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Protocol Creation and Setup

Protocols are the foundation of all OnCore functionality and features. Protocol information must be entered in OnCore before building calendars, creating a protocol budget, enrolling subjects, tracking subject visits, or invoicing sponsors.

The PC Console (Protocol Coordinator Console) is the central repository for protocol information. Protocol coordinators track protocol ID numbers, objectives, assigned staff, sponsors, participating institutions, regulatory information, investigational drug and device information, and other details of each research study.

Building Blocks of OnCore

- **Tracking Receipts**
- **Sponsor Invoicing**
- **Payment Milestones**
- **Coverage Analysis**
- **SAEs Deviations**
- **Consent Eligible On Study**
- **Subject Details**
- **Charge Master**
- **Pre-Award Budgeting**

**Calendars**

- Subject Visit Tracking
- Data Monitoring
- Data Export

**Protocols**

- study details, accrual goals, committee reviews, treatment details, staff and sponsors
Create a new protocol in the PC Console

1. Navigate to Protocols > PC Console.

The PC Console is used to view and update protocol information. The PC Console is organized by vertical tabs on the left such as Treatment, Institutions, and Status. Above the vertical tabs is the Select Protocol field, a find-as-you-type field used to locate protocols in OnCore. Find an existing study by searching for any of the following identifiers:

- Protocol ID
- IRB No.
- Pharmacy No.
- PRMC No.
- Sponsor No.
- NCT ID.

2. Click New Protocol.

New Protocol is the last vertical tab on the left.

**NOTE:** Protocol No., Library, Department, Organizational Unit, and Protocol Type are required when creating a new protocol in OnCore.

Other fields will be required; see the GWCC Protocol Creation Guidance document for details.

3. After you enter the required data, be sure to click Submit.

Assign management groups to a protocol

1. Assign this protocol to appropriate teams/groups in the Administrative Groups section of Main > Management. Click Select, and add the appropriate groups.

2. Select the Primary checkbox for the appropriate administrative groups.

3. Click Submit to save the protocol details.
**Assign staff to a protocol individually**

1. Navigate to **PC Console > Main > Staff**.
   
   If you created this protocol in OnCore, you have been automatically added as Protocol Staff with a role of Protocol Creator.

2. Add other staff members to the protocol, selecting their Role, Staff Name, and Start Date.

3. Click **Add**.
   
   The selected staff records have been added to the protocol.

**Assign staff to a protocol by selecting team members from another study**

If staff members often work together on protocols, you can save time when assigning staff by copying staff assignments from another study.

1. On the **PC Console > Main > Staff** tab, click **Select Team**.

2. Search for another protocol and then click **Show Team**.

3. Select all staff members to be assigned to your new protocol and then click **Submit**.

   **NOTE:** You can click **Edit** next to any assigned staff person to add start/stop dates, change the institution to which they are assigned for this study, or delete any staff assignments added in error.
Grant access to additional subjects on this study

The Protocol Organization Access column shows the contact’s current level of access to subjects on this protocol. When a person is added to a protocol, the protocol organization access column matches the default organization access set in the contact’s user account.

1. Click the **Edit** link in the staff member’s row.

2. In the **Additional Protocol Access** column, set the **Can Access All Protocol Organizations** field to **Yes**. This will give the staff member access to subjects at all organizations, but for *this study only*.

3. Click **Submit**. The Protocol Organization Access column for the staff member should now display All Access.

**IMPORTANT:** You cannot change a user’s protocol organization access to *less* than the default organization access granted to him in his contact record.
Add a sponsor to a protocol

Multiple sponsors can be assigned to a protocol, but only one can be identified as the principal sponsor. All sponsors can be invoiced for procedures or visits during this protocol. The principal sponsor appears on the Data Table 4 Report and in the header of the PC Console, Financials Console, and other OnCore tools.

