Guide to Study Tab Views
CRMS Support Pool Help Topic

Overview
The Clinical Research Management Tool (CRMS) is an on-line tool for managing information about clinical research studies and their participants. The purpose of this help topic is to introduce the views into this information that CRMS provides, to make it easier to find what you need.

When you log in to CRMS, the home page you see is the My Studies page, which lists the studies you are on, grouped by your role on those studies. Here is an example page, to introduce you to the general features shared by all of the pages in CRMS:

The annotations, by number, highlight these parts of the page:
1. At the top left of the page is a row of external links, that is, links that take you out of the application. The Help link opens a new browser window on the CRMS Help site, and Logout logs you out.
2. Your name is centered near the top of the page. Everything you see and do is logged, and must be done under your own name.
3. At the left of the page is the left hand navigation. Most of these items have their own help topic. All CRMS pages have these items in the left hand navigation. When you are looking at a study, there are additional items related to that study.
4. We are on the PI tab, and there is one other view, the Study Team tab. You will only see tabs that apply to you, e.g., a research coordinator would only see the Study Team Tab.

CRMS is linked to the electronic Institutional Review Board (eIRB), used by the Johns Hopkins Medicine Institutional Review Board (JHMIIRB), for some data shown under study tab views. Fields linked to eIRB, identified by an icon, can only be changed in eIRB. Changes made in eIRB are propagated to CRMS the evening after they are made, at 2AM.
CRMS will not allow you to edit these fields, even if you are allowed to edit the page. Data entry fields will be grayed out, or made inoperable in some other way.

Note that all tabs are views into the same collection of information. Fields may appear under more than one tab, and updating any one of them updates the underlying information.

The rest of this topic describes the tab views of a study. The tab list depends on the study, which may or may not have information in certain categories. It also depends on your roles, which control your access to information. All tabs that might be present are described below.

**General Tab**

The General Tab is the home page for a study. But before discussing specifics, have a look at the general layout of an example study page:

These differences are highlighted:

1. These are the new left menu items that show up because we are looking at a single study. The top item, CRMS-7553, is a link back to this tab, the study’s “home page.” Protocol Consents, Eligibility Criteria, and Enrollment have their own help topics. Regulatory Logs can be used to record information/correspondence about your study.

2. These tabs provide views into the information about your study. The Enrollment tab provides the same view as the Enrollment button in the left hand navigation.

The content under the General tab contains the basic information that identifies the study and provides some organizational overview:

- Tracking numbers and codes,
- PI name and department/division,
- Whether multiple sites are involved, and whether Hopkins is the coordinating center if there are,
- Basic information about the participant group (adult/pediatric, male/female), and
- Current accruals.

**Study Team Tab**

Study team membership and roles are shown under the **Study Team** tab. Most of this information is linked to eIRB. There are some exceptions, so if you are allowed to edit this page you can add team members and assign them these roles:

- Additional Staff: people who need access to the study and DO NOT need to be approved by the IRB.
• Q/A Specialist: the person responsible for the internal auditing or monitoring of the study.
• Administrative Program Managers: people who are involved with the study budget and need access to the Financial Tab view of this study.

Again, CRMS will not allow you to assign any roles that are linked to eIRB.

Internal and External Contacts sections can be used to provide a centralized repository of contact information for the people your team members need to contact often, like your study’s External Monitor.

**Regulatory/QA Tab**
The Regulatory/QA tab provides an overview of information important to regulators and auditors. Items include:
  • The type of study: is this a multi-site study and if so is Hopkins the coordinating center (if so, there will be a Coordinating Center tab)? Are new drugs or devices being tested (if so, there might be an IND/IDE tab)?
  • Important dates: Initial IRB Approval Date, IRB Expiration Date, and IRB Termination Date, are linked to eIRB, and the Latest IRB Approval Date, is entered in CRMS by the study team.
  • Study closure information: date, responsible role, and reason closed.
  • Accrual information: Projected accruals are defined in eIRB. Actual accruals, maintained in CRMS.

**Financial Tab**
Access to the Financial tab is limited to those people with responsibility for the budget. Data items include:
  • Dates indicative of the length of the study.
  • Sponsors.
  • Projected and actual accruals, because of costs associated with participants.
  • Screen failures, because of costs associated with each failure and a possible limit on the number of failures. Screen failures are usually defined as participants who were screened for the study but were determined to be not eligible for enrollment on the study.

When adding sponsors, you can enter a number of items about the sponsor:
  • Whether their sponsorship is material, financial, or both.
  • Contract and budget dates.
  • Certain fees.
  • Contact information.

**Coordinating Center Tab**
The Coordinating Center tab (abbreviated as Coord.Center) will appear if this is a multi-site study and if your site is indicated as the Coordinating Center in eIRB. That information is shown on the General Tab.

The Coordinating Center tab provides information about sites participating in the study. Data items include:
• The PI for each site, with contact information.
• Important dates, such as the date the IRB approved the site’s participation.
• The status of the site’s study, which is on its own schedule.
• Accruals at this site.

The sites listed under this tab are used under the Enrollment tab to help you maintain accurate enrollment information.

**IND/IDE Tab**
The IND/IDE tab will appear only if the study has an investigational new drug (IND) or an investigational device (IDE). That information is entered under the Regulatory tab.

The IND/IDE tab provides information about:
• Compliance.
• Reporting.

**Enrollment Tab**
The Enrollment tab is tracks the enrollment status of everyone on your study. As described in the Enrolling a Participant help topic, this is a four-stage process, with information gathered at each step. That information is used for essential regulatory reporting and research billing compliance, as well as conducting the study.

Here is an example Enrollment tab view:

The numbered annotations highlight these parts of the page:
1. The default view lists all participants in descending order of Consent Date. The highlighted choices allow you to see just what you want to see. You can limit results by enrollment status and site, change the sort key and order, and see all participants on one page instead of in batches. If Hopkins is not the Coordinating Center of a multi-site study, you will only see Hopkins participants. For studies where you are the coordinating center you would name people by some de-identified process such as Subject #1, etc.
2. These buttons are used to move participants through the stages of the enrollment process, as described in the Enrolling a Participant help topic.

3. The Search for Patient button allows you to search for your participant’s demographic information as found in EPR. The Create New Patient button would only be used if the person has not seen here at Johns Hopkins (i.e., does not have a JHH medical record number). All of the participants above were added from one of these two buttons.

4. A participant’s study progress is summarized in these fields, some of which can be entered directly from this page. Fields include tracking numbers, milestone dates, treatment related dates, and a shortcut for marking a participant not eligible.

For complete details, see the Enrolling a Participant help topic.

**Getting More Help**

Clinical Research Management System (CRMS) Support Pool:
- e-mail: crmshelp@jhmi.edu
- phone: 443-615-1186

CRMS Training Website:
- http://www.hopkinsinteractive.com

CRMS Website:
- https://research.jhmi.edu