## Application Overview

Department sign-offs are conducted in the web-based application, p360. This system has helped streamline the protocol approval process and provides inter-office transparency. Departments will now be able to read other departmental comments and keep track of their protocol queue. Additionally, departments can access this system anywhere the web is accessible, inside or outside the Partners' firewall.

Requesting Access

Activation agents (departmental employees who can provide sign-offs) and Research Managers (departmental research manager with view-only permission (no sign-off ability)) can request system access at the OHRS Systems Access webpage.

Signing In

After receiving access, navigate to the p360 website by using the Partners menu or by the following link: https://protocol-activation.dfci.harvard.edu/sign_ins. Use your Partners' username and password to log into the system as an activation agent.

Activation Agents

Partners ID *

Password *

Sign in
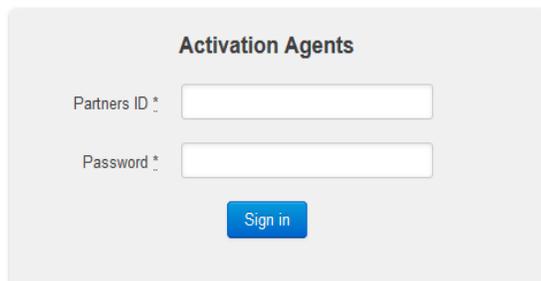
Getting Started – Dashboard page

We will use OHRS as our Department example. The image below shows an example dashboard page with several features labeled with red letters, which are described below.

A p360   **B** Find Protocol   **H** Signed in as: jx870
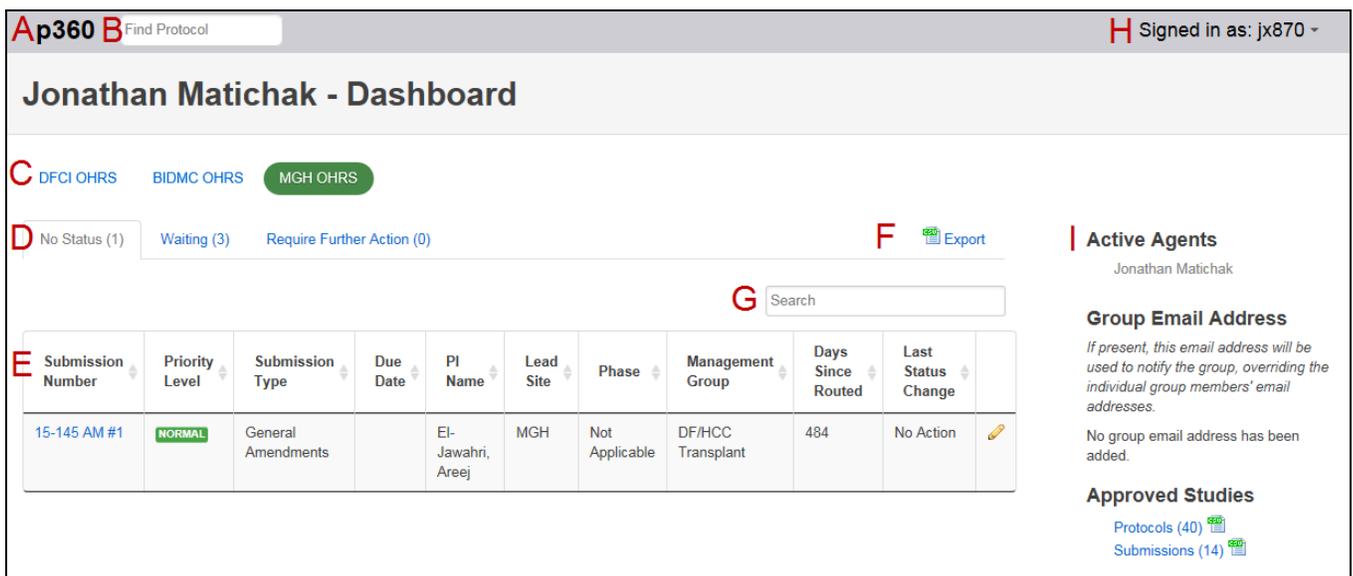
Jonathan Matichak - Dashboard

C DFCI OHRS   BIDMC OHRS   MGH OHRS

D No Status (1)   Waiting (3)   Require Further Action (0)   **F** Export   **I** Active Agents

Jonathan Matichak

G Search

Group Email Address

If present, this email address will be used to notify the group, overriding the individual group members' email addresses.