1. Navigate to **PC Console > Main > Sponsor**.

2. Click **Add Sponsor**.

3. Find the name of the sponsor in the **Search here for existing sponsor to add** field and then click **Add**.

4. Select the **Principal Sponsor** checkbox if this is the principal sponsor.

5. Enter the **Sponsor Protocol No.**

   Remember that the sponsor protocol number can be used when searching for protocols.

6. Click **Submit**. The primary sponsor will appear in the header of the PC Console.
Tracking Treatment Details and Disease/Diagnosis

When you navigate to the PC Console > Treatment tab, you will see two horizontal tabs: Details and Disease/Diagnosis.

- **Details**: Tracks the protocol’s steps, treatment arms, treatment levels, drugs, devices, and modalities
- **Disease/Diagnosis**: Lists the subject conditions or diagnoses evaluated by this research study

A protocol’s treatment plan is organized into steps, arms, and levels. Each arm can be associated with drugs, devices, and/or modalities being studied through the data collected for subjects on that arm.

**Step**
A group of treatment arms (for organizational purposes only; does not drive any OnCore functionality). Choose Registration or Randomization as applicable to the protocol.

**Arm**
Within a step, one arm or multiple arms can be defined. Every protocol that has a clinical calendar requires at least one arm.

**Modalities**
The arm’s method of treatment, such as surgery or chemotherapy.

**Drugs**
The drugs (agents) being administered to subjects on the treatment arm. Adverse events can be attributed to drugs listed in the PC Console > Treatment tab.

**Devices**
The devices being used in the arm.

**Levels**
The dosage levels being tested. Usually used for Phase I trials when the maximum tolerable dose is being determined. If one arm has levels defined, all arms must have levels defined.

**NOTE**: A protocol must have at least one step and one treatment arm before a clinical calendar can be created for the study.
Enter the study’s treatment details

If a calendar has been created by Forte and imported, there is no need to fill out the information in this tab—it has already been generated for you. However, if the calendar is being built in-house, then you will want to follow these steps to add arms.

1. Navigate to **PC Console > Treatment > Details**.

2. Enter a **Step Code** of 1, choose between **Registration** and **Randomization**, then click **Add**.

3. Click **Arms**.

4. Create the relevant treatment arms. After entering each arm’s code and description, click **Add**.

5. Click **Modalities/Drugs/Devices** for the first arm. Add the appropriate **Modality** and **Drugs** (or device) for that arm.

6. Do the same for any other arms.

7. Click **Close** three times to return to the Details page shown below:
Enter the disease/diagnosis

1. Click the Disease/Diagnosis horizontal tab.

2. Enter the protocol’s Diagnosis or Disease Site. (The label Disease Site is used in the Oncology library only.)
   - For protocols using the Medicine library, Diagnosis values are items in the Diagnosis reference list.
   - For the Oncology library, the Disease Site values come from the Data Table 3 Disease Site reference list.

3. Click Select to choose the Diagnoses or Disease Sites being studied on this protocol. (Click Update first, if necessary.)

4. Click Add.
Recording Participating Institutions and Study Sites

In order to register subjects to a protocol, you must have at least one active study site at the Research Institute or another participating organization. Participating organizations (affiliates) are recorded on the PC Console > Institution tab.

Add participating institutions

1. Navigate to PC Console > Institution. (Click Update, if necessary.)
   No institutions are added to new protocols automatically. The institute and any participating affiliates or consortium members must be added here.

2. Click Add.

3. In the Institution field, find the George Washington Research Institute and then click Save.

4. Selecting the institution automatically adds all of its study sites. To remove a study site from the list, click on the name of the Institute and then click the Study Sites tab. Click the Update button, uncheck the study site you wish to remove, and click Submit.

5. Click PC Console to return to the Institution tab.

6. If you need to add another institution, click Add again and go through the above steps.

7. Select the Uses Research Center IRB? checkbox if the other institution(s) will be using GW’s IRB.

8. Click Save.
Documenting Committee Reviews

Protocols have a status of New until the first committee review is documented for the study (either an IRB or PRMC review). The current protocol status appears in the PC Console header; a history of the protocol’s status changes can be seen in the Status tab.

