

The OnCore SIP Console must be configured if a study team would like their study posted to the [Duke Health Clinical Trials Directory](#). The Recruitment Innovation Center (RIC) will review your SIP Content Worksheet, provide feedback, then complete the SIP Console configuration for you.

Prior to working with the RIC on your SIP content, you will need to review and enter information in the **PC Console**.

1 Navigate to **Protocols> PC Console**

2 Type the IRB protocol number in the Select Protocol field.



A screenshot of a web form element labeled "Select Protocol". It consists of a text input field with a downward-pointing arrow on the right side, indicating a dropdown menu.

3 The protocol will open on the **Main>Details** tab. Click **Update**.

4 Verify the box beside **Exclude Protocol on Web** is checked.

**If not, please click it.** This will block the transfer of the SIP Console information to the web. Once the RIC has configured your SIP Console, they will un-check the box. Click **Submit** to save changes.



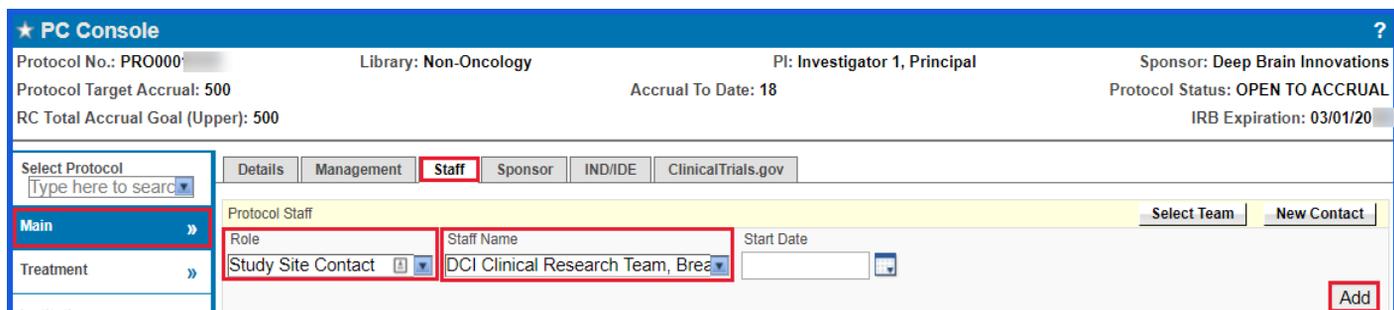
A screenshot of a checkbox labeled "Exclude Protocol on Web". The checkbox is checked, and the label is highlighted with a blue border.

5 Click on the **Main>Staff** tab to add a Study Site Contact.

6 Select the **Role of Study Site Contact** from the drop down list.

7 Enter the **Staff Name** (Select a study staff member or a central contact (e.g., the name of a central email box) from the dropdown list. This information will appear on Dukehealth.org)

8 Click the **Add** button



A screenshot of the OnCore PC Console interface. The top navigation bar shows "★ PC Console" and a help icon. Below the navigation bar, there are several tabs: "Details", "Management", "Staff", "Sponsor", "IND/IDE", and "ClinicalTrials.gov". The "Staff" tab is selected. The main content area shows a form for adding a staff member. The "Role" dropdown is set to "Study Site Contact" and the "Staff Name" dropdown is set to "DCI Clinical Research Team, Bre...". The "Start Date" field is empty. At the bottom right, there is a red "Add" button. The top of the page displays protocol information: "Protocol No.: PRO000", "Library: Non-Oncology", "PI: Investigator 1, Principal", "Sponsor: Deep Brain Innovations", "Protocol Target Accrual: 500", "Accrual To Date: 18", "Protocol Status: OPEN TO ACCRUAL", "RC Total Accrual Goal (Upper): 500", and "IRB Expiration: 03/01/20".

The Dukehealth.org website will categorize each clinical research study in order to enhance search capabilities for the public.

The category is selected in OnCore. Information from Oncology studies and Non-Oncology studies migrate differently; therefore, setup will vary depending on the Library.

Next steps for **ONCOLOGY** studies:

- 1 Navigate to **PC Console>Main>Management** tab.
- 2 Confirm the correct Oncology Group has been selected.

