

The Oncology Protocol System (OncPro) User Guide

OncPro Access

Requesting access to the Oncology Protocol System (OncPro) depends on your Dana-Farber/Harvard Cancer Center (DF/HCC) Affiliation. Please follow the instructions below or visit the [OHRs Systems Access](#) page.

If you have any questions, please call the Office for Human Research Studies (OHRs) main line (617-632-3029). You may also email your questions to ohrs_systems@dfci.harvard.edu

Please choose one of the following in order to gain access to OncPro:

[For Partners Users Click Here](#)

[For Beth Israel Deaconess Medical Center Users Click Here](#)

[For Boston Children's Hospital Users Click Here](#)

[For DF/PCC Network Affiliate Users Click Here](#)

You will receive an email with your username and password when your request has been processed.

- For Partners users, please access through **Partners Menu → Oncology Protocol System → OncPro**
- For Non-Partners users, please access through: <http://webctportal.partners.org>

OHRs Submit Access

Please note that OncPro access must be obtained prior to requesting access to OHRs Submit.

In order to submit documents to OHRs via OHRs Submit, please complete the following form. Upon completion of the form, you will be provided further instructions in order to gain access.

[Access Request Form](#)

You will receive an email when your request has been processed.

- For Partners users, please access through **Partners Menu → Oncology Protocol System → OHRs Submit v2.1**
- For Non-Partners users, please access through: <http://webctportal.partners.org>

Info Sheet – Oncology Protocol System

Clinical Trials Management System Portal Home

The Clinical Trials Portal can be accessed through your Partners applications menu by clicking through Start > Partners Applications > Oncology Protocol System. Please note that the page which opens up (shown below) is not the Oncology Protocol System (OncPro), but rather a portal page which houses links to many applications and websites.



Notice: Links to QACT, CTEO and CRU are now accessible through Clinical Research Support

Network Affiliates Web Site
All Site Admin
OncPro
OncPro Admin
OHRs Submit
OHRs Submit Administration
Chemo Order Set Tracker
PORTAL Administration
Clinical Trials Billing Tables
Office for Human Research Studies (OHRs)
Clinical Research Support (QACT, CTEO, DF/HCC SOPs)
Clinical Investigator Toolkit
Non-Research Regimens
Transplant Core FORMS

At the CTMS home page, you can access most of the OHRs external applications including OncPro and OHRs Submit. Other main websites are also available: OHRs, CTRIO and ODQ. (Please Note: You will only see areas to which you have access. The list above does not represent access granted to the typical OncPro user.)

OncPro Home

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DANA-FARBER/HARVARD CANCER CENTER	Oncology Protocol System		
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The protocol is the confidential and proprietary information of the Sponsor. It cannot be released to any individual or party outside of DF/HCC without permission of the Sponsor. Within DF/HCC, the protocol may be shared only with those DF/HCC personnel involved in the study or who otherwise have a need to access it for purposes of the study. It may not be used for other research projects. Any breach of confidentiality is considered a serious Non-Compliance and must be reported to the DFCI IRB

[Guidelines For Emergency Uses](#)

[Priority List](#)

[Protocol Index](#)

[Protocol Lookup](#)

[Priority List Report](#)



Clicking on OncPro will bring you to the OncPro homepage. This homepage lists the various ways you can access clinical trials:

Priority List – lists protocols first by participant population and then by disease grouping

Protocol Index – lists protocols by the year they were submitted to OHRS.

Protocol Lookup – allows users to search either by the protocol number or by the Overall Principal Investigator

Priority List Report – allows users to print off a section of the priority list to show where a protocol should be placed when submitting a new study.