**All protocols in OnCore must have an IRB review documented before opening to accrual.** Other committee reviews might be required by your organization, but they are not required by the application. They can be tracked in OnCore for informational purposes, and OnCore can send a notification to appropriate staff members when an IRB or PRMC review is about to expire.

**Document an IRB review**

The following instructions show you how to record IRB information on the **PC Console > Reviews > IRB** tab.

**NOTE:** Affiliate IRB information (if the affiliate is using its own IRB for the protocol) is recorded on the **PC Console > Institution (then click the name of the affiliate) > IRB Reviews** tab.

1. Navigate to **PC Console > Reviews**.
   
   The Summary tab provides a read-only view of all Research Center committee reviews documented for this protocol.
   
   If any of the participating affiliates use their own IRB committee, reviews for those institutions must be entered in the Institution tab.

2. To document an IRB initial review for this protocol, click the **IRB** horizontal tab.

3. Click **Add**.

4. Click the down arrow in the **Review Date** field.
   
   All review dates entered for other protocols are listed in this field. This is because several studies are often reviewed at the same IRB meeting.
5. Choose a review date for this protocol.

**NOTE:** The Review Date field is unique in that it does not have "date widget" functionality. If a Review Date is not available, you can add a date using MM/DD/YYYY format.

6. Indicate that the review was submitted prior to the meeting.

7. Choose the committee that reviewed this protocol.

8. Enter the type and reason for the review.

9. Indicate the committee’s action and the review’s expiration.

**NOTE:** The IRB Expiration date is shown in the PC Console header after adding the IRB Initial Review. The date is shown in red if it is past the IRB Expiration date.

10. Click **Submit**.

The Protocol Status in the PC Console header is now IRB Initial Approval.

**Add a reviewed consent form**

Supporting documents are often reviewed when a study is submitted to the IRB. These documents can be uploaded to OnCore and attached to the IRB review at which they were approved. Approved consent forms appear in the Subject Console when registering new patients. The patient’s decision regarding each consent form (consented or refused) is recorded by the study team.

1. With an IRB review open, in the Details section, click **Add**.

2. Choose the document **Type** (most likely **Treatment Consent**).

3. Indicate the date that the consent was submitted to the IRB and approved.
4. Type a brief description for this consent form, to help study team members distinguish between different versions in the future. For example:

- **Description**: Tx Consent V1

5. Click **Save**.

You can now attach a corresponding document within the review.

6. To attach the consent document, click **File**, and then click **Choose File**. Select the document on your computer and then click **Submit**.

7. Select the **Release** checkbox and then click **Submit**.

**NOTE**: Releasing an attached document makes it available for download (to users with the appropriate permissions) in Protocols > Document Search. Non-consent forms that are attached to IRB reviews and released will also be available on the PC Console > Documents tab.

**Good to know**

To indicate that a single consent document covers multiple types of consent (for example, Treatment Consent, HIPAA Consent, and Tissue Consent), click the Type link and select the appropriate checkboxes in the Detail Type Update window.
Include affiliate institutions on the Research Institute’s IRB review

In the PC Console > Institution tab, the IRB dates will appear for the George Washington Research Institute but not for any affiliates listed on the study, even though the affiliate may have been configured to use GW’s IRB. An additional step is necessary to “pass along” the IRB decision and consent documents to the affiliate institution:

1. With the Research Institute’s IRB review open in PC Console > Reviews, click Edit to the right of the Institution field in the review:

2. In the window that appears, select the checkbox for the affiliate(s) and click Submit.

3. Click Submit and Close to return to the PC Console.
Using Task Lists to Track Progress

The protocol start-up process typically involves many activities from various groups. OnCore’s task management functionality is a robust system used to track protocol start-up activities that provides flexibility in creating tasks and assigning owners.

