

Human Subjects Research Oversight
and Accountability Database
HSROAD



System Description

NIAID/DMID Office

Washington, DC
March 2007

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Introduction

The Human Subjects Research Oversight and Accountability Database (HSROAD) for the Division of Microbiology and Infectious Diseases (DMID) of the National Institute of Allergy and Infectious Diseases (NIAID) consists of several major modules and an administrator module. The major modules contain user interfaces, processes, and a centralized data repository to capture and manage the data related to the management of clinical research involving human subjects. These modules cover activities related to the awards process including the specific processes for contracts, grants, cooperative agreements, development & management of trial protocols, related sites, protocol investigator information, study design, IND submissions, project management and many other details related to these activities and their corresponding involved personnel according to their level of responsibility.

HSROAD is based upon World Wide Web (WWW) technologies. As such, it consists of a single database accessed by users across the Internet using a web browser, such as Netscape's Navigator or Microsoft's Internet Explorer. This approach provides the advantages of a centrally supported system as well as increased accessibility through the Internet. Using a web browser, users access HSROAD server and log into the HSROAD application. After completing the login process, the user is presented with welcoming information and a menu of available options. Information related with HSROAD data can then be entered, retrieved, or modified by the user just as if the data were located on his or her personal computer.

There are three components that must be considered by users who want to access the WWW: hardware, software, and network connectivity. All three must be present and established in order to access the web effectively.

HSROAD has been developed and targeted for users with version 4.0 or above of Microsoft's Internet Explorer browsers. The screens have been developed for a minimum screen resolution of 640 x 480 pixels. This will ensure that users with a wide array of monitor sizes and resolutions can see the system screens without scrolling sideways. The database has been developed following best practices for relational database design, data normalization, and development. This database is deployed on the Microsoft's SQL Server 2000 v.8.0 database server. The Web server software for this project is Microsoft's Internet Information Services 6.0 (IIS). Finally, the Cold Fusion Enterprise MX application server is used as the application server to connect the Web application to the database and provide dynamic content for the browser based HSROAD application. All this architecture is based on the Microsoft's Windows 2000 server software. DMID, via Fisher BioServices Inc, is providing the necessary server hardware and software licenses required for the project. HSROAD utilizes electronic mail extensively as a means to communicate notifications of new transactions from users at different locations and responsibility levels.

It is very important to present at this moment the fact that there are many secondary screens and menu option screens throughout the system that facilitate the navigation and data filtering according to user roles and access levels. Because of this, a linear presentation of screen flows is not entirely accurate. Each screen has many built-in rules to dynamically determine the data to be presented to any given user and also to control the presentation of menus and screen options. For instance, a given screen may appear different to two separate users with different access levels. The screens presented in this document are not taking these factors into consideration and contain all the possible data elements that could be accessed by a user with no access restrictions. A high-level system flowchart is presented in Appendix A. Specific modules from that overall flow chart will be discussed below.

1. Project Description

1.1. Background

The customer, **National Institute of Allergies and Infectious Diseases (NIH)**, required a centralized system for the tracking of investigational new drugs that would allow collaboration with users worldwide. This system needed to be accessible for diverse platforms, have multiple levels of security and access, store and present large amounts of data, and provide complex reports for upper management and accountability compliance.

1.2. Solution

The Human Subjects Research Oversight and Accountability Database (HSROAD), a web-based system, was developed to capture and manage the data using ColdFusion, DHTML, and SQL Server 2000 database. Using a web application enables any user with access to the Internet entry to the application. An intricate access system with strict security measures directs authorized users to modules or information based on conditions given by a user role. The database architecture enables fast presentation of large quantities of data for online viewing and report requirements. The languages used provide dynamic and interactive access to information.

2. Functional Process Description

2.1. Order It Module

This module was designed as a mechanism for allowing privileged performance site users to order products related to their respective protocols. The module allows for these placed orders to be approved by the relevant parties prior to being imported into CARIM for processing. Additional features include the ability to check order status and view reports. This module is an effective solution for automating the ordering process and creating a relationship between the two systems. For more details regarding the functionality of the Order It Module, please refer to the Order It Module Version 1.5 System Description.

2.1.1. Order It Module Homepage

Users in roles which have Order it Module access automatically default to the module as their homepage. This homepage provides links for placing orders, system related announcements, Frequently Asked Questions related to the module, Technical Support contact forms, common troubleshooting solutions, links for leaving feedback and asking questions. The availability of these links being visible on the homepage is dependent on individual user account permissions within the module.

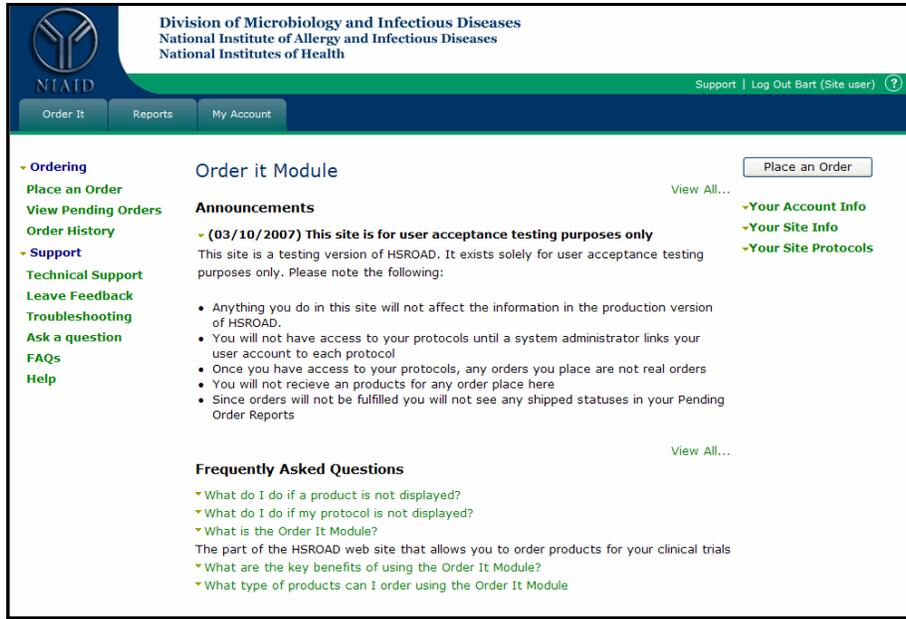


Figure 1 Order it Module Home Page (User with ordering privileges)

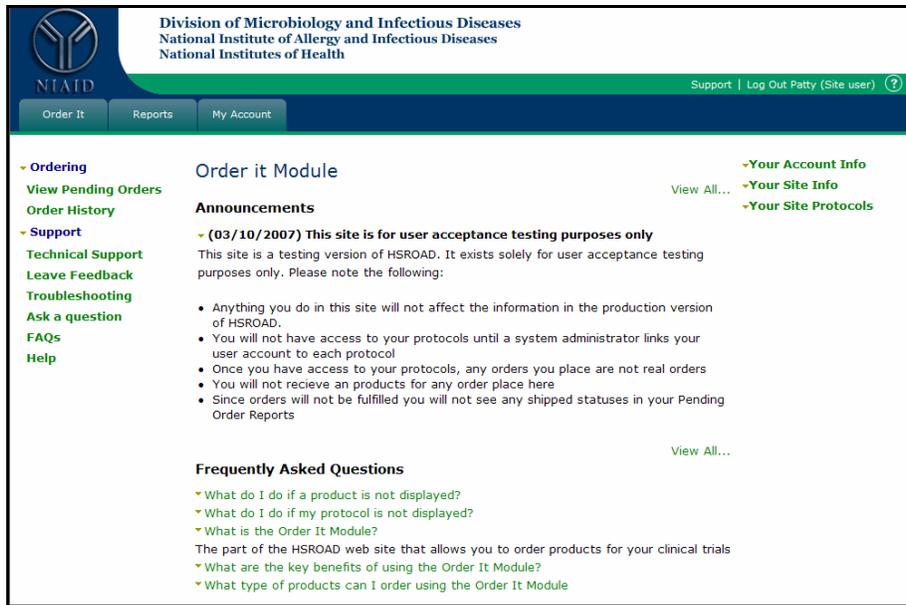


Figure 2 Order It Module Home Page (User with view privileges)

The screenshot shows the 'Order It Module' homepage for users with approval privileges. The header includes the NIATD logo and the text 'Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health'. The navigation bar contains links for 'Order It', 'Protocols', 'Protocol Support', 'Project Management', 'Agreements', 'Reports', and 'System Administration'. The main content area is titled 'Order it Module' and features a 'Place an Order' button. A notification box states: 'You have orders pending your approval. View pending orders'. A sidebar on the left lists navigation options: 'Ordering' (Place an Order, View Pending Orders, Order History), 'Support' (Technical Support, Leave Feedback, Troubleshooting, Ask a question, FAQs, Help), and 'Your Account Info'. The main content includes 'Announcements' dated 03/10/2007, stating the site is for user acceptance testing purposes only, and 'Frequently Asked Questions' with links to view all questions.

Figure 3 Order It Module Homepage (Users with approval privileges)

The screenshot shows the HSROAD Reference page for a user without Order It Access. The header is identical to Figure 3. The navigation bar includes 'Home', 'Protocol Support', 'Project Management', 'Agreements', 'Reports', and 'System Administration'. The main content area is titled 'HSROAD Reference' and features a 'Your Account Info' link. A sidebar on the left lists navigation options: 'Support' (Technical Support, Leave Feedback, Troubleshooting, Ask a question) and 'Your Account Info'. The main content includes 'Announcements' dated 03/10/2007, stating the site is for user acceptance testing purposes only, and 'Frequently Asked Questions' with links to view all questions.

Figure 4 HSROAD Homepage for a user without Order It Access

2.1.2. Order a Product

Those users with permissions to order for their performance sites will have the Place an Order link and Place an Order button visible on their home page. (See Figure 1) The module currently allows only DMID IND held products intended for human use to be ordered for their respective protocols. The placement of orders consists of a series of continuous steps.

In the first step the order form questionnaire is displayed when the either link is clicked by the user. The questionnaire presents the user with two questions to verify the type of product being ordered and the protocol number. These questions are required and must be answered before the user is allowed to move to the second step.

In the second step the remaining order information is collected. This order form summarizes information related to the protocol selected the questionnaire, information

related to the shipment site(s), and the product information, as well as a form to collect remaining information. The products displayed are associated with this protocol and available balance (from CARIM) is prefilled in the form. Users must complete all required fields before the form can be submitted. Once submitted, Email notifications are generated to a pre-determined recipient list to advise all relevant persons of the pending order. Each email contains specific instructions to each role about further actions required to process the order.