OncPro – Priority List

The screenshot shows the Oncology Protocol System interface. On the left is a navigation tree with the following structure:

- Priority Management
 - Adult (selected)
 - Adult Survivorship
 - Breast
 - Preventative Therapy
 - Local Therapy
 - Surgical
 - Radiation
 - Other
 - Preoperative Therapy
 - Adjuvant Therapy
 - Metastatic
 - Supportive Care
 - Ancillary Care
 - DCIS
 - Closed as of 11/26/2003
 - Correlative Lab
 - Treatment
 - Cutaneous
 - Diagnostic Radiology
 - Endocrine

The main content area displays the 'Priority List' for 'Breast :: Local Therapy :: Surgical'. The table below shows the protocols listed:

Protocol	Status	Protocol Title	Principal Investigator
10-355	Pending Pharmac	Ph1 2302032A AntignSpec Ca Immunotherapeutic NSCLC	Sequist
10-070	Active - Enroll	Significance of Mastectomy Margin Status	Bellon
PROT MEMO			
04-164	Active - Enroll	The incidence of adjacent synchronous	Nakhlis
PROT CONS ELIG FORM MEMO			
97-585	Active - Closed	Treatment Of T1N0 Invasive Breast Carcinoma By Loc	Taghian
PROT CONS ELIG FORM MEMO			

At the bottom of the page, there is a copyright notice: Copyright © 2007 Oncpro. All rights reserved. Unauthorized use of this system is prohibited.

The priority list structure was established by the various disease program leaders and built on a 4-tier structure. A protocol can be listed in more than one place on the priority list. The protocols are not just prioritized by disease group, sub-category and modality, but also by the protocols listed in each section.

To expand each section, the user must click on the “plus” sign next to the word on the left navigation. Above, you will see that the user has clicked on the “plus” sign next to “Adult”, making the list expand to show all adult disease groups.

On the right frame, you will notice a protocol is highlighted. 04-164 is the protocol number. Next to that is a truncated overall status of the protocol which pulls from the OHRS database. Next to the overall status are the protocol short title and the last name of the overall principal investigator. These are also pulled from the OHRS database.

OncPro – Protocol Index

The screenshot shows the Oncology Protocol System interface. On the left, a navigation menu is visible with the following items: "Oncology Protocol System", "Lookup By Protocol Number" (with a search box and "Search" button), and "Lookup by Year" (with sub-items for "Adult", "2011", "2010", and "2009"). The "2011" and "2010" items are circled in red. The main content area displays the "Oncology Protocol System" header with "DANA-FARBER/HARVARD CANCER CENTER" and navigation links for "Home", "Contact Us", "Help", and "Logout". Below the header is the "Protocol Index" table.

Protocol ID	Status	Protocol Title	Principal Investigator
11-802	Active - Enroll	Prochymal for refractory GVHD	Antin
PROT CONS MEMO			
11-800	Active (1 AM Pe	Compassionate use of BS1-201 with Temoz in GBM	Batchelor
PROT CONS MEMO			
11-004	Submitted	Clinical Outcomes following Radiation Treatment fo	Lee

The protocol index is categorized first between Adult and Pediatric as you can see on the left navigation. If you only have access to see adult protocols, you will not see Pediatric as an option and vice-versa. This is also true with the Priority List.

The protocols are then separated by year. The first two digits of the DFCI protocol number are the year the protocol was submitted to the OHRS for activation, not necessarily when a protocol was activated. If a protocol was submitted toward the end of 2010, it might not have been activated until 2011, though it would still carry a "10-" at the beginning of its number.

The protocols are then listed in order by overall status and then numerically.

Circled on the left navigation, you will also see that users can search by the 5-digit DFCI protocol number. Users can type in the protocol number with or without the dash (e.g. 11-004 or 11004).

OncPro – Protocol Lookup

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Protocol Lookup

ALERT:
**ALL PROTOCOLS MUST BE VIEWED
AT 100% OR GREATER TO ENSURE
ACCURATE INFORMATION IS
DISPLAYED.**
FOR FURTHER HELP [CLICK HERE](#)

Lookup By PI Name		Lookup By Protocol Number
Partial Name Lookup:	<input type="text"/>	Protocol Number: <input type="text"/>
Name List	PI Name <input type="button" value="v"/>	
<input type="button" value="Submit"/>		

The protocol lookup feature allows you to go directly to a protocol if you know the 5-digit DFCI protocol number. You can enter this number on the right either with or without the dash (e.g. 11-004 or 11004).