A task list is a group of related tasks that can be managed in one place. Tasks lists can be managed at the protocol or participating institution level in PC Console > Status > Task Lists.

Use your widgets to find tasks assigned to you

The easiest way for a user to find the active tasks assigned to them is to log in to OnCore and check their home screen widgets. There are two widgets for task management: the Active Tasks widget and the Upcoming Tasks widget.

1. Click the OnCore logo in the top left corner to navigate back to your home screen.

2. Add the Active Tasks and Upcoming Tasks widgets if you do not already have them:
   - Click the gear icon under the User Menu.
   - Select the Add checkboxes for the Active Tasks and Upcoming Tasks widgets.
   - Click Save.

3. Click the OnCore logo again to navigate back to your home screen.

   You have three tasks assigned to you; one task appears in the Active Tasks widget, and two tasks appear in the Upcoming Tasks widget.
<table>
<thead>
<tr>
<th>Widget Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active Tasks</td>
<td>Displays upcoming tasks assigned to a user by name or role. Active tasks have a Target Date and are not waiting on any previous tasks to be completed. Active tasks represent to-do items that the user can complete as soon as possible.</td>
</tr>
<tr>
<td>Upcoming Tasks</td>
<td>Displays upcoming tasks assigned to a user by name or role. Upcoming tasks have a Target Date and have at least one incomplete previous task or have no Target Date yet. Upcoming tasks represent to-do items that the user does not have to work on right away.</td>
</tr>
</tbody>
</table>

4. Click a task in your Active Tasks widget.

   The task list in the PC Console opens. If you close this task list, you will be back in the **PC Console > Status** tab.

**Complete a task**

Once a task is completed, you can mark that task as completed on your task list.

**NOTE:** Target Dates calculate based on earlier Target Dates, *not* on completion dates.

1. Enter a **Completed Date** for any completed task.

2. Click **Save**.

**Good to know**

Task lists can be accessed from the **PC Console > Status > Task Lists** page or via the Tasks Widget on your home screen. The Tasks Widget displays the upcoming tasks for which you are the owner. For more information on the Tasks Widget, see Using the Tasks Widget section of the Learning Portal.
This task no longer appears in your home screen widgets. If another task is assigned to you, it will now appear in your Active Tasks widget.

**Add communications and attachments to a task**

For each task on your task list, you can enter communications to be read by other users of the task list. You can also add files and URLs as attachments to a task.

1. Click the **Communications** link.

2. Fill in the **Date** field. This is a required field.

3. In the **Communication** field, enter *comments* regarding the task.

4. Click + **Add**. This communication will now be added to this task and can be viewed by other users of this task list. Click **Done**.

5. To add a file attachment or a URL to the task list, click the **Attachments** link. Follow the directions described above to add the attachment.

6. Click **Close** to return to the PC Console.
Opening a Protocol for Accrual

An institution must have an approved IRB review before subjects can be enrolled to that institution or any of its study sites. Affiliate institutions can be associated with the institution’s IRB review, or a separate IRB review can be documented for an affiliate institution.

After the IRB approves a protocol and all other setup-related tasks are complete, the study can be opened for subject accrual. Each participating institution must complete their study setup and open for accrual independently; it is unlikely that all participating institutions will open on exactly the same date.
Complete signoffs required by the institution

A protocol approved by an IRB can be opened to accrual in OnCore, but other intermediate steps or reviews might be required by your institution. For example, your institution might require signoffs from a CRA, a data monitor or biostatistician, a pharmacist, etc. These signoffs are customizable in each OnCore system and configurable by library.

Only users with the appropriate permission can complete the signoff for a protocol. The instructions below assume that your access role has the permissions required to complete each signoff.

1. Navigate to PC Console > Status. If you are in update mode, click Close to return to view-only mode. (The signoff buttons are only visible in view-only mode.)

   Signoffs must be given sequentially. The names of signoffs and their order will vary depending on your system.

2. Click PRMS Signoff (or the first signoff available in your system).

3. Fill in the Status Date field and then click Submit.

   The protocol status changes to PRMS Signoff in the PC Console header.

