. If you have questions about who has been assigned the role, you can navigate back to the PC Console and view Details, then Staff tab.
    b. Click the **Attachments** link in the right column to either download or upload these files.
10) Once each task has been completed, you'll enter the **Completed Date** in that column.
    a. Shortcut: You can enter 'T' in the entry field to quickly enter today's date.
11) Click the **Save** button.
    a. Note that you'll see a green 'Success!' banner pop up to confirm.
12) Click the **Close** button to close the Task List.

Next Steps: Once all tasks from a particular Task List have been completed, that Requirement will be flipped to green on SASP.

See a video demonstration on this process here: http://bit.ly/2TzFA0M

Submitting Study Lifecycle Events (Amendments, Continuing Reviews, etc)

During the course of your study you will need to report Study Lifecycle Events. These events could potentially include:

- **Amendment**: You will submit an amendment if you are changing something on the study (ex: The Sponsor gives you a new protocol document, or you need to add a new test.)
- **Administrative Amendment**: You can submit an administrative amendment for changes that do not require full board review (ex: Adding or removing personnel, translation of Informed Consent Form.)
- **Continuing Review**: An application to renew your study.
- **Reportable Event**: This is where you'll report exceptions to the protocol (ex: If you need to report someone who had an adverse reaction.)
    - Previously, you would have emailed the IRB when this occurs. As of March 2019, this process is now handled in WRG through a Reportable Event.
- **Closure Report**: This will close out the study.

(!) IMPORTANT: You must add a Study Lifecycle Event through the Submission Package on the protocol. Do not click Create New Protocol to add these. This could potentially result in misrouted forms.

Search for your Initial Protocol

These Study Lifecycle Events are submitted as a supplement to your Initial IRB Application, so you must search for that original protocol.

Note: If your original protocol was in eIRB, you may need to repopulate information on the form.

- **Quick Find**
    - If you have the Protocol Record Number, you can type it in the **Quick Find entry field** in the top navigation menu.
    - In the Results list, hover over the **Record Number**, hover over **Edit**, click **Master Record**.
- **My Items**
    - Click **My Items** in the top navigation menu.
    - A general listing of all your WRG items will appear.
    - Hover over the **Record Number**, hover over **Edit**, click **Master Record**.
- **Search for Items**
    - Click **Search for Items** in the top navigation menu.
    - Click the **Human Subjects checkbox**.

- Select one or multiple of the Available fields to search by.
- A search field will populate to the right depending on what you've chosen, enter your criteria and click the orange Search link.
- In the Results list, hover over the **Record Number**, hover over **Edit**, click **Master Record**.

Add a Study Lifecycle Event to your Submission Package

1) After searching for your record you'll be taken to your Submission Package Summary.
2) Click the orange **Submissions** link toward the top of the form.
3) Click the **dropdown menu** toward the right side of the form, and select the **appropriate submission**.
4) Click the **Add** button.

Fill Out and Submit your Study Lifecycle Event

1) Click the **orange link** that pertains to your Study Lifecycle Event from the Documents/Form column.
2) Note the Pre Review Checklist is for the IRB staff for administrative review.
3) Answer all the questions on the form. As you run through the form, note the following:
4) Questions are dynamic. Additional questions may populate based on how you answer.
5) Definitions for certain questions may appear once an option is selected.
6) If you forgot to answer a required question, an Incomplete Mandatory Fields box will appear. You can click the question in that box to jump right to it on the form.
7) When you've answered all questions, click the **Save + Complete** buttons at the top of the page.
8) Back on the Submission Package you'll note the Status column reads as Completed.
9) Click the orange **Submit** button.

Important: The submission will not be routed for review until the Submit button is clicked. It's easy to miss this step!

Next Steps: After submission, your Study Lifecycle Event will go through a review process which you can see by clicking the Show Route button after you click Submit. You'll also want to note:

- You may receive this protocol back from the IRB with Modifications Required. You'll be notified via email if this is the case.
- No additional personnel certification is required for the Study Lifecycle Events listed in this article.

Conducting a Board Member Review of IRB Applications

This article is intended for: IRB Committee Members who review applications

Trigger: You will receive an email both in your Outlook inbox, as well as your Messages on WRG. You will also receive an Action Item in WRG.

1. **Log in** to the Weill Research Gateway (WRG) with your CWID and Password at: http://wrg.weill.cornell.edu
2. Click the **Action Item**, which will state 'Your action is required' and include the Human Subjects protocol number.
3. Note the links under the **Form/Document section**. This list contains everything submitted by the study team.
4. Click the **Reviewer Checklist** and **IRB Application**.
    - Best Practice: Resize the windows to place them side by side or slightly overlapping for easier navigation between the two forms.
5. On the Reviewer Checklist's first screen, click the **eForm link**: '**Reviewer Checklist …**' and position it above the first checklist page.
    - You'll note this originally says incomplete. This will change once you've conducted your review and marked Complete on your specific checklist.
6. **Answer the questions** contained on your specific Reviewer Checklist while reviewing the IRB application
    - Note the sections of the form are dynamic and appear based on what was entered on the IRB application.
    - There is branching logic associated to this checklist. For example, answering questions a certain way may prompt additional questions or a text box where you can enter clarifying information.
    - You may see sections on the checklist that do not need to be completed. For example, if you're conducting a review of an amendment – you'll only need to complete that section. If this is for a continuing review, you'll need to complete that section.
    - For initial IRB applications, all sections should be reviewed.
    - At the end of each section of the checklist, you'll see a textbox for Reviewer Comments. This is where you'll add comments that pertain to the section above. These comments will be aggregated at the bottom of the checklist for easier reference.
7. After you conduct your review and answer the questions on your Reviewer Checklist, click the **Save** button, followed by the **Complete** checkbox.
8. Confirm the eForm link reads as **Complete** back on the first Reviewer Checklist page.
9. Close both the Reviewer Checklist window, as well as the IRB application.
10. Back on the Action Item page, click the **Review Status dropdown** and make a selection for each applicable Form/Document.
    - You don't have to worry about updating any greyed out dropdown menus.
    - All other dropdowns should have a selection made. The system will prevent you from moving forward if any of them read as Un-Reviewed.
11. Under Finalize Task / Assignment section, click the **Reviewer Determination dropdown** and make a selection.