Program Areas <sup>DT4</sup>	Status	Primary	Delete
Solid Tumor Therapeutics	Approved	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Cancer Control and Population Sciences	Approved	<input type="checkbox"/>	<input type="checkbox"/>

Oncology Group	Primary	Delete
Gastrointestinal Cancer	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Cancer Control and Population Sciences (CCPS)	<input type="checkbox"/>	<input type="checkbox"/>

Management Group	Primary	Delete
Gastrointestinal Cancer	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Medicine - Onc	<input type="checkbox"/>	<input type="checkbox"/>

- 3 If the Oncology group is missing, please contact DCI to update the group for you.

Next steps for **NON-ONCOLOGY** studies:

- 1 Navigate to **PC Console>Treatment>Disease Diagnosis** tab.

★ PC Console

Protocol No.: PRO000 Library: Non-Oncology PI: Investigator 1, Principal

Protocol Target Accrual: 1000 Accrual To Date: 8

RC Total Accrual Goal (Upper): 1000

Select Protocol [Type here to search]

Main »

**Treatment** »

Institution

Details **Disease/Diagnosis**

Diagnosis		
Code	Description	Delete?
No information entered		

Select

- 2 Click **Select**. A pop-up window will appear.
- 3 Select the diagnosis group(s) that apply to your study (you may select more than one). Click **Add**

Once you have completed the review of the PC console, open the [SIP Content Worksheet](#).

The SIP Worksheet allows you to answer questions used to populate the SIP Console. Data in the SIP Console is automatically pulled from the PC Console but you will need to provide additional information to the RIC so they may complete the SIP Configuration.

1 Download the SIP Content Worksheet ([Word Document](#))

2 Use the worksheet to add content for the following sections :

- **Treatment**
- **Objective**
- **Description**
- **Key Eligibility**

\*Please see the next page for content guidelines for each field.

3 Be sure to use Principles of Good Readability:

- Use first person, active voice (“We are doing this study to learn...”)
- Reduce medical jargon and complex words (e.g., “about” instead of “approximately”)
- Use white space effectively (bullets over paragraphs of dense text)
- Use active verbs to reduce passive sentences
- Do not call people “subjects” - they are people, participants, or volunteers

4 Once you have entered the SIP content in the Worksheet, email it to the RIC at [studyrecruitment@duke.edu](mailto:studyrecruitment@duke.edu) with the Protocol number and a request to review the SIP content.

5 The RIC will provide edits to the document in “tracked changes” so the study team can see what was changed. If the study team is in agreement with the changes the RIC will post the content into the SIP portal. If the study team wants to provide their own edits they may do so and send back to the RIC to review. **Once all edits are negotiated and the RIC approves, the study will be posted around 10am the next business day (f the study is in a status of “open to accrual”).**

**Note:** Easily understandable language must be used when completing these sections.

\*\*\*Please do not cut and paste from the scientific protocol.\*\*\*

**Hint:** Information from the concise summary of the IRB consent form will be helpful.

The following OnCore Field Names will not push to dukehealth.org: Objective, Treatment, Description, and Key Eligibility. Instead, the information entered in these sections of the Worksheet will push to dukehealth.org as answers to a specific question. Please be sure you are answering the question for each section.

OnCore Field Name:	Dukehealth.org Question:	Tips for completion:
Objective	What is the condition being studied?	Provide a simple description of the condition under study. Example: Asthma, Breast Cancer, Stroke, etc.
Treatment	What is involved?	<p>Please provide 5-7 key statements about study activities, treatment, and interventions.</p> <p>Example: If you join the study you will...</p> <ul style="list-style-type: none"> <li>- Have 10 visits that will last 2-3 hours each</li> <li>- Have 3 blood tests at each visit</li> </ul> <p><b><i>If you would like to include a link to an IRB approved website or pre-screening survey, add it here.</i></b></p>
Description	What is the purpose of this study?	<p>Describe why the study is needed, and what important questions it is designed to answer. Please limit the information to 1 or 2 short easily understandable sentences.</p> <p>Example: We are doing this study to learn more about the effects of exercise and diet on knee pain and how well you are able to move around.</p>
Key Eligibility	Who Can Participate in the study?	<p>Include information from your inclusion/exclusion criteria that the public will know and understand.</p> <p>You may include characteristics like: Age, Gender, Diagnosed with XX for at least 3 months, Newly diagnosed with XX. Please do not include eligibility terms that the public would not know (e.g., lab values)</p>