4. If more signoffs are required, repeat steps 2 and 3 for all additional signoffs and continue until the Open button appears.

Open the protocol at the institution

When the Open button appears in the PC Console, the study can be opened for accrual.

1. In the PC Console > Status tab, click Open.

2. Enter the Status Date (when everything was approved) and then click Submit.

   The protocol now has a status of OPEN TO ACCRUAL in the PC Console header.
Open the protocol at participating affiliates

Opening a protocol at the Research Center does not automatically open the protocol at all participating affiliates; each institution must record its own review dates and status change.

1. Navigate to **PC Console > Institution**.

2. Click on the name of the affiliate institution.
   
   The Protocol Institution console opens for the selected institution.

3. Click the **Status** tab and then click **Update**.

4. For **Status**, select **Open to Accrual**.

5. Enter a **Status Date**.

6. Click **Add**.
   
   In the header of the Protocol Institution console, the Institution Status now matches the overall Protocol Status:

7. Click **PC Console** to return to the list of participating institutions.
Close, suspend, or terminate a protocol

In the PC Console > Status tab, a protocol can be closed to accrual (temporarily or permanently) by clicking the Closed to Accrual, Suspend, or Terminate buttons. The following diagram shows the protocol statuses in OnCore:
Protocol Statuses in OnCore

NEW
- Basic protocol information has been entered in OnCore.
- Protocol requires review and approval.
- Status will still be NEW if an approver rejects or defers the protocol.

SRC/PRMC APPROVAL
- The SRC or PRMC has reviewed and approved the protocol (name and requirements vary by organization).

IRB INITIAL REVIEW
- The IRB has reviewed and approved the protocol.

OTHER SIGNOFFS (vary by site)
- Other required reviewers have recorded their sign-off in OnCore.
  *Varies by organization. Might include Pharmacy, Biostatistician, CRA, etc.

OPEN TO ACCRUAL
- Consent forms have been approved and added to the protocol.
- Eligibility requirements have been added to the protocol.
- Subjects can be added to the study.
- Data is being analyzed.

CLOSED TO ACCRUAL
- Accrual target has been reached.
- Subjects can no longer be added to the study.
- Results can still be collected and recorded.

IRB STUDY CLOSURE
- The expected outcome has been achieved.
- No further action on this protocol is expected.

ON HOLD
- Before opening a study to accrual, a sponsor might announce that the protocol is ON HOLD.
- A status of ON HOLD indicates that the protocol is temporarily stopped, but it is possible that the study will resume.
- When the PC removes the ON HOLD status, the protocol reverts back to its previous status.
- The ON HOLD status is only available before a protocol is opened for accrual.

SUSPENDED
- After opening a study to accrual, the PC can set the protocol status to SUSPENDED to prevent new subjects from being added.
- Existing subjects will not continue to receive therapy involving an investigational drug unless specifically permitted in the interest of patient safety.
- A status of SUSPENDED indicates that enrollment of participants will potentially resume in the future. PC can “Undo Suspended” to re-open the study to accrual.

ABANDONED
- Before opening a study to accrual, a trial might be ABANDONED due to safety concerns, low accrual, drug availability, insufficient staff, loss of funding, etc.
- A protocol can only be ABANDONED before the study is opened for accrual.
- No further action on this protocol is expected.

TERMINATED
- After opening a study to accrual, a trial might be TERMINATED due to safety concerns, low accrual, drug availability, insufficient staff, loss of funding, etc.
- A status of TERMINATED indicates that the protocol ended prior to completing the expected outcome.
- No further action on this protocol is expected.
Other Supporting Documentation for a Protocol

Once a protocol is created, you can attach protocol-related documents, record protocol FAQs, and record document archive information. There are specific tabs to create and manage eligibility questionnaires, enter data in custom protocol annotations, and record and view protocol deviations. You can also associate the protocol with a correlative or companion study.