12. Scroll back to the top of the Action Item. Click **Save** and then the **I am done** button.
    - You should now see this Action Item drop off your list.

Next Steps: After making your final Reviewer Determination, the application gets routed back to the IRB office who will take action depending on what you selected.

- Modifications Required: If you requested mods, the IRB office will communicate these to the study team directly.
- Approval: If you've selected approval, the application will be added to the meeting agenda pending the IRB's administrative review (see below).

The IRB office will also conduct an administrative review for pending items, like CITI training and conflicts of interest.

See a video demonstration of this process here: http://bit.ly/2JO7vqC

Clinical Trials

What is the Clinical Trials Module?

The Clinical Trials module of WRG is also known as OnCore. This system manages the administration of subject enrollment into clinical trials here at Weill Cornell. Some of the various tasks you'll need to complete for research study activation also need to be completed in the Clinical Trials module.

For a video demonstration of the entire Subject Enrollment process, click here: http://bit.ly/2JBSdIQ

Weill Cornell Medicine

Registering a Subject

Once a study has gone through the application and approval process, it is considered activated and you can begin enrolling subjects to it. You will receive a system-generated email notification once this happens, which you can consider your trigger to enter the Clinical Trials module of WRG.

1. Log in to the Weill Research Gateway with your CWID and password.
    - http://wrg.weill.cornell.edu
2. Click the **Clinical Trials** module from the left navigation menu.
    - This will bring you to our Clinical Trials Management System also known as OnCore.
    - You may be prompted again to enter your CWID and password.
3. Click the **Menu** from the top navigation menu.
4. Hover over **Subjects**.
5. Click the **CRA Console**.
    - Note that you can save this console as a Favorite by clicking the star. The CRA Console will appear in the top navigation menu, making it more easily accessible in the future.
6. Enter the **Protocol Record Number** in the entry field on the left navigation menu, and select it from the list that populates.
    - If subjects were enrolled through the JIRA process, they will be migrated to this screen.
7. Click **Register Subject** from the left navigation menu.
8. Enter the **Study Site**: Begin typing **WCM/NYP** in the entry field and select it from the list.
9. Search for the subject:
    - **MRN**: You can search by the subject's Medical Record Number (MRN).
        - Note the MRN that displays in OnCore is the EMPI. This can be found in the SnapShot activity in Epic. MRNs should never be updated.
    - **Last Name**: You can search by the subject's Last Name.
    - **DOB**: You can add the subject's DOB for a more specific search (ie, if there are multiple John Smiths listed in the system.)
10. Click the **Find** button.
    - Results will display below.
11. Click the **MRN number**, which will appear as a blue link.
12. Review the Subject Details.
    - This information should be carried over from Epic, but you'll want to ensure the information is up to date and accurate.
13. Click the **Add** button
    - This subject is now added to your study.
    - Important: If you accidentally registered a subject who should not be on the study, email: WRG-Support@med.cornell.edu

Next Steps: After registering a subject you will want to consent them. This can occur immediately after registering them to a study.

Consenting a Subject

After registering a subject in the system, you should immediately record their consent.

Access the Subject Console

The first six steps are if you need to log back into the system completely. If you're already in the Subject Console after registering them, you can skip ahead to the next section, Recording the Subject Consent.

1. From the WRG Homepage, click the **Clinical Trials** module from the left navigation menu.
   - This will bring you to our Clinical Trials Management System also known as OnCore.
   - You may be prompted again to enter your CWID and password.
2. Click the **Menu** from the top navigation menu.
3. Hover over **Subjects**.
4. Click the **CRA Console**.
5. Enter the **Protocol Record Number** in the entry field on the left navigation menu, and select it from the list that populates.
   - You should see a list of your registered subjects here.
6. Click the subject's **MRN number**.

Record the Subject's Consent

1. Click the **Consent** tab from the left navigation menu.
2. Click the **Update** button to open this form for editing.
3. Click the **Select Consents** button.
4. Review the list of Available Consents.
   - For studies that have not gone through an approval in the WRG Human Subjects module, this will say Migrated Consent. You can choose this option until a consent is available after the next IRB approval in the Human Subjects module.
5. In the **Signed Date** field, record the date the subject signed the consent form.
   - Shortcut: You can enter 'T' in the entry field to quickly enter today's date.
6. Record the Status by selecting either the **Accepted** or **Refused**.
7. Click the **Save** button.
8. Click the **Submit** button at the bottom of the page.
9. The Subject Status (top right corner of the page) should switch over to say CONSENTED.