The final step in the order process is the confirmation page. This page provides a summary of the order including the unique order number of the order (for reference purposes). Users are advised in the confirmation page of any missing regulatory documents which may delay the fulfillment of the order.

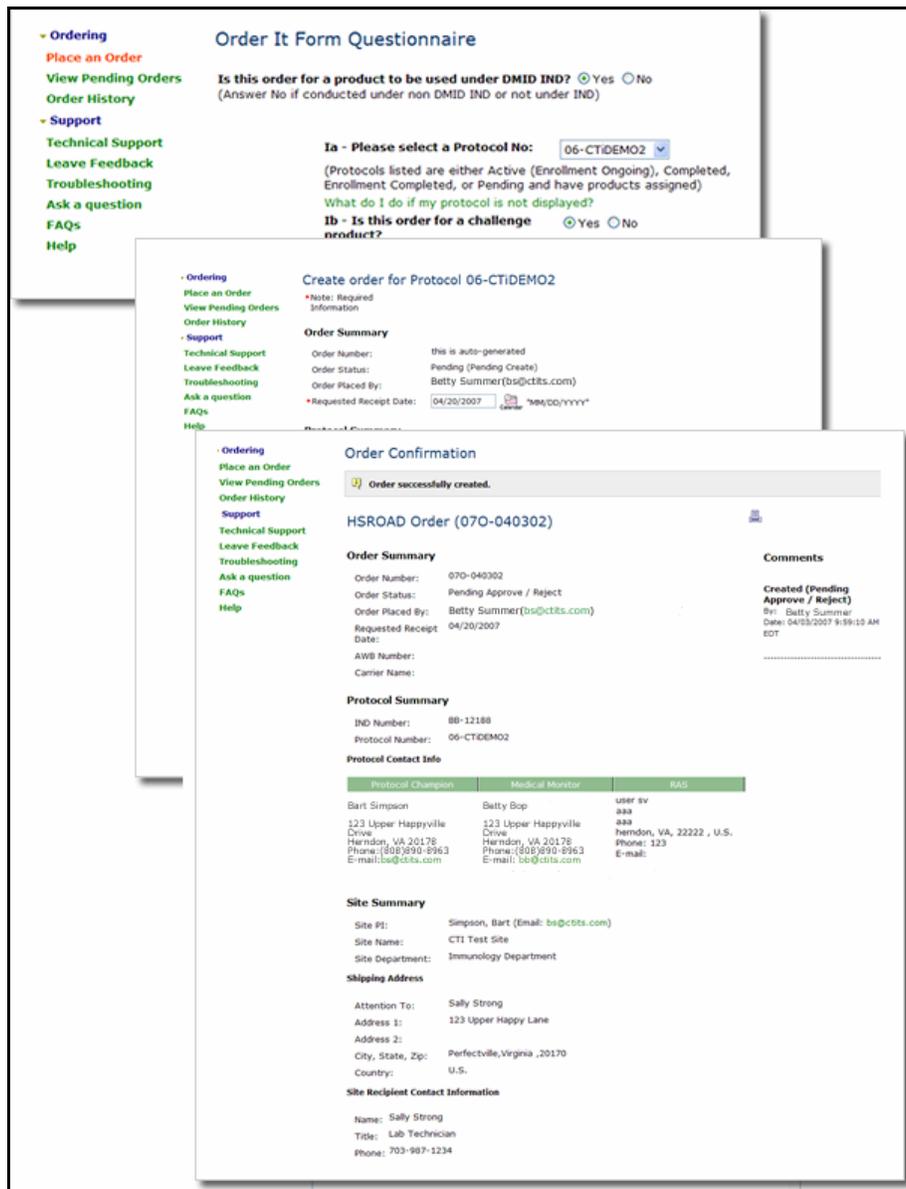


Figure 5 Order a Product 3 step process

2.1.3. View Pending Orders

The View Pending Orders link provides real-time reports for orders placed within the module. The orders displayed here are either pending approval/rejection or have been already approved but not yet shipped by the clinical agent repository. Users may only view orders for sites and protocols that they are linked to in HSROAD (according to the protocol rule). Privileged users (those users granted permissions for modifying and deleting orders) have action buttons visible in an action column. These buttons allow these privileged users to edit or delete any unapproved order for their site. (See Figure 7). If an order is modified or deleted, an email notification is generated to the pre-determined recipient list advising them of the update or delete of the order.

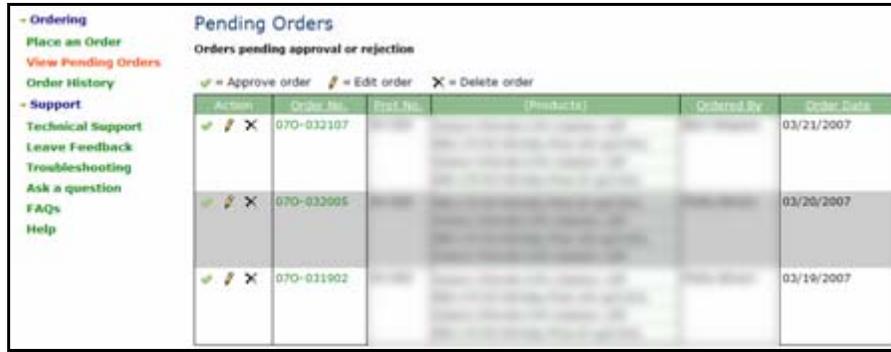
- Support						
Technical Support Leave Feedback Troubleshooting Ask a question FAQs Help						
Status	Order No.	Prot No.	(Products)	Ordered By	Order Date	
Created	070-040302	06-CTIDEMO2	M&M's chocolate candy Reese's Peanut Butter cups A CTI Test product - one.	Donna Munroe	04/03/2007	
Created	070-040301	06-CTIDEMO2	A CTI Test product - one. Reese's Peanut Butter cups M&M's chocolate candy	Rebecca Brewer	04/03/2007	
Created	070-033005	06-CTIDEMO2	M&M's chocolate candy Reese's Peanut Butter cups A CTI Test product - one.	Nelli Salatova	03/30/2007	
Created	070-032609	06-CTIDEMO2	M&M's chocolate candy Reese's Peanut Butter cups A CTI Test product - one.	Rebecca Brewer	03/26/2007	

Figure 6 View Pending Orders Report (User with view privileges)

- Ordering						
Place an Order View Pending Orders Order History Support Technical Support Leave Feedback Troubleshooting Ask a question FAQs						
Pending Orders						
Orders pending approval or rejection						
Action	Order No.	Prot No.	Products	Ordered By	Order Date	
<input type="checkbox"/> <input checked="" type="checkbox"/>	070-031401			Patty Brown	03/14/2007	
Approved orders not yet shipped						
Status	Order No.	Prot No.	Products	Ordered By	Order Date	
Imported	070-031302				03/13/2007	
Approved	070-031901				03/10/2007	
Imported	070-030973				03/09/2007	

Figure 7 View Pending Orders Report (User with ordering privileges)

Those HSROAD roles designated as order approvers can also use this report to review, approve or reject pending orders. For order approvers, the approve button is enabled in addition to the edit and buttons in the action column. (See Figure 8).



Actions	Order No.	Prod. No.	(Products)	Ordered By	Order Date
✓ ✎ ✕	070-032107				03/21/2007
✓ ✎ ✕	070-032005				03/20/2007
✓ ✎ ✕	070-031902				03/19/2007

Figure 8 View Pending Orders Report (Approvers)

2.1.3.1. Approving and Rejecting Orders

Designated approvers (those users with a role having approval/rejection privileges and linked to the protocol) are advised of a pending order requiring their approval by an email notification. This notification is generated when an order is placed. Additionally, when an approver logs into HSROAD, they are advised onscreen of any orders pending their approval by an announcement displayed on their homepage.

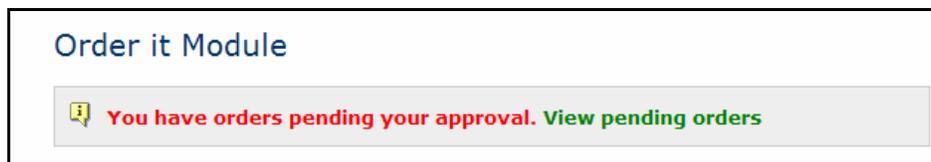


Figure 9: Approver pending order notification

To approve or reject an order, an approver clicks the approve button shown in Figure 8 next to the order they which to approve or reject. The Approver form displays the pending order details for review. Approvers have the option to edit the requested receipt date and the quantities requested by the order creator. Comments become a required field if either data is changed. When the approver submits their approval or rejection of the order, email alerts are generated to the pre-determined recipient list advising specific order related persons of the approval/rejection of the order. A confirmation page is displayed to the Approver displaying the new status of the order, either approved or rejected.

Ordering

[Place an Order](#)

[View Pending Orders](#)

[Order History](#)

Support

[Technical Support](#)

[Leave Feedback](#)

[Troubleshooting](#)

[Ask a question](#)

[FAQs](#)

[Help](#)

Approve Order 070-032107

Order Summary

Order Number: 070-032107
Order Status: Pending approve / reject
Order Placed By: Bert Simpson (Email: bsimpson@cascaadestech.com)
Requested Receipt Date: 09/30/2007

Protocol Summary

IND Number: 88-12435
Protocol Number: 04-059
Protocol Description: [Show / Hide](#)

Site Summary

Site PI: Hesse Simpson (Email: bsimpson@cascaadestech.com)
Site Name: Baylor College of Medicine
Site Department:

Shipping Address

Attention To: Patsy Brown
Address 1: One Baylor Plaza, Room 2370B, M.S. BCM-280
Address 2:
City, State, Zip: Houston, Texas ,77030
Country: U.S.

Site Recipient Contact Information

Name Title: Patsy Brown
Phone: 700-332-1504
Fax:
Email: pbs@cascaadestech.com

Alternate Site Recipient Contact Information

Name Title:
Phone:
Fax:

Investigational Agents Ordered Product Summary

What do I do if a product is not displayed?