No group email address has been added.

E Submission Number	Priority Level	Submission Type	Due Date	PI Name	Lead Site	Phase	Management Group	Days Since Routed	Last Status Change	
15-145 AM #1	NORMAL	General Amendments		El-Jawahri, Areej	MGH	Not Applicable	DF/HCC Transplant	484	No Action	✎

Approved Studies

Protocols (40)
Submissions (14)

A. The "p360" button can be clicked from any p360 webpage to return to your dashboard.
B. The "Find Protocol" box can be used to find any protocol of interest. You must use the hyphen in the "XX-XXX" format.
C. The Activation groups that you belong to will be listed in this area. Many agents only belong to one group.
D. There are three Status Tabs: No Status, Waiting, and Require Further Action. These display a count of the number of submissions with these sign-off statuses.
E. The submission information can be found in this area. All of the columns are sortable. Clicking on the "Submission Number" for the submission of interest will bring you to the Detail Page (described below).
F. The "Export" button will generate a spreadsheet of all the submissions from each Status tab, which will include comments.
G. This is a filter that will only display text that appears in one of the fields of the submissions. For example, this can be useful for separating "AM" and "NP".
H. This is used to sign-out of the system.
I. The information in this section describes the Activation Group such as the current agents in the group and the protocols and amendments that have been reviewed by the group.

Review Protocols – Details Page

After clicking on a submission (or clicking on a system generated email) it will bring you to the Details Page.

1) **Top banner**: This shows protocol-specific information including the Protocol Number, Title, Overall Principal Investigator, Lead Site, Population, Management Group, Phase, Expiration Date, and Assigned HRC.
2) **Left panel**: This shows submission-specific information including Submission #, Priority Level, Submission Status, Submission Type, and various dates. The OHRS Submit Date field is the date the protocol or submission was initially submitted to OHRS. Date Routed for Activation refers to the date OHRS routed the study for Department sign-off.
3) **Right Panel**: This is the relevant Activation information and will be discussed in more detail below.

A Activation Documents (4) | **B** Progress Report

Activation Signoffs

C Submission Note

D Activation Due Date:

E

Activation Group	Status	Date of Signoff	History	Actions
DFCI Nursing	Approved	01/30/2017	View	
MGH Nursing	Approved	01/26/2017	View	

F Site Activations

Site	Date of Activation	Activating User	Actions
DFCI	01/30/2017	lg693	
MGH	01/30/2017	lg693	✏

G Holds

Start Date	End Date	Duration	Reason	User	Actions

A. The documents associated with the submission are attached in the "Activation Documents" with the number of documents being counted in parenthesis. Clicking into this page leads you to a list of the documents to be reviewed and the date they were uploaded.

B. The Progress Report is useful for Research Managers because it collects all of the Reviews and Signoffs into one place and displays the most recent comment for each signoff.

C. Important information may be listed in the Submission Notes, such as a note stating multiple AMs need to be activated together or the study is re-opening to accrual.

D. The Activation Due Date is the expected maximum that all final signoffs will be received. A submission should be reviewed with this in mind, leaving ample time in case additional action is required.

E. This is a list of all the Activation Groups that need to signoff and provides the Status and Status date.

    a. History "View": Clicking this link will bring you to the previous actions and comments of that group. If a Department initially marked the study as "Require Further Action", then "Waiting", then "Approved", all of these status and comments would show in order of most recent to first comment entered. Clicking on the protocol number, circled below, will bring you back to the protocol details page.

    b. Actions: There are two icons which may appear in this column for your Department:

        🔵 This icon is to add a comment

        ✏ This icon is to update your comment.