Additional Note: For studies will billing risks, the study information will appear in the subject's Research Studies activity in Epic when the allowing providers to link screening visits to the study.

Upload the Signed Consent Form

1. From the **Consent** tab on the Subject Console, click the Documents/Info tab from the left navigation menu.
2. Click the **Attachments** tab.
3. Click the **Add** button.
4. Click the **Document Type dropdown** and select **Signed Consent**.
5. Enter the **Version Date**.
   - This information is typically found in the footer of the consent form
6. Click the **File** link to choose and upload your file.
7. Click the **Add** button in that same gray box.
   - Note that you do not want to click the Add button in the yellow section heading further down.
8. You'll see the Signed Consent form appear in the list of Subject Attachments.

Screen Failing a Subject

1. On the **Consent** tab, you'll note Subject Screen Fails under the Other Consent Status section.
2. Click the **Status dropdown.**
3. Select **Withdrawn**.
4. Enter the **Status Date**.
   - Remember, you can enter T for today's date.
5. Enter '**Subject screen failed**' in the comments field.
6. Click the **Submit** button.

An alternate option for modifying the subject's status is to notify the Central OnCore team by sending an email to jctoctms@med.cornell.edu.

Next Steps: After your subjects have been consented, our central offices will determine the subject eligibility and formally add them to the study, at which point you would log back in and add their Treatment [include deep link to Treatment KB].

Adding Subject Treatment

After your subject is registered and consented, our central offices determine the subject's eligibility and place them formally 'On Study.' At this point, you can begin adding their treatment.

Access the Subject Console

The first six steps are if you need to log back into the system completely. If you're already in the Subject Console after registering them, you can skip ahead to the next section, Adding Treatment Arms for the Subject.

1. From the WRG Homepage, click the **Clinical Trials** module from the left navigation menu.
    - This will bring you to our Clinical Trials Management System also known as OnCore.
    - You may be prompted again to enter your CWID and password.
2. Click the **Menu** from the top navigation menu.
3. Hover over **Subjects**.
4. Click the **CRA Console**.
5. Enter the **Protocol Record Number** in the entry field on the left navigation menu, and select it from the list that populates.
    - You should see a list of your registered subjects here.
6. Click the subject's **MRN number**.

Upload the Completed Eligibility Checklist and Treatment Assignment

1. From the Subject Console, click the **Documents/Info** tab from the left navigation menu.
2. Click the **Attachments** tab.
3. Click the **Add** button.
4. Click the **Document Type dropdown** and select the document type you want to upload.
5. Enter the **Version Date**.
6. Click the **File** link to choose and upload your file.
7. Click the **Add** button in that same gray box.
    - Note that you do not want to click the Add button in the yellow section heading further down.
8. You'll see the uploaded document appear in the list of Subject Attachments.

Record Treatment to a Subject

1. From the Subject Console, click the **Treatment** tab.
2. Click the **Add** button

  - After clicking Add, you'll see the steps that were listed to your protocol from the central offices.
3. Click the **Arm dropdown** and make the appropriate selection.
4. Enter the **On Arm Date**.
5. Enter the **On Treatment Date**.
6. Optional: Later you may come back to this tab to enter an **Off Arm Date**.
7. Click the blue Save link.
  - Subject Status will change to ON TREATMENT.

Next Steps: After adding treatment, your next steps would fall under Subject Disenrollment. This includes recording a subject being 'Off Treatment' or 'Off Study.' You can also schedule follow ups.

Disenrolling Subjects

Disenrollment would occur when a subject needs to be moved to Off Treatment, Off Study, or to schedule follow up.

Access the Subject Console

The first six steps are if you need to log back into the system completely. If you're already in the Subject Console after registering them, you can skip ahead to the next section, Adding Treatment Arms for the Subject.

1. From the WRG Homepage, click the **Clinical Trials** module from the left navigation menu.
    - This will bring you to our Clinical Trials Management System also known as OnCore.
    - You may be prompted again to enter your CWID and password.
2. Click the **Menu** from the top navigation menu.
3. Hover over **Subjects**.
4. Click the **CRA Console**.
5. Enter the **Protocol Record Number** in the entry field on the left navigation menu, and select it from the list that populates.
    - You should see a list of your registered subjects here.
6. Click the subject's **MRN number**.

Moving a Subject Off Treatment or Off Study

1. Click the **Follow Up** tab from the left navigation menu.
2. Enter an **Off Treatment/Study Date** in the appropriate field.
3. Click the **Off Treatment/Study dropdown** menu and make the appropriate selection.
4. Enter any clarifying details in the **Explain** field.
5. Click the **Submit** button.

For studies with billable risks, the disenrollment information will appear in Epic and visits can no longer be linked to the study.

Add a Subject to a Follow Up Schedule

1. In the Subject Follow-Up Update section, you'll fill out the necessary fields that pertain to your subject follow up.
2. Click the **Submit** button.

Conclusion: The Subject Status would be recorded ,depending how you filled out this page, to either Off Treatment, Off Study, or Follow Up.