Investigational Agent Description (ID - Lot number - shelf name)	Expiration Date (mm/dd/yyyy)	Units Available (U)	Units Requested	Units Approved	
277 - 20-237-DK - Sodium Chloride 0.9% Injection, USP	06/02/2007	2 ml / vial	178	10	<input type="text" value="0"/>
281 - 6753 - 158-175 RE No/Adj-Phos 140 88/5 305	None	0.7 ml / vial	62	0	<input type="text" value="0"/>
284 - 22-248-DK - Sodium Chloride 0.9% Injection, USP	06/02/2007	2 ml / vial	492	0	<input type="text" value="0"/>
279 - 6763 - 158-175 RE No/Adj-Phos 20 ug/0.5ml	None	0.7 ml / vial	2	0	<input type="text" value="0"/>

Order Approval/Rejection

Do You Want To Approve This Order?
 Yes No

Comments

Enter any comments you have about this order (required if you change the quantity or receipt date)

DMID Repository Contact Info

DMID Clinical Agent Repository
607A Loftstrand Lane
Rockville, MD 20850

FAX: (301) 251-3883
Phone: (301) 424-6452
Email: DMID.CA@thermofisher.com

Comments

Created (Pending Approve / Reject)
By: Bert Simpson
Date: 03/25/2007 11:20:03 AM EDT

Figure 10: Approver Form

2.1.4. Order History

This link reports historical DMID IND for human use orders placed using the Order It Module. The user is presented with a table listing of orders which have been fulfilled (shipped), deleted or rejected for the site. Historical orders displayed in this report are restricted by the user's relationship to the protocol named in the order (according to the protocol rule).

This report may be sorted by Order Number (Order No), Protocol number (Prot No), user who placed the order (Ordered by) or the Order Date (Order Date) by clicking the respective column header. Order details for a specific order can be viewed by clicking the specific order number link.

2.1.5. Technical Support

This link provides access to the contact form for reporting issues encountered or error messages received while using the system to the Technical Support team. The Support link located in the top navigation bar also provides access to this form.

Ordering
Place an Order
View Pending Orders
Order History
Support
Technical Support
Leave Feedback
Troubleshooting
Ask a question
FAQs
Help

Contact Support for HSROAD

Please use this form to notify someone of a situation needing immediate attention. This form will send an email message to the system administrator.

How can we reach you?
Your contact information is listed in our database as:
Patty Brown
dmunroe@cascadestech.com
703456798

Please enter a phone number where you may be reached:

Please note the situation needing attention:

- Access problem [?]
- Error message [?]
- Unexpected result[?]
- Incorrect data[?]
- Display problem[?]

Please cut and paste the error message here: [?]

Please provide a description of the situation:

Figure 11 Technical Support Contact Form

2.1.6. Leave Feedback

This link provides the user with access to a feedback form which can be used to document positive and/or negative experiences encountered while using the module. An email confirmation alert is generated to the user and an email notification alert is sent to the system administrator upon submission of the form. All feedback provided is stored in the database for future consideration. As of this version there is no reporting or publishing of submitted feedback using HSROAD.

Figure 12 Leave Feedback Form

2.1.7. Troubleshooting

This link provides access to a list of commonly encountered issues that a user may encounter while using the Order it Module. Issues encountered that prevent the user from performing their task (which are not addressed in this section or the FAQs) may be reported by using the Technical Support form.

Figure 13 Troubleshooting FAQs

2.1.8. Ask a Question

This link provides the user the ability to ask questions not addressed in the Frequently Ask Questions section or in the companion Help section. An email confirmation alert is generated to the user and an email notification alert is sent to the system administrator upon submission of the form. All submitted questions are stored in the database for

future consideration. As of this version, there is no reporting or publishing of submitted questions using HSROAD.

The screenshot shows a web interface for asking questions. On the left is a sidebar with a tree view containing links: Ordering, Place an Order, View Pending Orders, Order History, Support, Technical Support, Leave Feedback, Troubleshooting, Ask a question (highlighted), FAQs, and Help. The main content area is titled 'Ask a question about the Order It Module'. It contains a 'Question form' section with a 'Note: Required Information' and two text input fields: 'Enter Question Title:' and 'Enter A Detailed Description Of Your Question:'. A 'Submit' button is located below the description field. At the bottom of the form, there is a 'Sample question' section with a 'Sample question' and a 'Detailed description'.

Figure 14 Ask a Question Form

2.1.9. Frequently Asked Questions (FAQs)

Frequently asked questions and their answers (regarding the Order It Module features and functionality) are covered in this section. The five most commonly viewed questions are provided on the home page for easy reference. Users may also click the View all button to review all questions in the list. This FAQ list can be updated manually with those questions received via the Ask a question form which are related to the module or functionality. As of this version, there is no reporting or publishing of submitted questions using HSROAD.

The screenshot displays a 'Frequently Asked Questions' page. On the left, there is a sidebar with navigation links: Ordering, Place an Order, View Pending Orders, Order History, Support, Technical Support, Leave Feedback, Troubleshooting, Ask a question, FAQs (highlighted), and Help. The main content area is titled 'Frequently Asked Questions' and lists several questions. One question is highlighted with a larger view on the right: 'What type of products can I order using the Order It Module?'. The answer provided is 'Currently you can only order For Human Use products to be used under DMID IND protocols.' Below the answer are three buttons: 'Back', 'List all', and 'Order It home'. At the bottom of the highlighted question view, it shows 'Published On: 03/10/2007' and 'Last Updated On: 03/10/2007'.

Figure 15 FAQs Listing

2.1.10. Help

Detailed instructions for using the Order It module are provided in this link. Related FAQs and Help Files have been cross referenced within individual instruction pages for easy user access.

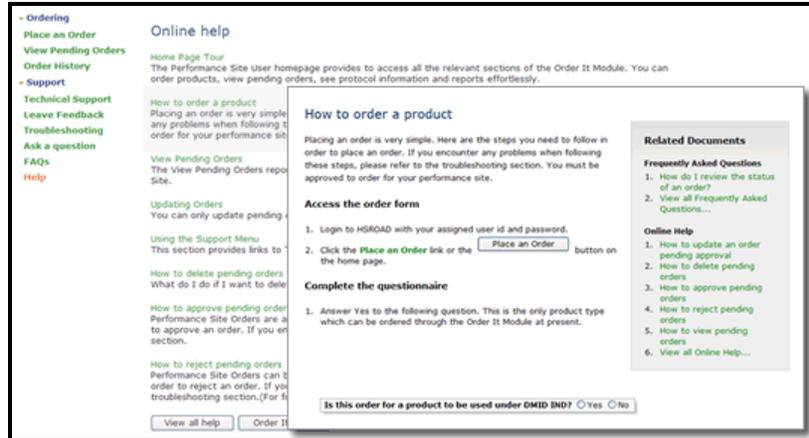


Figure 16 Order it Module Help Files

2.2. Protocols Module

The Protocols module is used to view or modify all information pertaining to a protocol. Users no longer have the option to create new protocols through HSROAD's Protocols module. The Protocols module is updated every night by uploading XML files captured from PPD's website, which contain information regarding new and existing protocols and their associated awards. This module also provides links to the performance sites, products, holds, and documents of the selected protocol. These links can be accessed through the edit screen for the selected protocol.

The module can be entered from the HSROAD main menu and is only available to users with the appropriate role. Depending on the user's level of access, options will be presented to modify or delete the protocol information. Upon entering the Protocols module, the user will be presented with a table listing of all the available protocols. By clicking on the column headers, the table can be sorted by protocol number, IND number, or protocol short name. The user can search for a protocol by entering a portion of the protocol number or the protocol title in the search box.

Users with delete access level for protocols will see archived records, which will be indicated by a red dot in the Archive column. These records can then be permanently deleted from the system if desired.

For a listing and descriptions of any of the fields in the protocols module, the "?" icon located on the upper right-hand will provide a separate browser window with the information to be used as reference.

Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Support | Log Out Bart (Program / Project Officer) ?

Order It | Protocols | Protocol Support | Project Management | Agreements | Reports | My Account

Protocol Information

Select a Protocol below or enter a Protocol Number in the search to view or modify a Protocol record.

Search for Protocol Number or Title:

= Edit = Delete

Search criteria: All Protocols

Action	Protocol Number	IND Number	Protocol Short Name	Protocol Title
	06-CTIDEMO2	BB-12188	06-CTIDEMO2	ORDER IT DEMO - This is a TEST protocol to be used by CTI

Figure 17 Protocol List (user without delete level of access)

2.2.1. Protocol Performance Sites

The Protocol Performance Sites section is used to add, modify, or delete all performance site information pertaining to the selected protocol. Depending on the user’s level of access, options to add, modify or delete Performance Site information will be presented. Upon entering the Performance Site section, the user will be presented with a table listing all the linked sites to the selected protocol. The table can be sorted by performance site by clicking on the column header.

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National Institutes of Health

Support | Log Out Bart (Program / Project Officer) ?

Order It | Protocols | Protocol Support | Project Management | Agreements | Reports | My Account

Protocol 06-CTIDEMO2
Performance Sites
Products
Holds

Protocol 06-CTIDEMO2 Performance Site

Add Site Notes For Protocol 06-CTIDEMO2 Performance Site

DateAdded	UserName	Notes
01/23/2007 10:45:00	Salatova, Nelli	test

◆Add a Performance Site

= Edit = Delete

	Performance_Site	Department	Protocol PI at Site	Protocol Coord. at Site	Site Status	Regulatory Documents
	1. CTI University Center	Infectious Diseases	Minnie Mouse		Active	Regulatory
	2. CTI Test Site	Immunology Department	Bart Simpson	suser4 4	Active	Regulatory
	3. Perfectville Hospital	DEPT OF PEDIATRICS	Angela Mermaid		Active	Regulatory

1 - 3 of 3 records

Page 1

Figure 18 Performance Sites List

Users with delete access for Performance Site Information will be able to permanently delete the associated performance site from the protocol if desired.

For a listing and descriptions of any of the fields in the Performance Site section, the “?” icon will provide a separate browser window with the information to be used as reference.

2.2.1.1. Protocol Access for Site Personnel

This feature, located within the Performance site form, allows System Administrators to link site users and other related personnel to the related Site protocol. This is the mechanism which allows those users in the **Site User** role to have Order It Module access for viewing, creating, modifying or deleting orders for their performance site (see Figure 19).

There are three levels of protocol access available for each site user (predetermined by the Protocol Champion). Site users may not access the protocol, or they may view data related to the protocol, or they may view data and place orders for products related to the protocol. Users displayed in this form are linked to the site via the user form in the System Administration module.