The Principal Investigator (PI) Name field only searches by the Overall PI and not the Site PI. You will notice that the drop down box will change as you start typing in the last name of the PI (last name first, first name last). Alternatively, you can click on the drop-down arrow on the Name List field and scroll to the PI you are looking for.

After finding the PI you are searching for, or if you type in the specific protocol number, you then click “submit”.

Info Sheet – Oncology Protocol System

OncPro – Documents

Protocol ID	Status	Protocol Title	Principal Investigator			
03-330	Active - Closed Enrollment	IBCSG 24-02: SOFT-SUPPRESSION				Burstein
			Dose Levels/Arms	Active Staff	Sites	Priority
PROT CONSI ELIG ORDRI MEMO						

Below the protocol title are links to the clinical trial documents. PROT links to the protocol document. CONSI links to the consent form. ELIG links to the eligibility checklist. FORM links to the case report forms. ORDR links to the Doctors Order Sheets. MEMO links to the approval memo which marks when the next continuing review is due. Please note that if there is an “I” at the end of the link, it means that clicking the link will bring you to an “Index” of multiple documents. For instance, the “ORDRI” brings you to the Doctors Orders Index:

[Doctors Orders Index](#)

[Arm A](#)

[Arm B](#)

[Arm C](#)

And clicking the “CONSI” brings you to the Consent Form Index:

[Consent Index](#)

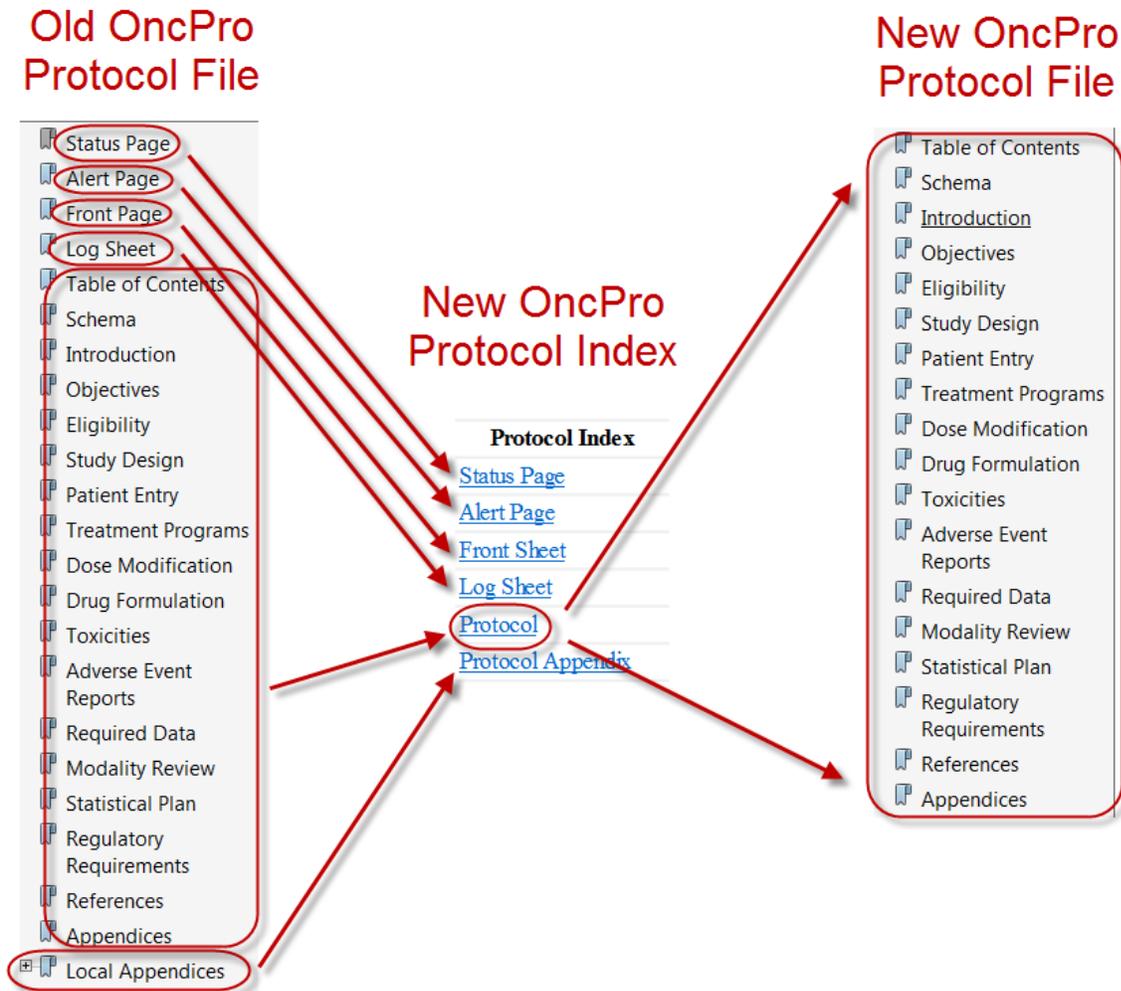
[Main Consent Form](#)