Research Safety

What is the Research Safety Module?

The Research Safety module of WRG allows you to confidently manage compliance with federal, local, and institutional requirements for use of potentially harmful biological, chemical, and radioactive substances in your research.

Reviewing a Safety Protocol in WRG

Trigger (EHS):	>	Labs / PI:	>	EHS:	>	Committee:	>	EHS:
Initiates the protocol		Reviews the protocol; adds information		Prepares protocol for Committee review + meetings		Conducts review of protocol		Runs monthly meetings

Trigger for reviewing safety protocols in WRG

You will receive safety protocols one of two ways:

- You may receive a system-generated email and WRG Action Item stating the completed form is in the route, which you must review and approve.
- A direct, email communication from EHS. These are typically sent if there's more information required on the form, which you must input.
- Additionally, your lab's EHS Safety Advisor will connect with you in advance of receiving a protocol for review.

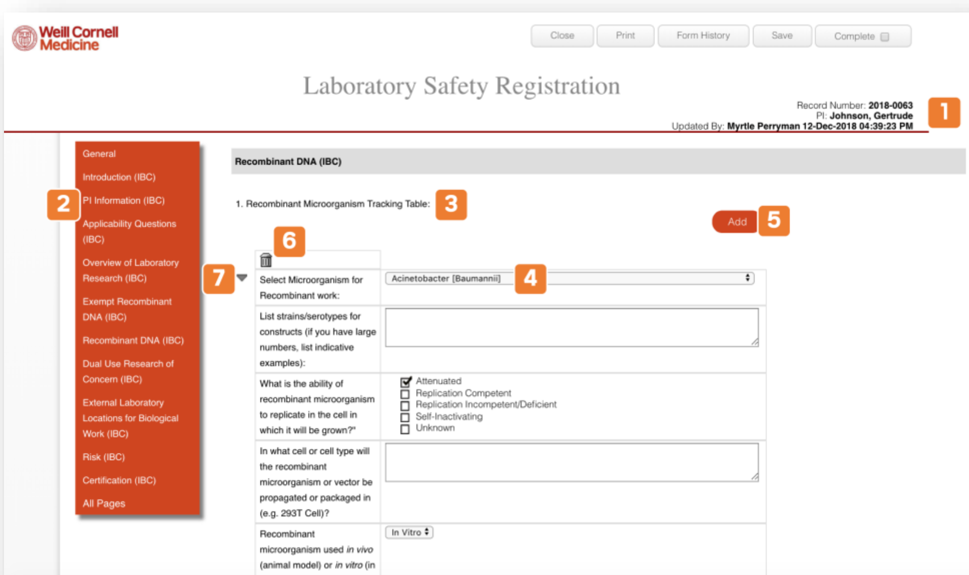
Review a protocol sent to you via the route

- You'll know when a protocol has been sent to you by the following methods:
  - *An* ***email*** *to your @med.cornell.edu address indicating you have an action item. The subject line will start with 'ACTION REQUIRED.'*
  - *You will see an* ***Action Item*** *when you log in to WRG.*
- Click the link contained in the **Action Item**. This will bring you to the Reviewer Dashboard.
- Note the 'How to Review' instructions.
- Click the green **Review** tab.
- Click the blue '**Laboratory Safety Registration**' link, which will take you directly into the protocol in WRG, where you can leave comments.
  - *Optionally, you can view a read-only version of the protocol by clicking* **PDF**.
- Review the responses on the protocol.
  - *You can click the* ***Pencil icon*** *next to a particular question to offer feedback to EHS. Note that you can't edit or add comments to the PDF version.*
  - *You can also uncheck the Completed* ***checkbox*** *and make changes to the form.*
- Once you've completed your review, click **Save**.
  - *If you unchecked the Completed checkbox, ensure you click the checkmark again after you Save.*
- Return to the **Reviewer Dashboard** (the window should still be open, but may be behind other screens).
- Click the **Review Status dropdown** and select Reviewed.
- Click the **Approved** button.
  - *Note that if you click Disapproved, the protocol will be returned back to you in the route, adding some unnecessary steps.*
- A Certification Statement will appear which you must read and **Accept**.

Complete a protocol sent to you manually by EHS

- In the email from EHS, note the **Record Number**.
- Log in to WRG: http://wrg.weill.cornell.edu
- Enter the **Record Number** in the **Quick Find** text entry field.
  - *If you're a PI, you can also find the form by clicking the My Items tab in the top-level navigation menu. Here, you can see all protocols assigned to you.*
- Hover over the **Record Number,** which should appear as an orange link in the search results.
- Hover over **Edit** and click '**Lab Registration – Initial**' (the link will also include the title of the protocol).
- On the screen that pops up, click the orange **Laboratory Safety Registration** link.
- Review the protocol in its entirety:
  - *Ensure information that came in populated is accurate.*
  - *Respond to any unanswered questions on the form*
  - *A sample IBC form with a Recombinant Microorganism is listed on the following page to display some features and functions to consider as you complete the form.*
- Click the Save button once your review is complete. This will take you back to the main page of the Laboratory Safety Registration.
- Back on the main page, click the **Submit** button.
  - *Note the route this protocol will take.*
- On the route screen, click the **Submit** button one final time to send this protocol into the route.
- Click **Done** back on the main page.