Protocol 06-CTiDEMO2 Performance Site

Sites:
A test Cti site -

Primary Performance Site:

Status:
Active

Site Personnel

Protocol PI at Site:

Site Coordinator:

Site User Access

Last Name, First Name	No Access	View Reports	Create Orders
(2537) site, user	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

Figure 19 Performance Site form (protocol-site user privilege)

2.2.2. Protocol Products

The Protocol products section is used to add, modify, or delete product information pertaining to the selected protocol depending on the user’s level of access. Upon entering the Protocol Products section, the user will be presented with a table listing all the linked products to the selected protocol. The table can be sorted by product name by clicking on the column header.

The screenshot shows the HSROAD system interface for the Division of Microbiology and Infectious Diseases. The page title is "Protocol 06-CTiDEMO2 Products". The interface includes a navigation menu with options like "Order It", "Protocols", "Protocol Support", "Project Management", "Agreements", "Reports", and "System Administration". The main content area displays a table of products for Protocol 06-CTiDEMO2. The table has columns for "Action", "Product Name", "Manufacturer", and "Lot Number". A single record is shown: "A test HSROAD product from CTi" by "Abbott Laboratories" with "Test" as the lot number. The page indicates "Page 1" and "1 - 1 of 1 records".

Action	Product Name	Manufacturer	Lot Number
	A test HSROAD product from CTi	Abbott Laboratories	Test

Figure 20 Protocol Products List

In addition, note that the field names with the red dot denote the “required” or “mandatory” fields. These fields must be filled before the product information record can be saved.

Users with delete access level for Protocol Products will be able to permanently delete the associated products from the protocol if desired.

For a listing and descriptions of any of the fields in the Protocol Products section, the “?” icon will provide a separate browser window with the information to be used as reference.

2.2.3. Protocol Hold

The Protocol Hold section is used to maintain all hold information pertaining to the selected protocol. Depending on the user’s level of access, options will be presented to add, modify or delete the hold information. Upon entering the protocol hold section, the user will be presented with a table listing all the holds associated with the selected protocol. The table can be sorted by hold type, start date, and end date by clicking on the column headers.

The screenshot shows the HSROAD system interface for the Division of Microbiology and Infectious Diseases. The page title is "Protocol 06-CTiDEMO2 Holds". The interface includes a navigation menu with options like "Order It", "Protocols", "Protocol Support", "Project Management", "Agreements", "Reports", and "System Administration". The main content area displays a table of holds for Protocol 06-CTiDEMO2. The table has columns for "Action", "Hold Type", "Start Date", and "End Date". A single record is shown: "1. Other" with a start date of "03/19/2007" and an end date of "03/30/2007". The page indicates "Page 1" and "1 - 1 of 1 records".

Action	Hold Type	Start Date	End Date
	1. Other	03/19/2007	03/30/2007

Figure 21 Protocol Holds List

In addition, when adding or modifying a hold record note that the field names with the red dot denote the “required” or “mandatory” fields. These fields must be filled before the information record can be saved.

Users with delete access level for Protocol Hold will be able to permanently delete the holds associated with the protocol if desired.

For a listing and descriptions of any of the fields in the Protocol Hold section, the “?” icon will provide a separate browser window with the information to be used as reference.

2.2.4. Documents

The Documents section is used to enter information about the documents assigned to the selected protocol and upload documents related to the selected protocol. This section can be entered from the Protocols Menu for users with the appropriate role. The user will be presented with a menu on the left-hand side with a link to this area of information.

Upon entering the protocol documents section, the user will be presented with a table listing all the documents associated to the selected protocol. The table can be sorted by document title, document type, source, protocol version, and related performance site (if any) by clicking on the column headers. The user can search for a document by entering a portion of the document title in the search box.

The permissions attributed to the users will determine the actions that will be available to them. Users with the appropriate permissions will be able to attach, view, edit and delete all documents (Figure 19a). Users with only View Document permission will only be able to view the document and indexing information. No link for adding attachments will be visible (Figure 19b).

Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Support | Log Out Donna (System Administrator) ?

Order It | Protocols | Protocol Support | Project Management | Agreements | Reports | System Administration

Protocol 06-CTiDEMO2 Documents

Search Document Title: Filters: Document Type Document Source Performance Site Go

Attach a Document to this Protocol

View Edit Delete

Action	Doc ID - Title	Document Type	Source	Protocol Version	Performance Site
	Doc 6670 - Test 1572	FDA1572	Attachment		CTI Test Site
	Doc 6671 - Informed Consent Test	Informed Consent	Attachment		CTI Test Site

Page 1 1 - 2 of 2 records

Figure 22 Document List, Document Admin

2.2.5. Study Design

The Study Design module is used to view study design information on the selected protocol. This module can be entered from the Protocols menu by users with the

appropriate role. The user will be presented with a menu on the left-hand side with links to the individual areas that compose the Study Design module. These areas include General Information and Clinical Agreements. In the General Information area, users are only allowed to view available information.

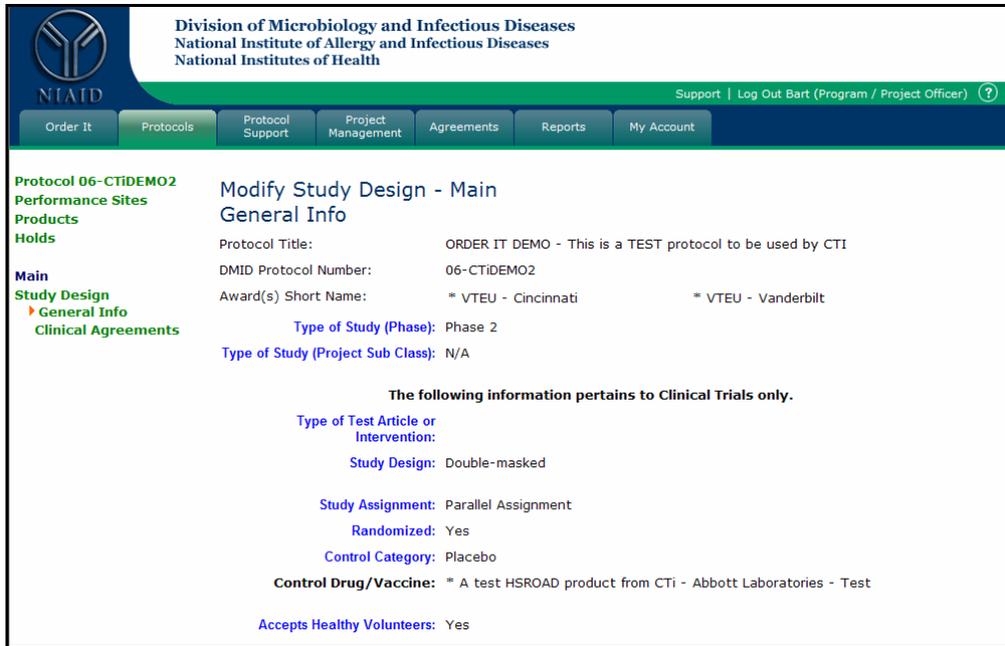


Figure 23 Study Design, General Information

Upon entering the Clinical Agreement area, the user will be present with a table listing all the clinical agreements associated with the selected protocol. The table can be sorted by effective date by clicking on the column header. Depending on the user’s level of access, options will be presented to create, modify, or delete the clinical agreement information.

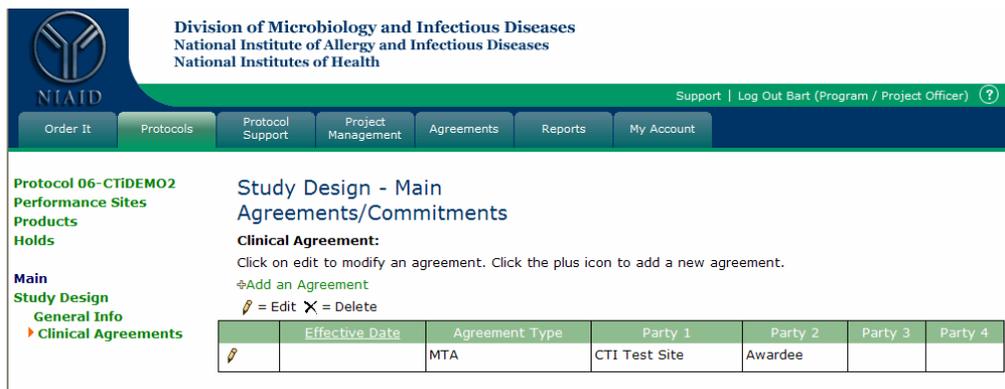


Figure 24 Clinical Agreement Area

Note: The field names with the red dot denote the “required” or “mandatory” fields. These fields must be filled before the information record can be saved.

Users with delete access for Clinical Agreements will be able to permanently delete agreements associated with the protocol if desired.

For a listing and descriptions of any of the fields in the Study Design module, the “?” icon will provide a separate browser window with the information to be used as reference.

2.2.6. Sub-Protocol Extension

The sub-protocol extension link is used to view an extension to an existing protocol. This area can be entered from the Protocols Menu for users that have access to this module. The user will be presented with a menu on the left-hand side with a link to this area of information. Users with the appropriate role will be able to permanently delete an extension associated with the protocol if desired.

2.3. Protocol Support Module

The Protocol Support module is composed of five modules used to search, create, view, modify, and delete information pertaining to awards and protocols. These five modules are:

1. IND Submission
2. Old INDs/ Barcode & Tracking
3. Pre-IND Information
4. Products
5. Site information

The Protocol Support module can be entered from the HSROAD Main Menu by users with access to any or all of these areas. The user will be presented with a menu on the left-hand side with links to each of the individual modules that they have access to.

2.3.1. IND Submissions

The IND Submission module is used to add or modify all information pertaining to every submission of an Investigational New Drug application (*IND*). This module can be entered from the Protocol Support module, and depending on the user’s level of access, options will be presented to create, modify or delete the IND information. Upon entering the IND Submissions module, the user will be presented with a table listing all the available INDs. The table can be sorted by IND number and IND title by clicking on the column headers. The user may search for a listing by entering a portion of the IND number or title in the search box.

IND Submissions

Select an IND below or enter an IND title in the search to view or modify an IND Submission record. Click the 'Create an IND' link to create a new IND.