[Optional Pharmacogenetic Consent Form](#)

Info Sheet – Oncology Protocol System

OncPro – Protocol Index

As of 04.10.2017, the indexing feature has been upgraded to allow for indexing of the various documents associated with the Protocol, such as the Front Sheet, Drug Diaries, and any other accompanying documents that do not exist within the body of the Protocol. This allows for quicker navigation and increases overall ease-of-use. The newly indexed Protocols will be delineated by the link “PROTI”. Please see the screenshot below:



Please note that the status page will also exist as a separate document within the Consent Form Index:

Consent Index
Status Page
Main Consent Form
Optional Pharmacogenetic Consent Form

OncPro – Priority List Report

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**DANA-FARBER/HARVARD
CANCER CENTER**

Priority List Report

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Select population: Adult Pediatric
Select disease group:

Population: Adult Disease group: Breast Date: 2/7/2011 9:58:34 AM

Category	Subcategory	Modality	Priority	Protocol	Title	PI	IRB Status
Preventative Therapy			1	10-458	Tissue Repository for Individuals at High Risk of Cancer; ACT for Others	Garber	Pending SRC, IR
Preventative Therapy			2	10-451	Correlation of Tissue Oxygen Saturation with Mastectomy Skin Flap Necrosis, Infection, and Implant Loss in Immediate Breast Reconstruction	Colwell	Pending SRC, IR
Preventative Therapy			3	06-216	Statins and Breast Cancer Biomarkers Evaluation of Breast Density and Serum Biomarkers in Response to	Garber	Active - Enroll

The priority list report allows users to find the disease group for which they need to place a new protocol. Every new protocol must have a priority list submission. Users can search both for adult and pediatric disease listings and then find the disease for which their protocol belongs.

If your protocol does not fit into any of the disease groups listed in the drop-down, you can request that a new disease group heading be established. This can be done within the new project application form in the priority list section.