Laboratory Safety Registration Protocol Overview



1) **Basic Information**: This is where you can find protocol-specific information, like the record number, PI, and when the protocol was last updated and by whom.
2) **Left Navigation Menu**: This lists the various sections of the form. Note that additional sections may populate based on how certain questions are answered.
3) **Tracking Table**: Any microorganisms that are added to the form will be listed here.
4) **Microorganism Selection**: This is where you'll select the microorganism you want to add to the form, the subsequent questions pertain to that microorganism.
5) **Add**: If you need to add multiple microorganisms to this form, you'll click here.
   a. Note that the added microorganisms will display at the end of this table.
6) **Trashcan**: Deletes the selected microorganism from the protocol.
7) **Collapse / Expand**: Use this feature for ease of use when adding multiple microorganisms to the safety protocol.

What happens next?

- In both cases, the protocol would either enter or continue in the route for review. Eventually the protocol will be added to the corresponding committee's agenda.

Committee Review of Lab Safety Protocols

Trigger (EHS):	>	Labs / PI:	>	EHS:	>	Committee:	>	EHS:
Initiates the protocol		Reviews the protocol; adds information		Prepares protocol for Committee review + meetings		Conducts review of protocol		Runs monthly meetings

Trigger for Committee Review of protocols

You may be chosen for an initial Member Review of a protocol, which serves as a pre-review in advance of the monthly Committee Review. You will receive both an email in your inbox as well as a WRG Action Item if you need to pre-review an item in advance of the meeting.

Conduct an initial Member Review of a protocol

- Click the **WRG Action Item** which would have the subject 'Review Assignment…'
- Click the blue **Laboratory Safety Registration** link under Form/Document.
- Review the responses on the protocol.
  - *You can click the* **Pencil icon** *next to a particular question to offer feedback for discussion at the full Committee meeting.*
  - *Click the* **Comments Panel** *button at the top of the protocol to view an aggregated list of your comments.*
  - *Note that you cannot edit or add comments to the PDF version.*
- After completing your review and adding comments, click the **Save** button, followed by the **Close** button.
- Back on the Action Item, click the **Review Status dropdown** menu select **OK As Is**.
  - *You should select Action Required if you think changes are needed to the proposal. This response should also correspond with the following Reviewer Determination.*
- Under Finalize Task / Assignment, click the **Reviewer Determination**(recommendation) dropdown and make a selection.
  - *This should correspond with the previous response. If you selected OK As Is above, you should select Passes Review here. If you selected Action Required above, you should select Changes Required here.*
- Optionally, you can add any Provisions or Comments in the corresponding fields below. These will show up for discussion when the protocol is reviewed by the full committee.
- Click the **I am done** button at the top of the screen.
  - *This will notify the EHS Regulatory Coordinator that your initial Member Review is complete.*

What happens next?

Your Member Review will be forwarded to EHS who will add your reviewed protocol to the meeting agenda for discussion during Full Committee review.

Conflicts of Interest

What is the Conflicts of Interest Module?

The Conflicts of Interest tab is where you will report any financial relationships you may have that pertain to your institutional responsibilities here at Weill Cornell Medicine. Potential conflicts may be detected between people and sponsors, sponsors and projects, projects and funding applications, etc.

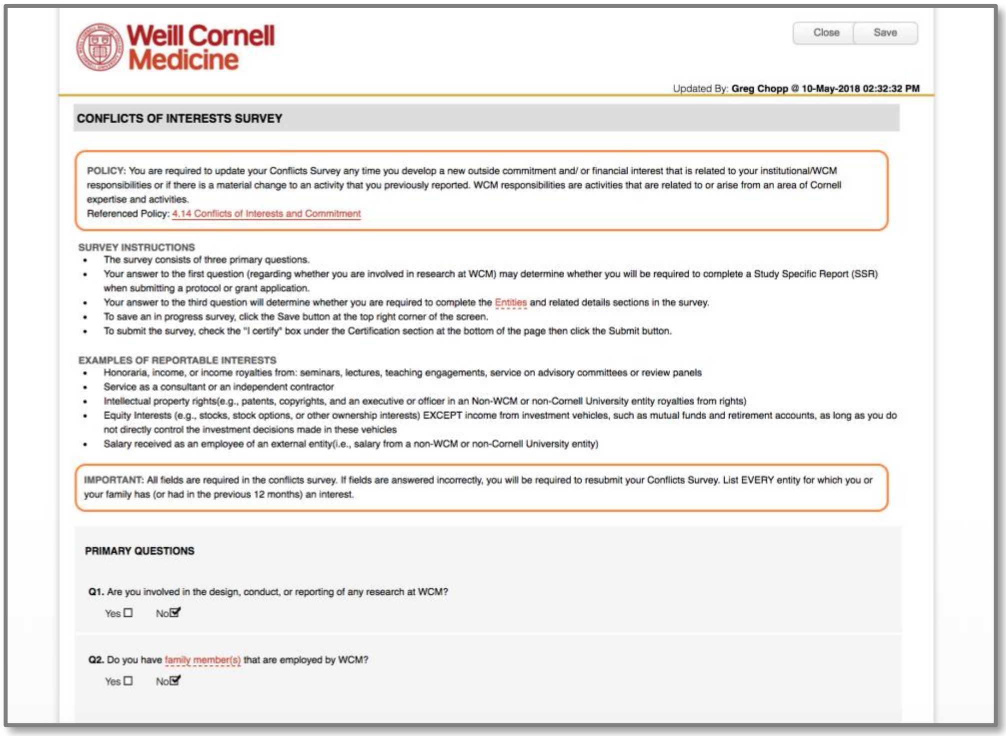
There are two primary submission types within the Conflicts of Interest module:

1) **Annual Conflicts Survey**: All WCM employees must complete the Conflicts Survey. You are required to update your Conflicts Survey any time you develop a financial relationship related to your institutional responsibilities here at WCM that may present, or appear to present, a conflict of interest. Any new relationships must be reported through the Conflicts Survey within 30 days of acquiring them. If you have no relationships to report, you must still certify once a year.
    a. **Note**: In the past, Travel Disclosures were a separate transaction accessed through the Conflicts of Interest module. With the most recent upgrade of the transaction, Travel Disclosures are now submitted as part of the Annual Conflicts Survey. Travel disclosures should be submitted by all WCM employees who receive travel support that is not sponsored by Weill Cornell Medicine. Note that all paid or reimbursed travel paid for by “for-profit” entities must be disclosed within 30 days of completing travel.
2) **Study Specific Reports (SSR)**: SSRs are used for capturing information on one’s external relationships in the context of a project and should be submitted at the time of grant proposal or Institutional Review Board (IRB) application, and prior to release of an award.

Submitting Your Conflicts Survey

Helpful Tip: The Show button at the top of the screen provides field help that may come in handy to clarify questions.

1) From the home page of WRG, select the **Conflicts of Interest** tab on the left navigation menu.
2) Select the **Create Initial Conflicts Survey** button.
    a. Note that if you’ve previously submitted a conflicts survey, this button will read **Recertify / Update Conflicts Survey**.



4) On the above page, read over the Policy, Survey Instructions, and Examples of Reportable Interests.
5) Answer the four **Primary Questions**.
    a. Note that if you are a physician, you must read the **Open Payments** section beneath the question and take action if necessary.
    b. Note that if you need to leave the survey before Certification and Submission, you must click the **Save** button in the top right corner of the screen.
6) If you answer **Yes** to **Question 2**, follow the steps below to add your family member:
    a. A popup window will appear after answering Yes.
    b. **Select the first letter** of your family member's last name from the top menu.
    c. Type the last name in the **Search for a particular entry** field.
    d. Select the **dropdown menu** above the search entry field.
    e. Ensure your **family member's name** is selected.
    f. Click the **Select** button.
    g. You should see your **family member listed** on the Conflicts Survey.
    h. *Optional: Click the **+Add** button to add any additional family members.*
7) If you answer Yes to Question 4 an additional Entities section will open beneath the Primary Questions, which you must fill out.
    a. Scroll down to the Entities section.
    b. Search for your Entity in the text entry field.
        i. As you type a list will populate beneath the entry field. Make your selection from this list.
        ii. If the entity you are trying to select is not in the dropdown list, **email Sponsor-Creation@med.cornell.edu** with the subject "COI Entity

Request." They will add the sponsor and notify you when you can go back in to select that entity.

c. Click the **+Add** button.

d. **Answer the questions** for the entity, noting that answering questions in a certain way may prompt additional branching questions which must also be answered.

e. Answering **Yes** to **Question 12** will expand the **Travel** section where you must add information about expenses reimbursed by the entity for travel.

i. **Travel Start Date**: Click the calendar icon to select the start date of your travel.

ii. Enter the **Destination**, **Duration**, and **Value** reimbursed for your travel.

iii. Click the **dropdown** menu and select a **Purpose** for travel.

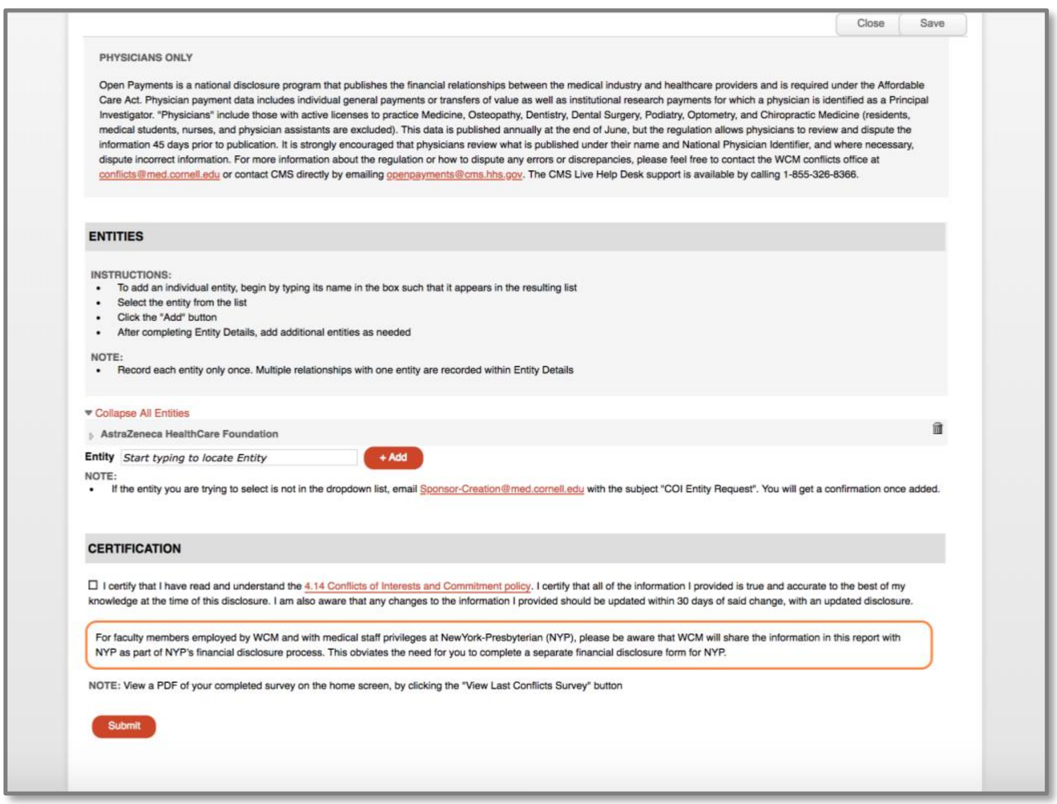
iv. *Optional: Click the **Add New Row** button to report another line item of travel for this entity.*