⚙️ Create an IND

✏️ = Edit ✕ = Delete

Search criteria: All INDs

Search IND Title or Number:

Action	IND Number	IND Title	Documents	Archived
✏️ ✕	BB-01111	Test IND created by Cti for testing and development	View	
✏️ ✕	BB-10004	Single Recombinant Type 2a Vaccine Strains (Japanese Encephalitis Cell 1204 and Cell 1206), Live, Oral	View	
✏️ ✕	BB-10028	Recombinant poliovirus Recombinant Vaccine (Live, Attenuated) Vaccine with Escherichia coli Heat Labile Endotoxin Adjuvant (2012)	View	

Figure 25 IND Submission

Note: The field names with the red dot denote the “required” or “mandatory” fields. These fields must be filled before the IND Submission record can be saved.

Users with delete access for IND Submission will see archived records, which will be indicated by a red dot in the Archive column. These records can then be permanently deleted from the system if desired.

For a listing and descriptions of any of the fields in the IND Submissions module, the “?” icon will provide a separate browser window with the information to be used as reference.

2.3.2. Old INDs/Barcode and Tracking INDs

The Old INDs/Barcode and Tracking INDs module has two functions: (1) to create, modify, or delete information pertaining to inactive INDs records and (2) to generate barcode labels to record and track the location of paper-based documents using the Barcode & Tracking (B&T) system. The B&T system uses data collected from HSROAD to generate labels. This module can be entered from the Protocol Support module. Depending on the user’s level of access, options will be presented to create, modify or delete Old INDs records. Upon entering the Old INDs/B&T INDs, the user will be presented with a table listing all old INDs. The table can be sorted by IND number and IND title by clicking on the column headers. The user may search for old INDs by entering a portion of the IND title or number in the search box.

Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Support | Log Out Donna (System Administrator) ?

Order It | Protocols | Protocol Support | Project Management | Agreements | Reports | System Administration

Protocol Support

IND Submission
Old INDS / B&T
PPD Monitoring Schedule
Pre-IND
Products
Site Information

Old INDS / Barcode and Tracking INDS

Select an IND below or enter an IND title in the search to view or modify an IND record. Click the 'Create an IND' link to create a new IND.

✚ Create an IND

Search IND Title or Number: Search

✎ = Edit ✕ = Delete

Search criteria: All INDS

Action	IND Number	IND Title
✎ ✕	08-0024	Parainfluenza Virus Vaccine Types 1, 2, and 3
✎ ✕	08-0061	Mycoplasma pneumoniae Vaccine Lot 15-01
✎ ✕	08-0071	Adenovirus vaccine, Type 4, Live, Oral
✎ ✕	08-0083	Parainfluenza Virus Vaccines, Types 1, 2, and 3, Inactivated
✎ ✕	08-0125	Mycoplasma pneumoniae Vaccine
✎ ✕	08-0140	Respiratory Syncytial Virus Vaccine, Inactivated
✎ ✕	08-0162	Influenza A2 Virus vaccine, Live, Egg Origin, Strains 68 and 54
✎ ✕	08-0171	Immune Gamma Globulin

Figure 26 Old INDS/Barcode and Tracking INDS

Note: The field names with the red dot denote the “required” or “mandatory” fields. These fields must be filled before the IND record can be saved.

Users with delete access for Old INDS/ B&T INDS will be able to permanently delete Old INDS if desired.

For a listing and descriptions of any of the fields in the Old INDS/Barcode and Tracking INDS module, the “?” icon will provide a separate browser window with the information to be used as reference.

2.3.3. Pre-IND

The Pre-IND module is used to add, modify, or delete potential new IND award and protocol, Pre-IND, information. This module can be entered from the Protocol Support module, and depending on the user’s level of access, options to create, modify or delete Pre-INDs information will be presented. Upon entering the Pre-IND module, the user will be presented with a table listing all Pre-IND information. The table can be sorted by Pre-IND title and DMID Regulatory Officer by clicking on the column headers. The user may also search for a Pre-IND by entering a portion of the Pre-IND title in the search box.

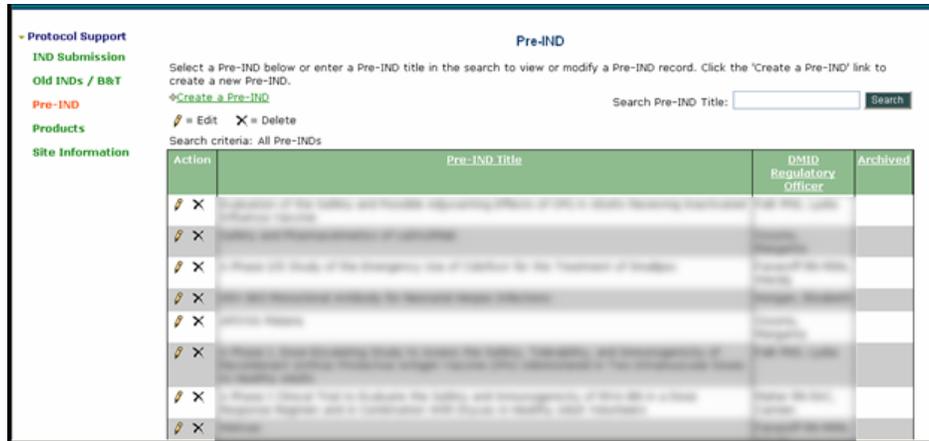


Figure 27 Pre-IND

Note: The field names with the red dot denote the “required” or “mandatory” fields. These fields must be filled before a Pre-IND record can be saved.

Users with delete access for Pre-IND will see archived records, which will be indicated by a red dot in the Archive column. These records can be permanently deleted from the system if desired.

For a listing and descriptions of any of the fields in the Pre-IND module, the “?” icon will provide a separate browser window with the information to be used as reference.

2.3.4. Products

The Products module is used to enter or modify all information pertaining to every product that is or will be used in a protocol. This module can be entered from the Protocol Support module, and depending on the user’s level of access, options will be presented to create, modify or delete the product information. Upon entering the Product module, the user will be presented with a table listing all available products. The table can be sorted by product name, manufacturer, product group, and product category by clicking the column headers. The user may search for a product by entering a portion of the product name in the search box.

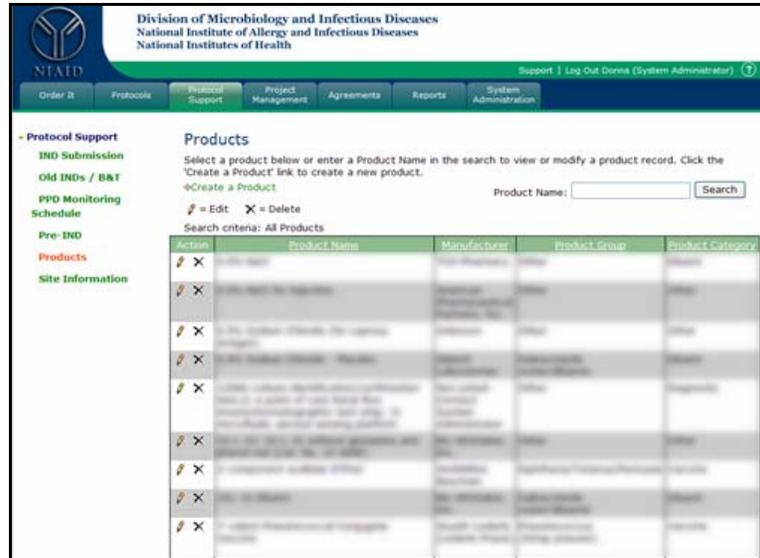


Figure 28 Products

Note: The field names with the red dot denote the “required” or “mandatory” fields. These fields must be filled before the product record can be saved.

Users with delete access for the Products module will be able to permanently delete product information if desired.

For a listing and descriptions of any of the fields in the Product module, the “?” icon will provide a separate browser window with the information to be used as reference.

2.3.5. Site Information

The Site Information module is used to enter or modify all information pertaining to every research site that is related or will be related to awards and protocols. This module can be entered from the Protocol Support module, and depending on the user’s level of access, options will be presented to add, modify or delete the site information. Upon entering the Site Information module, the user will be presented with a table listing all the available sites. The table can be sorted by site name by clicking on the column header or the user can search for a site by entering a portion of the site name in the search box.

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National Institutes of Health

Support | Log Out Donna (System Administrator) ?

Order It | Protocols | Protocol Support | Project Management | Agreements | Reports | System Administration

Protocol Support

- IND Submission
- Old INDs / B&T
- PPD Monitoring Schedule
- Pre-IND
- Products
- Site Information

Site Information

Select a site below or enter a site name in the search to view or modify a site record. Click the 'Create Site' link to create a new site.

⚙️ Create Site Search Site Names: Search

✎ = Edit ✕ = Delete

Search criteria: All sites

Action	Site Name	Department	Site Address	Archived
✎ ✕	●
✎ ✕	●
✎ ✕	●
✎ ✕	●
✎ ✕	●
✎ ✕	●
✎ ✕	●
✎ ✕	●
✎ ✕	●

Figure 29 Site Information

Note: The field names with the red dot denote the “required” or “mandatory” fields. These fields must be filled before the Site Information record can be saved.

Users with delete access level for the Site Information module will see archived records, which will be indicated by a red dot in the Archive column. These sites can then be permanently deleted from the system if desired.

For a listing and descriptions of any of the fields in the Site Information module, the “?” icon will provide a separate browser window with the information to be used as reference.

2.4. Project Management

The Project Management module is used to create, modify, or delete all information pertaining to specific projects.

2.4.1. Auditing Schedule Info

The Auditing Schedule Info menu for the Project Management module will display links to the various areas that compose this area, such as Audit Request and Auditing Schedule.

2.4.1.1. Audit Request Form

The Audit Request Form module is used to create, modify, or delete audit request information for ongoing projects. This section can be accessed from the Project

Management module. Depending on the user's level of access, the user can also enter the Audit Request Form module from the home page. Upon entering the Audit Request Form module, the user will be presented with a table listing all the audits requested and their respective information. The table can be sorted by project name, requested by, and date submitted by clicking on the column headers or the user can search for an audit request by entering a portion of the project name in the search box.

Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Support | Log Out Donna (System Administrator) ?

Order It | Protocols | Protocol Support | **Project Management** | Agreements | Reports | System Administration

Audit Request Information

Select a Record below or enter a title in the search to view or modify a record. Click the 'Create a New Record' link to create a new record.