OncPro – Protocol View

The screenshot displays the OncPro Protocol View interface. On the left is a 'Bookmarks' sidebar with a list of protocol sections: Alert Page, Front Page, Table of Contents, Synopsis, Introduction, Objectives, Study Design, Eligibility, Patient Entry, Treatment Programs, Dose Modification, Drug Formulation, Toxicities, Dose Escalation, Adverse Event Reports, Required Data, Statistical Plan, Regulatory Requirements, References, Appendices, and Toxicity Grading Criteria. The 'Alert Page' is selected. The main content area shows 'Page 1 of 1' at the top right, with submission and posting dates: 'Date Submitted: [09/17/2010]' and 'Date Posted: December 14, 2010'. Below this is the title 'Alert Page' in red, followed by 'DF/HCC Protocol #: [10-100]'. A 'Dose Escalation Table' is presented with the following data:

Effective Date	Dose Level / Cohort #	MM-111 dose	Trastuzumab dose
7/14/2010	Cohort 1	3 mg/kg	Loading dose of 4 mg/kg. Weekly dose of 2 mg/kg.
9/17/2010	Cohort 2	6 mg/kg	Loading dose of 4 mg/kg. Weekly dose of 2 mg/kg.
12/09/2010	Cohort 3	12 mg/kg	Loading dose of 4 mg/kg. Weekly dose of 2 mg/kg.

Note: The row for the current dose level is highlighted and bolded.

When you click on the PROT link in OncPro, the protocol will be downloaded to your computer as a pdf document to be opened with either Adobe Reader or Adobe Acrobat. The bookmarks on the left are provided to bring you directly to that place within the protocol. For studies posted prior-to 04.10.2017, the first page of the protocol will be the front sheet unless there is an Alert page (as shown), or a Status Page (e.g. On Hold or Closure page). The page directly after the front sheet is the Log Sheet which has a list of all submissions affecting the protocol and consent form logged after a protocol has been activated.

For studies posted after 04.10.17, the “Protocol” document will only contain bookmarks associated with the protocol itself (table of contents, synopsis, intro, etc.), as all accompanying documents (front sheet, alert page, log sheet, etc.) will exist as separate documents. Please note that if the Protocol document contains sponsor-created bookmarks, OHRS will default to their use.

OncPro – Consent Form

5/8/2017 9:32 am

**Research Consent Form
for Biomedical Research**

Dana-Farber/ Harvard Cancer Center

BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates



OHRS 04.22.16a

Protocol Title: An Open Label, Phase II Trial of Continuous Low-Irradiance Photodynamic Therapy (CLIPT) Using Verteporfin (Visudyne®) for the Treatment of Cutaneous Metastases of Breast Cancer

DF/HCC Principal Research Doctor / Institution:

Steven Jay Isakoff, MD, PhD/Massachusetts General Hospital

DF/HCC Site-Responsible Research Doctor / Institution:

Beth Overmoyer, MD/Dana Farber Cancer Institute

We have implemented a time/date stamp in the upper left hand corner of the consent form. This date will change dynamically to reflect the exact date and time the consent form was opened by the user to ensure that the subject is signing the most recent consent form. This time and date will reflect the time and date of the computer that the document is opened on.

At the top right hand corner of the consent form are fields which the study staff can type in and have populated on every page of the consent form automatically.

For further information regarding the consent forms, please see the Information Sheet [Use of Informed Consent Documents Posted to OncPro](#)

OncPro – Waiver of Consent

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Protocol Lookup

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Protocol Title	Principal Investigator		
PSYCHIATRY CONSULTATION FOR PTS W CANCER	Irwin		
Dose Levels/Arms	Active Staff	Sites	Priority
Waiver(s): Authorization Waived ; Consent Waived ; Documentation of Consent Waived			
Consent waived for clinicians. Documentation of consent waived for patients.			

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If a study includes documentation of Waiver of Consent, this information will show up below the Dose Level/ Arms, Active Staff, etc. links on OncPro. Hovering over the Waiver information will show any specific details about the Waiver.

OncPro – Backups

In case of OncPro downtime (planned or otherwise) access to OncPro is available via instant download.

Backups of OncPro are run every Friday and distributed via email.

Please contact your institution's clinical trials, research nursing, or research pharmacy office for access to these files.

If you have any questions regarding the Oncology Protocol System, please contact the Office for Human Research Studies at 617-632-3029 or ohrs_systems@dfci.harvard.edu