v. *Optional: Click the **trash can** to the right of the line item to delete the row.*

8) Click the **Certification checkbox** to certify your entries.

9) Click the **Submit** button.

a. At the top of the page, you should see a timestamp of your submission as well as a PDF icon where you can print a copy of your conflicts survey.



Conflicts Survey: Additional Notes

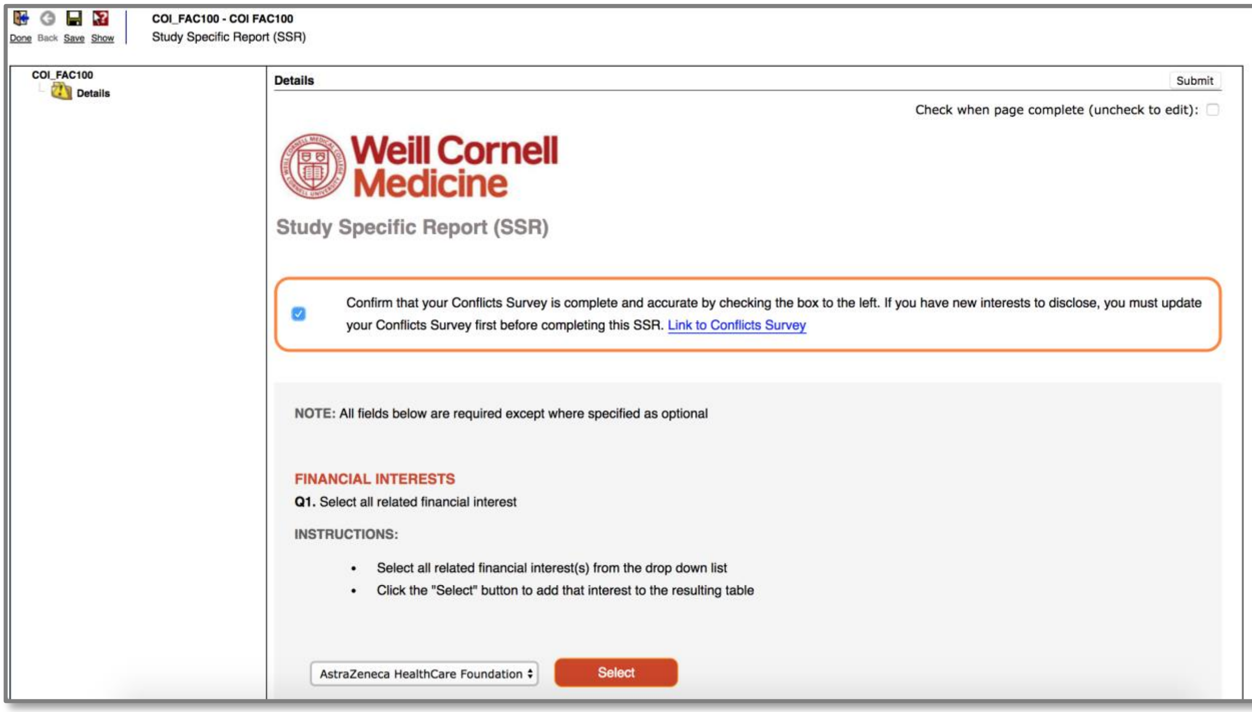
The Conflicts Survey needs to be completed by every WCM employee at least once per year and within 30 days of acquiring a new conflict. You can recertify with the following steps:

1. From the WRG Homepage, click **Conflicts of Interest.**
2. Click the **Recertify/Update Conflicts Survey** button.
3. You will still want to review each section of the survey, adding any entities as necessary.
   a. Click the **Certification** checkbox after your review.
   b. You can update details of an existing entity by clicking the **carat** to expand the line item.
   c. You can remove an entity entirely by clicking the **Delete** (trash can) icon.
   d. You can add new entities by following the steps listed in the previous section.
4. All paid or reimbursed travel paid for by "for-profit" entities must be disclosed within 30 days of completing travel.