[Create a New Record](#) Search Project Name:

= Edit = Delete

Search criteria: All Records

Action	Project	Requested By	Date Submitted
	Artisan Annual Model Testing	Hearts, Judith	01/03/2006
	Artisan Annual Model Testing	Nolan PhD, Edwin	01/12/2006
	Artisan Annual Model Testing	Lynn, Freya	
	Art-BioSolutions NeuroScreen Web	Taylor, Katherine	02/15/2006
	Barbar H99G	Kim, Sonnie	04/11/2006
	Barbar H99G	McPherson, Jean	04/07/2006
	Barbar SARS	Carroll PhD, Frederick	06/18/2006
	Barbar SARS	Carroll PhD, Frederick	06/28/2006

Figure 30a: Audit Request Information

Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Support | Log Out Donna (System Administrator) ?

Order It | Protocols | Protocol Support | **Project Management** | Agreements | Reports | System Administration

Create a Record for the Audit Request Form

To Be Completed by Program

Request Submitted By:

Phone:

Date Submitted: "MM/DD/YYYY"

Project/Product:

Contract Officer:

Funding Mechanism:

Audit Type Requested:

- Assay Validation
- Batch Record Review
- GLP
- GMP
- Other
- Post-Award
- Pre-Award

Audit Site:

ORA Representative:

Figure 31: Audit Request Form

Note: The field names with the red dot denote the “required” or “mandatory” fields. These fields must be filled before the Audit Request Form can be saved.

Users with delete access level for the Audit Request Form module will be able to permanently delete audit request forms if desired.

2.4.1.2. Auditing Schedule

The Auditing Schedule module is used to create, modify, and delete information for Auditing Schedule, depending on the user’s level of access. This module can be accessed from the Project Management module. Upon entering the Auditing Schedule module, the user will be presented with a table listing all auditing schedule information. The table can be sorted by audit visit date, visit date confirmed, project name, company, manufacturer/ audit site, and audit report received by clicking on the column headers. The user can also search for an auditing schedule record by entering a portion of the company name, manufacturers/ audit sites, and project name in the search box.

Action	Audit Visit Date	Visit Date Confirmed	Project	Company	Auditor	Manufacturer/Audit Site	Audit Report Received
	04/17/2007	Yes	Hudfield Vaccines Arkana (MVA)	Compliance, Inc.	John Bennett	Ingellicoflex, Desmar Tomasu GmbH	No
	03/23/2007	No	In vivo GMP technology services	Lucinda M. Vengry	Lucinda M. Vengry	OT Research Institute	No
	02/27/2007	Yes	MS	Pharm Regulatory Associates, Ltd.	Edward Fitzgerald Frank Pattan	Aerica Biotechnology	No
	02/05/2007	Yes	Regen Vaccine Project	Biologic Consulting Group, LLC	John Cordoba Nashua Walter Thomas J. Cartesian	Aerica Biotechnology	No

Figure 32: Auditing Schedule Module

Note: The field names with the red dot denote the “required” or “mandatory” fields. These fields must be filled before the Auditing Schedule Information record can be saved.

Users with delete access level for the Auditing Schedule module will be able to permanently delete auditing schedule information if desired.

For a listing and descriptions of any of the fields in the Auditing Schedule module, the “?” icon will provide a separate browser window with the information to be used as reference.

2.4.1.3. Manufacturers/ Audit Sites

The Manufacturers/Audit Sites module is used to create, modify, and delete information related to Manufacturers and Audit Sites. This module can be entered from the Project Management module. Upon entering the Manufacturer/Audit Sites module, the user is presented with a table listing all the manufacturers/audit sites and their respective information. The table can be sorted by manufacturer or audit site name, location, and product name by clicking on the column headers. The user can also search for a manufacturer/audit site by entering a portion of the manufacturer or audit site name in the search box.

The screenshot displays the NTATD web application interface. The header includes the NTATD logo and the text: "Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health". The user is logged in as "Donna (System Administrator)". The navigation menu includes: Order It, Protocols, Protocol Support, Project Management, Agreements, Reports, and System Administration. The main content area is titled "Manufacturer/Audit Site Information" and contains instructions: "Select a manufacturer or Audit Site below or enter a manufacturer or Audit Site name in the search to view or modify a record. Click the 'Create Manufacturer/Audit Site' link to create a new manufacturer or Audit Site." Below this is a search bar with the text "Search Manufacturer or Audit Site Names:" and a "Search" button. A legend indicates that a pencil icon represents "Edit" and an 'X' icon represents "Delete". The search criteria is set to "All Manufacturers". A table lists the following data:

Action	Manufacturer or Audit Site Name	Location	Product
	Algenis, Inc.	Fremont, California	Antibody Production Facility
	Acambis	Cambridge, Massachusetts	MSK
	AcadT Immunotherapeutics	Newport, Massachusetts	TYRO2 vaccine
	Aerona Biotechnology	Beddley, Manchester	MSK
	Aerona Pasteur	Lyon	SARS Cov
	Bartle BEST Center	Abertan, Maryland	MSK reagent qualification
	Bartle Memorial Institute	West Jefferson, Ohio	MSK
	Bovarian Nordic A/S	2300 Copenhagen S	MSK
	Baxter BioScience	Ork and Vienna	MSK and HSD
	Baxter Pharmaceutical Solutions	Westborough, Indiana	MSK

Figure 33: Manufacturers/Audit Sites

Note: The field names with the red dot denote the “required” or “mandatory” fields. These fields must be filled before the Manufacturer/Audit Site Information can be saved.

Users with delete access level for the Manufacturer/Audit Site module will be able to permanently delete manufacturer/audit site information if desired.

For a listing and descriptions of any of the fields in the Manufacturer/Audit Site module, the “?” icon will provide a separate browser window with the information to be used as reference.

2.4.1.4. Projects

The Projects module is used to create, edit, and delete information related to projects, depending on the user’s level of access. This module can be entered from the Project Management module. Upon entering the Project module, the user is presented with a table listing all projects. The table can be sorted by project name by clicking on the

column header. The user can also search for a project by entering a portion of the project name in the search box.

The screenshot displays the 'Project Information' page within the HSROAD system. The header includes the NIAID logo and the text 'Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health'. A navigation bar contains tabs for 'Order It', 'Protocols', 'Protocol Support', 'Project Management', 'Agreements', 'Reports', and 'System Administration'. The left sidebar lists various menu items under categories like 'Auditing Schedule Info', 'Consultant Info', and 'Contract Info'. The main content area features a 'Project Information' section with a search box, a 'Create Project' link, and a table of projects. The table has columns for 'Action' and 'Project Name'. Each row in the table includes an edit icon (pencil) and a delete icon (X).

Action	Project Name
	Andrew Animal Model Testing
	Anti Botulinum Neurotoxin MAb
	Antibody Production Facility
	Assay Validation Course
	Aventis SARS
	Baxter H5N1
	Baxter SARS
	Botulinum Neurotoxin Vaccine
	Chiron Influenza H5N1
	Chiron Influenza H5N2
	Flu Pneumococcal Study

Figure 34: Projects

Note: The field names with the red dot denote the “required” or “mandatory” fields. These fields must be filled before the Project Information can be saved.

Users with delete access level for the Projects module will be able to permanently delete project information if desired.

For a listing and descriptions of any of the fields in the Project module, the “?” icon will provide a separate browser window with the information to be used as reference.

2.4.2. Consultant Info

The Consultant Info menu for the Project Management module will display a link to the Auditors/Subcontractor Consultants, which provides contact information for consultants.

2.4.2.1. Auditors/Subcontractor Consultants

The Auditors/Subcontractors Consultants module is used to create, modify, and delete information related to Auditing Companies, Subcontractors, and Consultants. This module can be entered from the Project Management module, and depending on the user’s level of access, options will be presented to create, modify or delete the company information. Upon entering this module, the user will be shown a table listing the contact information for all auditing companies, subcontractors, and consultants. The table can be sorted by company name, phone number, state, and country by clicking the column headers. Users can also search for an auditing company, subcontractor, or consultant by entering a portion of the company name in the search box.

Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Support | Log Out Donna (System Administrator) ?

Order It | Protocols | Protocol Support | Project Management | Agreements | Reports | System Administration

Auditing Schedule Info
 Audit Request Form
 Auditing Schedule
 Manufacturers/Audit Sites
 Projects

Consultant Info
 Auditors/Subcontractor Consultants
 Contract Info
 Contract Office Submissions
 General Contracts

Company Information
 Select a company below or enter a company name in the search to view or modify a company record. Click the 'Create Company' link to create a new company.
 Create Company
 Search Company Names: Search
 Edit = Edit Delete = Delete
 Search criteria: All auditors

Action	Company Name	Phone Number	State	Country
	Andree Smith	609-339-4381	Massachusetts	U.S.
	Alan Demarest	301-524-1830	Maryland	U.S.
	AMC	301-688-0520	Maryland	U.S.
	Artisala			U.S.
	Baxter Healthcare SA			Switzerland
	Biological Consultant	(717) 899-9611	Pennsylvania	U.S.
	Biologics Consulting Group, LLC	(703) 739-8885	Virginia	U.S.
	Biophance Corporation			

Figure 35: Company Information

Note: The field names with the red dot denote the “required” or “mandatory” fields. These fields must be filled before the company information can be saved.

Users with delete access level for the Auditors/Subcontractors Consultants module will be able to permanently delete company information if desired.

For a listing and descriptions of any of the fields in the Auditors/Subcontractors Consultants module, the “?” icon will provide a separate browser window with the information to be used as reference.

2.4.3. Contract Info

The Contract Info menu for the Project Management module will display a link to sub-modules that provide contract information.

2.4.3.1. Contract Office Submissions

The Contract Office Submissions module is used to create, edit, and delete information related to Contract Documents. This module can be entered from the Project Management module, and depending on the user’s level of access, options will be presented to create, modify or delete contract office submissions information. Upon entering this module, the user will be presented with a table listing the information for contract submissions. The table can be sorted by author, type of contract document, date submitted to FBS CO, and comments by clicking the column headers. Users can also search for a contract submission by entering a portion of the author’s name in the search box.

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National Institutes of Health

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Contract Office Submissions

Select an author below or enter an author name in the search to view or modify a record. Click the 'Add Contract Office Submission' link to create a new contract submission.