Below is a screen shot of the SIP console containing the dukehealth.org question. Special characters such as bullet points will cause formatting issues and will not push appropriately to dukehealth.org. You may use formatting in the Worksheet. The RIC will adjust it to fit the formatting limitations of the SIP.

The RIC will add the info from your [worksheet to the SIP Console](#).

Protocol No.: [REDACTED] Library: [REDACTED] PI: [REDACTED] Sponsor: [REDACTED]

Protocol Target Accrual: N/A Accrual To Date: 0 Protocol Status: [REDACTED]

DUHS Total Accrual Goal (Upper): N/A IRB Expiration: [REDACTED]

Short Title: [REDACTED] Configuration Status: Incomplete

Select Protocol [REDACTED]

SIP Configuration

Display Protocol? **Excluded** ← DO NOT change these boxes → Title

Phase [REDACTED]

Objective "What is the condition being studied?" Use Default Objective?

4000 character(s) remaining

Treatment "What is involved?" Override Cancer Control?

1024 character(s) remaining

Description "What is the purpose of the study?" Display Drugs?

4000 character(s) remaining Display Therapies?

Key Eligibility "Who can participate?"

4000 character(s) remaining

Detailed Eligibility

4000 character(s) remaining

Disease / Diagnosis Override

No overrides defined

Select

Protocol Attachments

No Records Found.

Select

Complete Submit Clear Close

The Recruitment Innovation Center (RIC) is responsible for reviewing all protocol submissions for posting in the SIP Console. Once you have entered the SIP content into the SIP Content Worksheet, please email it to the RIC at [studyrecruitment@duke.edu](mailto:studyrecruitment@duke.edu) along with the Protocol number. The RIC will correspond with the study team regarding necessary edits or changes. You can expect to receive feedback from them within 1-2 business days. If you would like assistance with completing your SIP Worksheet or you need a response sooner, please feel to reach out to them directly by emailing [studyrecruitment@duke.edu](mailto:studyrecruitment@duke.edu) or calling 919-681-5698.

Once the RIC has completed their review, they will enter your content into the SIP Console and "complete" the configuration status. Once your study status is "open to enrollment" the information will migrate to the dukehealth.org web-page and the trial information will be available for the public the following day.

If you have any questions about the completion of the SIP Worksheet please contact the Recruitment Innovation Center at [studyrecruitment@duke.edu](mailto:studyrecruitment@duke.edu) .

## Coming in September 2020

### Special Instructions for those who want a study on the directory with an OnCore status other than “Open to Accrual.”

There may be occasions when it may be appropriate to post a study to the Clinical Trials Directory whose OnCore protocol status is something other than “open to accrual,” including:

- Studies “on hold” for data analysis or other reasons
- Studies “suspended” (for example, studies temporarily paused due to COVID-19)
- Studies preparing to begin recruiting that would like to make visitors to the Directory aware that the study will soon open for enrollment (e.g., status is “institutional sign-off”)
- Studies that have received a IRB approval of “exempt” and a OnCore protocol status of “abandoned” but are still appropriate to have on the Directory (e.g., some Volunteer Registries)

Please indicate in your SIP Content Worksheet if you would like a study with any of the statuses described above considered for posting to the Directory.

The RIC will review these requests on a case by case basis.

The RIC is working with DHTS to make changes to the Directory to add a Study Status field that will translate the OnCore Status to a lay-friendly term and post it with each study.

These Statuses will include:

OnCore Status	Directory “Study Status”
Open to Accrual	Open for Enrollment
On Hold	Open for Enrollment Soon
Suspended	Enrollment Temporarily Closed
Abandoned (on a case-by-case basis)	Open for Enrollment
Institutional Approval Sign-Off	Open for Enrollment Soon