Submitting a Study Specific Report (SSR)

Note: You must have a current Conflicts Survey on file to be able to complete this form. You will only be allowed to select interests that have already been disclosed on the Conflicts Survey. If you have a new interest to report, please update your Conflicts Survey first.

1) From the homepage of WRG, select the **Conflicts of Interest** tab.
2) Click the **Edit/Submit Study Specific Report (SSR)** button.
3) **Review** information about the Policy and Survey instructions.
4) Click the **Create New** button.
5) On the next page, click the **checkbox** to indicate that your Conflicts Survey is complete and accurate.
   a. ****Helpful Tip****: If you have not yet completed your Conflicts Survey, there is a link included directly to it. You will need to complete your Conflicts Survey before completing an SSR.



6) After clicking the checkbox, a list of questions comes up. Use the **dropdown** menu to select the related financial interest.
    a. The dropdown menu will consist of entities previously entered in your Conflicts Survey.
7) Click the **Select** button.
8) **Provide answers** to the series of questions on the screen.
    a. Note: Additional fields may pop up when you answer certain questions. These are meant for you to clarify your answers or provide additional information relevant to the question.
    b. Under **Project Principal Investigator** – begin typing the name of your PI. As you a type, a list of PIs will populate and you can make your selection.
    c. Make sure to click the **Select** button after highlighting your choice.
9) After entering all the information, scroll to the top of the page and click the **Completed** checkbox.
10) **Verify** the completion of your SSR details by noting the green checkbox. 

11) Click the **Submit** button in the top right corner.

Study Specific Report: Additional Notes

1) Upon pressing the **Create New** button, the system will save the report. If you do not want to submit the form at a particular time, you can come back to it by searching for the time it was initiated under the **In Progress** header. To access the form, click on the folder under the column labeled **Open**.


Create New
IN PROGRESS
Created Date
Project Title
Principal Investigator
Grant Number(s)
Protocol Number
Open
Delete
11/7/2017 2:48:57 PM
[Title]
Investigator, Pete

Training, Help, and Support

How can I Get Help + Support?

There are a variety of ways for you to get Help + Support for the Weill Research Gateway, including both On-the-Job Support and Direct Support channels. We're here to make sure you have an exceptional experience within WRG.

On-the-Job Support

Videos

You can view video demonstrations of some of the more detailed transactions within WRG. These videos will provide step-by-step, visual instructions on completing these transactions. You can find all WRG videos on our Help Portal.

- Conflicts of Interest (including Travel Disclosures and Study Specific Reports)
- Annual Recertification of Conflicts Survey
- Approving Sponsored Programs Submissions

Quick Reference Guides

Sections of this job aid have been broken out into their own Quick Reference Guides for easy access. You can find all WRG Quick Reference Guides on our Help Portal for each section.

Courses

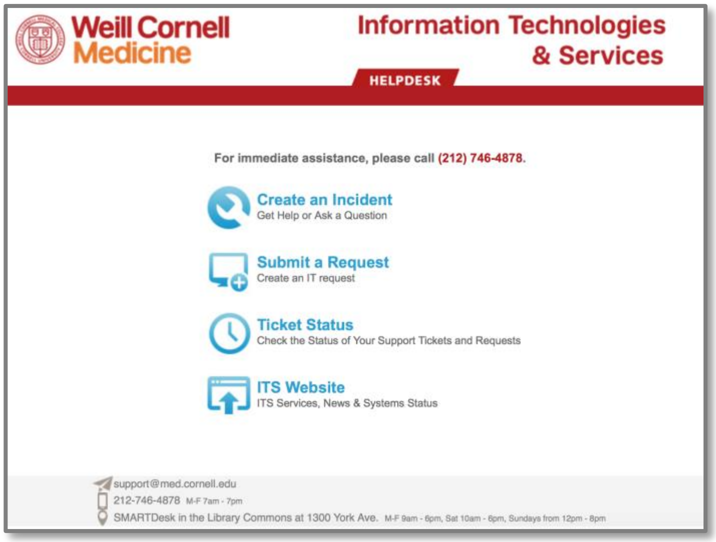
We also offer a series of interactive self-paced courses as well as classroom training for certain modules of WRG. You can register for these courses in our learning management system.

- Sponsored Programs – Basics
- Sponsored Programs – Budget

Direct Support

myHelpdesk

myHelpdesk is a self-service web portal that allows you to submit any issue or request online. When you fill out a simple form, your issue will be routed to our Client Services team to help fulfill your request or resolve your issues.



Follow these instructions to submit a ticket via myHelpdesk:

1) Click the **Open a ticket** link at the bottom of the WRG Homepage.
    a. You can also visit http://myhelpdesk.weill.cornell.edu.
    b. You may need to log in with your **CWID** + **password**.
2) Select Create an Incident.
3) **Answer** the questions on the following screen.
    a. Add a screenshot if you can, this will make it easier for Support to resolve your issue. Click the **Add Attachments** button to add a screenshot.
4) Click **Submit** to send your issue.
5) Take note of the **Incident Number** (format: INC0000000).
6) Support will reach out to you with a resolution.

Phone Support

(212) 746-4878
Extension: **64878 (6-GURU)**
You can contact the Support Desk at the number above to speak with a person right away. Depending on the nature of your issue, they may forward you to a specialized Application Support Group for Weill Research Gateway.