⚡ Add Contract Office Submission

Search Author Names: Search

✎ = Edit ✕ = Delete

Search criteria: All authors

Action	Author	Type of Contract Document	Date Submitted to FBS_CO	Comments
✎ ✕	Janice Connors	COA Request - CTI Mod 4	01/09/2007	
✎ ✕	Janice Connors	COA Request - Yorgy Mod 4	01/22/2007	Pending Fully Executed Mod. No. 4
✎ ✕	Theresa Lanthier	COA Request - Lansky Mod 9	01/18/2007	
✎ ✕	Ada Brooks	COA Request - Aranka Mod No. 2	01/12/2007	Pending Fully Executed Mod. No. 1
✎ ✕	Ada Brooks	COA Request - Rosendorf Mod No. 4	01/10/2007	Received Fully Executed Mod. No. 4 02/16/2007
✎ ✕	Janice Connors	COA Request - Drusans Mod 2	01/03/2007	Received Fully Executed Mod. No. 2 02/16/2007

Figure 36: Contract Office Submissions

Note: The field names with the red dot denote the “required” or “mandatory” fields. These fields must be filled before the contract office submission record can be saved.

Users with delete access level for the Contract Office Submissions module will be able to permanently delete a contract office submission record if desired.

For a listing and descriptions of any of the fields in the Contract Office Submissions module, the “?” icon will provide a separate browser window with the information to be used as reference.

2.4.3.2. General Contracts

The General Contracts module is used to create, edit, and delete contract information. This module can be entered from the Project Management module. Depending on the user’s level of access, options will be presented to create, modify or delete contract information. Upon entering the General Contract module, the user will be presented with a table listing all contracts and their respective information. The table can be sorted by contract number, subcontractor/consultant, title, and contract status by clicking the column headers or users can search for a contract by entering a portion of the contract number or title in the search box.

Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Support | Log Out Donna (System Administrator) ?

Order It | Protocols | Protocol Support | **Project Management** | Agreements | Reports | System Administration

General Contracts

Select an contract number below or enter a contract number in the search to view or modify a record. Click the 'Add Contract' link to create a new contract.

⚡ Add Contract Search Contract Number or Title:

✎ = Edit ✕ = Delete

Search criteria: All contracts

Action	Contract Number	Subcontractor/Consultant	Title	Contract Ceiling	Contract Status
✎ ✕	NHS-05413-41	Alison Demarest	Consulting Services	\$56,892.00	Active
✎ ✕	NHS-05413-40	Statistical Design	In-House Courses	\$13,850.00	Active
✎ ✕	NHS-05413-39	Melissa Smith	Consulting Services	\$56,247.00	Active
✎ ✕	NHS-05413-38	Phoenix Regulatory Associates, LLC	Facility Audits for NIAID	\$50,948.00	Active
✎ ✕	NHS-05413-37	Harol Aranha	Consulting Services	\$93,120.00	Active
✎ ✕	NHS-05413-36	Marian Stewart & Associates, Inc.	Facility Audits for NIAID	\$76,842.00	Active

Figure 37: General Contracts

Note: The field names with the red dot denote the “required” or “mandatory” fields. These fields must be filled before the contract information can be saved.

Users with delete access level for the General Contracts module will be able to permanently delete contract information if desired.

2.5. . Agreements

2.5.1. Material Transfer Agreements (MTA)

The MTA module is used to create, modify, or delete information pertaining to Material Transfer Agreements (MTAs). This module can be entered from the Agreements module, and depending on the user’s level of access, options will be presented to add, modify or delete MTA information. Upon entering the MTA module, the user will be presented with a table listing the MTAs and their respective information. The table can be sorted by DMID MTA number, OTD MTA number, MTA effective date, party 1 (DMID Program Officer), material name, protocol, and DMID IND by clicking on the column headers or the user can search for a MTA by entering a portion of the MTA number in the search box.

2.6.1. Awards

The Awards menu for the Reports module will display links to the Awards and Expired Awards reports.

2.6.1.1. Award Report

The Awards report lists the available awards, their information, and any associated protocols. The awards information is updated on a weekly basis by IMPACII, which transfers awards data from IMPAC to HSROAD. This report displays the following information fields per Award Number:

- Award Protocol Investigator (PI)
- Award Institution
- Award Start Date
- Award End Date
- Human Subject Code
- GM Exception Code
- Protocols
- Program Code
- Protocol Status
- Protocol Status Date

Sort Fields

- Award Number
- Award Short Name
- Award PI

Filters

- **Award Type**
 - Active Awards
 - Awards not assigned to a Protocol
 - Grants
 - Contracts
 - Interagency Agreements
 - Intramural
 - Cooperative Agreements
- **Award PI**
- **Program Code**
- **GM Exception Code**

Cross-links

- Award Institution – Cross-link to the Site Information report, which provides information for that protocol site such as address and contact information.
- Protocol Number – Cross-link to the Protocol Details report, which provides information for that protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.

- IND Number – Cross-link to the IND by Number report, which provides information for that protocol.
- Program Code – Cross-link to the Protocols by Program Codes report, which provides information for that protocol.
- Program Officer – Cross-link to the User's report, which provides information for that Program Officer such as address and contact information.

2.6.1.2. Expired Awards Report

The Expired Awards Report lists awards whose end date has passed, and are not associated with an active protocol. This report displays the following information fields per Award Number:

- Award PI
- Award Institution
- Award Start Date
- Award End Date
- Protocol Number and Title
- Protocol Status

Sort Fields

- Award Number
- Award Short Name
- Award PI

Conditions

- The award must be associated with a Protocol that does not have a status of completed, not done, or terminated.
- The award End Date must be earlier than the current date.

Filters

- **Award PI**

Cross-links

- Award PI – Cross-link to the User's report, which provides information for that Protocol Investigator such as address and contact information.
- Award Institution – Cross-link to the Site Information report, which provides information for that protocol site such as address and contact information.
- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.

2.6.2. DocuTrak

The DocuTrak menu for the Reports module will display links to the Documents, Book Inventory, and Inventory History reports.

2.6.2.1. Documents Report

The Documents report lists all available documents, their information, and any associated protocols and INDs. This report displays the following information fields per document ID and Title:

- Doc ID - Title
- Document Type
- Source
- Protocol Number
- Performance Site
- IND

Filters

- **Document Type**
 - Advertisement
 - FDA Letter
 - FDA1572
 - Informed Consent
 - Investigator's Brochure
 - IRB Approval
 - Lab Certificate
 - Lab Normal
 - Protocol
 - Supplement/Serial Number
- **Document Source**
 - Attachment
 - Inventory
 - Separator
- **Protocols**
- **Performance Sites**
- **INDs**

2.6.2.2. Book Inventory Report

The Book Inventory Report lists all IND books, their information, and allows users to make book requests if the user has the appropriate permissions to access this report. This report displays the following information fields per IND Number:

- IND Number
- Book
- Supplement/ Serial Number
- Location
- Recipient
- Submission Date
- Modified By
- History
- Book Requests

Filters

- **IND Number**
- **Books**
- **Users**
- **Locations**

Cross-links

- View Historical Data – Cross-link to the History of Data Changes for Book Inventory, which provides historical record of the book requests and locations for the book selected.
- Book Requests – Cross-link to form used to request the book selected via HSROAD.

2.6.2.3. Inventory History Report

The Book Inventory History report lists the history of transfer requests and locations for all INDs books. This report displays the following information fields per IND Number:

- IND Number
- Book
- Supplement/ Serial Number
- Location
- Transfer Date
- Modified By
- Date Modified
- Comments

Filters

- **IND Numbers**
- **Books**
- **Users**
- **Locations**

2.6.3. IND Submissions

The IND Submissions menu for the Reports module will display links to the various reports that compose this area such as the Annual Report, IND by Disease Report, IND Regulatory, etc.

2.6.3.1. Annual Report Status

The IND Annual Report Status is used to track the status of the annual reports for INDs. The report shows the last record “created” for an Annual Report Status. This report displays the following information fields per IND number by Anniversary Date:

- Anniversary Date
- IND Number
- Prepared By
- Date of Last Annual Report
- Current AR Status
- DMID Regulatory Officer
- Letter Sent To
- Date Letter Sent/ Second Date
- Date Draft Sent/ Second Date
- Date Final Sent
- Index Received
- Comments

Filters

- **By Month of the Year**
- **DMID Regulatory Officer**
- **Current AR Status**
- **Index Received**

Cross-links

- IND Number – Cross-link to the IND by Number report, which provides information for that protocol.
- Comments – Cross-link to any comments available for that protocol.

Conditions

- Report displays all INDs with a status of Active, Pending, or Hold.
- Items indexed for longer than 90 days will not appear on the report.

2.6.3.2. Annual Report

The IND Annual Report is used to track the annual report due date for protocols conducted under an IND. This report displays the following information fields per IND Number:

- Anniversary Date
- FDA Receipt Date
- IND/ MF Number
- IND/ MF Title
- Date of Last Annual Report

Filters

- **By Month of the Year**
- **DMID Regulatory Officer**
- **Program Code**

Conditions

- Report displays all INDs with a status of Active, Pending, or Hold
- Must not contain or begin with "MF" (Master File).

2.6.3.3. IND by Disease (excl. MF/DMF) Report

The IND by Disease Report lists the diseases under investigation with their associated INDs and protocols. This report displays the following information fields by disease per IND Number:

- IND Number
- IND Title
- Protocol Number
- Protocol Title
- Group Affiliation
- Status
- Type of Study
- Lead PI
- Performance Sites

Filters

- **IND Status**
- **Phases**
- **Protocol Status**
- **Groups**
- **Program Codes**

Conditions

- Lists diseases that have an IND associated with them.

Cross-Links

- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.
- Lead PI – Cross-link to the Users Report, which provides information for that Lead PI.
- Investigator – Cross-link to the Users Report, which provides information for that investigator.
- Site Name – Cross-link to the Site Report, which provides information for that site.

2.6.3.4. IND by Number (excl. MF/DMF) Report

The IND by Number Report lists all INDs with associated protocols. This report displays the following information fields per IND Number:

- IND Number
- IND Title
- Protocol Number
- Protocol Title
- Award Number
- Group Affiliation
- Status

- Type of Study
- Disease
- Lead PI
- Performance Sites

Filters

- **IND Status**
- **Phases**
- **Protocol Status**
- **Groups**
- **Program Codes**

Cross-Link

- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.
- Award Number – Cross-link to the Awards Report, which provides information for that award.
- Lead PI – Cross-link to the Users Report, which provides information for that Lead PI.
- Investigator – Cross-link to the Users Report, which provides information for that investigator.
- Site Name – Cross-link to the Site Report, which provides information for that site.

Conditions

- Must not contain or begin with "MF" (Master File).
- Report displays all INDs associated with a Protocol.