Clicking either icon in your Department sign off column will bring you to this screen:

i. Status: You can make your Status (i.e., determination) using this dropdown.
ii. The Statuses are explained in the "Click here for definitions of each Status

Status	Use	Result
Waiting	The activation agent is waiting on something outside of thier activation agent responsibility. (e.g., waiting for contract/budget finalization, drug to arrive, MD order sheets, in-service, protocol education sheets (PES), site initiation visit (SIV), COE/Beacon, etc.).	**Passive Status:** This status will NOT generate an email to the OHRS Activation Coordinators. The activation agent is responsible for updating the submission in P360 to a Action or Final Status when the outstanding item is resolved.
Require Further Action	The activation agent requires further action and/or clarification from the study team. Requests may include changes to documents that will be posted to OncPro (e.g., protocol, consent, alert page, etc.). Note: Protocol and Consent form Changes will require the study team to submit a new amendment for IRB review. Alert Page changes can be made by the study team without a new amendment.	**Action Status:** This status will generate an email to the OHRS Activation Coordinator who will forward the request for further action to the study team.
Approved	The submission is ready to activate according to the activation agent's department.	**Final Status:** This status will generate an email to the OHRS Activation Coordinator.
Denied	The submission cannot be approved. Denied may also be selected if the submission has no bearing on the research conducted at that Activation Agent's Site and the site has no plans to continue participation in the research.	**Final Status:** This status will generate an email to the OHRS Activation Coordinator.
Approval Not Required	The changes made in this submission do not need to be reviewed by the activation agent. This determination may also be used when the Activation Agent's Site is not yet participating in the study and it has no bearing on the research for the site at this time.	**Final Status:** This status will generate an email to the OHRS Activation Coordinator.

Close

iii. Date of signoff: This should be the date the "Status" was updated.
iv. Comment: This can be used to write messages to yourself or an activation agent. These can be viewed through the "View" button under the "History" column seen under the previous image.
v. Update Status: Click this when the other fields are complete.

F. This section shows what sites the submission has been activated. New protocols can often be activated at the primary site, but not the secondary sites. Amendments are usually activated at all sites at the same time.
G. This section describes any holds if they exist.

Communication

OHRS will send initial and follow-up communication to Departments when sign-off for a protocol is required. A link to the protocol is in the email (the link is circled below in an example email) for your convenience.

> **From:** do-not-reply@dfci.harvard.edu [mailto:do-not-reply@dfci.harvard.edu]
> **Sent:** Thursday, March 31, 2011 11:07 AM
> **To:** You
> **Cc:** DFCI OHRS Activation
> **Subject:** 10-108 AM #1 // Activation Sign-Off Requested
>
> Review request for:
>
> Protocol # 10-108
>
> Title: BH3 Profiling in Lymphoid Malignancies
>
> PI: Letai
>
> An OHRS administrator has requested that you review the following amendment:
>
> 10-108 AM #1
>
> Please review the materials and update the activation sign-off status.

Frequently Asked Questions

1. When I click on a link (e.g. Review Protocols), nothing shows up. Why?

   Congratulations! Your Department has signed off on everything in the Department's queue! If you believe this to be an error, please contact OHRS.

2. I typed a protocol number in the protocol search field, but the protocol I'm looking for isn't showing. Why?

   Make sure you have typed the 5-digit DFCI protocol number with a hyphen (e.g., 00-000). RTOG, EGOC, etc. numbers won't return a result. Also note that this application is not fed by other systems. Information is hand-keyed by OHRS. If there is a protocol you are searching for that is not showing, please contact OHRS.

Signing Out

When you are finished with the Protocol Activation application, you should always logout by clicking the **SIGN OUT** link in the upper right corner.

Logged in as: dcl5 | Sign Out

Technical Assistance/Who to call

Please do not hesitate to contact OHRS with any questions.

Phone: (617) 632-3029.