Attach protocol documents (not consents)

1. Select the Documents/Info vertical tab.
   The Attachments/Links horizontal tab is selected.

2. Click the Update button and then the Add button that appears at the upper right of the Protocol Attachments section.

3. Choose any Document Type.

4. Click the File link and then click Choose File to upload a document from your computer.

5. Enter a Version Date.

6. Type a Description of the document.

7. Click Add (to the left of the Cancel button) to save the record.

8. To add a second document, repeat steps 2-7, choosing a different Document Type.

   Staff can now reference the two documents attached to this protocol.
Answer frequently asked questions (FAQs)

The FAQs (frequently asked questions) section is used as a reference to assist staff. Common questions and answers regarding the protocol, subject eligibility, subject treatment, and so on can be entered here. Staff can view FAQs in the CRA Console.

1. Navigate to the PC Console > Documents/Info > FAQs horizontal tab.

2. Click New.

3. Enter a Question, Answer, and Keywords. For example:
   - **Question**: Will subjects be reimbursed for mileage?
   - **Answer**: Subjects whose home address is more than 15 miles from their registration site will be reimbursed $0.42/mile for each study visit.
   - **Keywords**: Reimbursement, mileage

4. Click Submit.
Create an eligibility questionnaire

If an eligibility questionnaire is created for a protocol, research staff can answer the questions directly in OnCore when enrolling a subject in order to determine whether or not the subject is eligible to participate.

An eligibility questionnaire consists of questions that must be answered Yes, No, or Not Applicable. Choose all answers for each question or criteria that would deem the subject eligible.

1. Navigate to the **PC Console > Eligibility** tab.

   There are three tables on the Eligibility tab:
   
   - **Eligibility Version History:**
     Lists the questionnaires that have been created for this protocol and the number of subjects who have completed each version.
   
   - **Eligibility Summary:**
     Counts subjects whose eligibility has been assessed for this protocol and how many were eligible and not eligible.
   
   - **Eligibility Details:**
     Lists all subjects who have completed the questionnaires.

2. Click **Create New Version** and then click **Add**.

   You have the ability to create your own eligibility questions and determine the order in which the questions appear. It is important to indicate the answers that will deem the subject eligible for this study by choosing Yes or No. If appropriate, include a possible response of NA.

3. Enter the first eligibility question.

4. Click **Add**.

5. Enter the rest of the eligibility questions in the same way.

6. Click **Add**.

7. Here is an example of using the **NA?** checkbox:
- **Display Order**: 3
- **Question**: Is the subject currently pregnant or nursing?
- **Eligible**: No
- Select the NA? checkbox so that staff can mark this question as not applicable for male subjects.

8. Click **Submit**.

**NOTE**: Eligibility criteria in question form are easier for staff to answer with a Yes, No, or NA. For example “Does the patient have any concurrent liver-related disease that would preclude participation?” is easier to answer than “No concurrent liver-related diseases that preclude study participation.”

9. Click **Release** to make this questionnaire available during subject registration and then click **Close**.

Once the eligibility questionnaire is released, a new version can be created for new subjects. This preserves the eligibility history of any subjects who have already been deemed eligible for this study.

If multiple versions of the eligibility questionnaire exist, the most recently released version is used when enrolling new subjects.

![Subject Console](image-url)  
**Answers which deem the subject eligible appear in green in the Subject Console**
**Track additional details in a protocol annotation**

*Protocol annotations* capture additional protocol details that are not tracked in the standard OnCore fields. Protocol annotations are customized using OnCore’s forms engine. Annotation forms can include number fields, free text, option lists, dates, and times.

One protocol annotation form is configured for each OnCore library. Generate a protocol annotation for this study based on this library’s annotation form:

1. Navigate to the **PC Console > Annotations** tab.

2. If no protocol annotation exists for a new study, click **Update** and then click **Create Annotation Form**.

3. Complete any required annotation fields and enter data in other fields per your organization’s SOPs. Then click **Save**.