2.6.3.5. IND Regulatory Report

The IND Regulatory Report is used to track INDs by the regulatory officer. This report displays the following information fields per IND Number:

- IND Number
- IND Title
- FDA Reviewer
- FDA Receipt Date
- DMID Program Officer
- DMID Regulatory Officer
- IND Status/ Status Date

Filters

- **IND Status**
 - Active
 - Hold
 - Inactive
 - Pending
 - Terminated
 - Transferred
 - Withdrawn

- Active/ Pending/ Hold
- Inactive/ Withdrawn/ Terminated
- **DMID Regulatory Officer**

2.6.3.6. IND Regulatory Short Summary Report

The IND Regulatory Short Summary Report provides a summary of the INDs listed on the IND Regulatory Report. This report displays the following information fields per IND Number:

- IND/ MF Number
- IND/ MF Title
- FDA Receipt Date

2.6.3.7. IND Summary Report

The IND Summary Report lists all INDS with their associated protocols. This report displays the following fields per IND Number:

- IND Number
- IND Title
- IND Status
- IND Status Date
- DMID Regulatory Officer
- Protocol Number
- Protocol Title
- Award Number
- Group Affiliation
- Status
- Type of Study
- Disease
- Lead PI
- Protocol Champion
- Protocol PI
- Performance Sites
- Products

Filters

- **IND Status**
 - Active
 - Hold
 - Inactive
 - Pending
 - Terminated
 - Transferred
 - Withdrawn
- **Protocol Status**
 - Active (Enrollment Ongoing)
 - Completed
 - Enrollment Completed

- Hold
- Not Done
- Pending
- Terminated
- Concept Approved
- Concept Deferred
- Concept Denied
- Concept Proposed
- Active/ Enrollment Completed/Pending
- **Program Codes**

Cross-links

- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.
- Award Number – Cross-link to the Awards Report, which provides information for that award.
- Lead PI – Cross-link to the Users Report, which provides information for that Lead PI.
- Protocol Champion – Cross-link to the Users Report, which provides information for that Protocol Champion.
- Investigator – Cross-link to the Users Report, which provides information for that investigator.
- Site Name – Cross-link to the Site Report, which provides information for that site.

2.6.3.8. Investigator's Brochures Report

The Investigator's Brochures Report is used to track the Investigator's Brochures sent to Principal Investigators by IND number. This report displays the following information fields per IND Number:

- IND Number
- Investigator's Brochure Title/ Description
- IB Version Date
- IB Version Edition/ Number
- DMID Regulatory Officer
- Serial Number
- Date Sent to FDA

Filters

- **IND Status**
 - Active
 - Hold
 - Inactive
 - Pending
 - Terminated
 - Transferred
 - Withdrawn
 - Active/ Pending/ Hold

- Inactive/ Withdrawn/ Terminated
- **DMID Regulatory Officer**

2.6.3.9. Old IND Summary Report

The Old IND Summary Report is used to track inactive INDs. This report displays the following information fields per IND Number:

- IND Number
- IND Status
- FDA Receipt Date

2.6.3.10. Pre-IND Summary Report

The Pre-IND Summary Report is used to track new concept for potential INDs. This report displays the following information fields per Pre-IND title:

- Pre-IND Title
- Meeting Date
- Investigational Agent
- Manufacturer
- DMID RAS/ PO
- Principal Investigator
- Follow-Up Prior to IND Submission
- IND Submission Date
- Comments

Filters

- **DMID Regulatory Officer**

Cross-links

- Comments – Cross-link to any comments available for that protocol.

2.6.3.11. Pre-IND Short Summary Report

The Pre-IND Short Summary Report provides a summary of the Pre-INDs listed on the Pre-IND Report. The report displays the following information fields per Pre-IND Title:

- Pre-IND Title
- IND Submission Date

2.6.3.12. Products by IND Report

The Products by IND Report lists INDs with their associated protocols and the products assigned to those protocols. This report displays the following information fields per IND Number:

- IND Number
- IND Title
- Protocol Number
- Protocol Title
- Protocol Status
- Products

Filters

- **Active INDs**
- **Active Protocols**
- **Active/ Pending/ Hold Protocols**
- **Product Categories**
- **DMID Regulatory Officer**
- **Program Codes**

Conditions

- Report displays list of products that have an IND associated with them.

Cross-Links

- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.
- Product Name – Cross-link to the Products Report, which provides information for that product.

2.6.3.13. Signature Block Report

The Signature Block Report is a distribution list that specifies which individuals receive certain reports. This report displays the following information fields per IND Number:

- IND Number
- IND Short Title
- DMID Regulatory Officer
- DMID Program Officer(s)
- CC Transmittal Memo
- CC Entire Submission
- Special Requests

Filters

- **IND Status**
 - Active
 - Hold
 - Inactive
 - Pending
 - Terminated
 - Transferred
 - Withdrawn
 - Active/ Pending/ Hold
 - Inactive/ Withdrawn/ Terminated

- **DMID Regulatory Officer**

2.6.4. Monitoring

The Monitoring menu for the Reports module will display links to the various reports that provide site monitoring information such as the Monitoring Report, Clinical Monitoring Report, Foreign Monitoring, etc.

2.6.4.1. Clinical Monitoring Report

The Clinical Monitoring Report is used to track monitoring visits by PPD to Protocol Performance Sites for protocols done under IND and for protocols where PPD is selected as the Primary or Secondary Site Monitor. This report displays the following information fields per Visit Date:

- Start Date – End Date
- Site Name
- IND No./ DMID Regulatory Officer
- Protocol Number
- Monitor(s)
- Close-Out
- Monitoring Report Received by FBS
- Date Monitoring Report Received by FBS

Filters

- **Protocol Status**
- **DMID Regulatory Officer**
- **Study Close-Out**

Cross-link

- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.

2.6.4.2. Foreign Monitoring Report

The Foreign Monitoring Report is used to track monitoring visits by PPD to Protocol Performance Sites for protocols not done in the United States and for protocols where PPD is selected as the Primary or Secondary Site Monitor. This report displays the following information fields per Visit Date:

- Start Date – End Date
- Site Name
- Location
- IND No./ DMID Regulatory Officer
- Protocol Number
- Study Director (Lead PI) / Performance Site PI
- Contact

- Language
- Monitoring Frequency
- Comments

Filters

- **Protocol Status**
- **Country**

Cross-link

- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.

2.6.4.3. International Monitoring Contact Report

The International Monitoring Contact Report is used to display contact information for international monitoring. This report displays the following information fields by Group Affiliation:

- Group
- Name
- Title
- E-Mail Address
- Address
- Phone
- Cell Phone
- Fax

Filters:

- **Group Affiliation**

Cross-link

- Name – Cross-link to the Users Report, which provides information for that user.

2.6.4.4. Monitoring by Site Report

The Monitoring by Site Report displays the same information as the Monitoring Report, sorted out by site. This report displays the following information fields by Site per IND number:

- Site Name
- IND Number
- Protocol Number
- Protocol Title
- Status
- DMID Regulatory Officer
- Lead PI
- Monitoring Info:
 - Frequency of Visits

- Goal For Monitoring
- Monitoring By Certain Date
- Custom Monitoring Plan
- Site PI
- Protocol Coordinator
- Study Close-out
- Close-out Date
- Primary Site Monitor
- Last Monitoring Visit
- Secondary Site Monitor
- Last Monitoring Visit

Filters

- **Last Monitored**
 - Not monitored in the past 6 months
 - Monitored in the past 6 months
 - Not Monitored in the past year
 - Monitored in the past year
- **Protocol Status**
 - Active (Enrollment Ongoing)
 - Completed
 - Enrollment Completed
 - Hold
 - Not Done
 - Pending
 - Terminated
 - Concept Approved
 - Concept Deferred
 - Concept Denied
 - Concept Proposed
 - Active/ Enrollment Completed/ Pending
- **DMID Regulatory Officer**
- **Study Close-out**
 - Done
 - Not Done
 - N/A
 - N/A or Not Done
- **Primary Site Monitor**
- **Secondary Site Monitor**
- **States**

Conditions

- Report displays all protocols regardless of status.
- Report displays only Protocols associated with an active IND.
- Primary Site Monitor is NOT “No monitoring required.”

Cross-Links

- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.

- DMID Regulatory Officer – Cross-link to the Users Report, which provides information for that DMID Regulatory Officer.
- Lead PI – Cross-link to the Users Report, which provides information for that Lead PI.
- Site PI – Cross-link to the Users Report, which provides information for that Site PI.
- Protocol Coordinator – Cross-link to the Users Report, which provides information for that Protocol Coordinator.

2.6.4.5. Monitoring Report

The Monitoring Report for Protocols displays the site monitoring information for protocols that are associated with an active IND. This report displays the following information fields per Protocol Number:

- Protocol Number
- IND Number
- Protocol Title
- Status
- DMID Regulatory Officer
- Lead PI
- Frequency of Monitoring Visits
- Goal for Monitoring
- Monitoring By Certain Date
- Custom Monitoring Plan
- Monitoring Info:
 - Site Name
 - Site PI
 - Protocol Coordinator
 - Study Close-out
 - Close-out Date
 - Primary Site Monitor
 - Last Monitoring Visit
 - Secondary Site Monitor
 - Last Monitoring Visit

Filters

- **Last Monitored**
 - Not monitored in the past 6 months
 - Monitored in the past 6 months
 - Not Monitored in the past year
 - Monitored in the past year
- **Protocol Status**
 - Active (Enrollment Ongoing)
 - Completed
 - Enrollment Completed
 - Hold
 - Not Done
 - Pending
 - Terminated

- Concept Approved
- Concept Deferred
- Concept Denied
- Concept Proposed
- Active/ Enrollment Completed/ Pending
- **DMID Regulatory Officer**
- **Study Close-out**
 - Done
 - Not Done
 - N/A
 - N/A or Not Done
- **Primary Site Monitor**
- **Secondary Site Monitor**
- **States**

Conditions

- Report displays all protocols regardless of status.
- Report displays only Protocols associated with an active IND.

Cross-Links

- DMID Regulatory Officer – Cross-link to the Users Report, which provides information for that DMID Regulatory Officer.
- Lead PI – Cross-link to the Users Report, which provides information for that Lead PI.
- Site Name – Cross-link to the Site Report, which provides information for that site.
- Site PI – Cross-link to the Users Report, which provides information for that Site PI.
- Protocol Coordinator – Cross-link to the Users Report, which provides information for that Protocol Coordinator.

2.6.4.6. PPD Monitoring Schedule Report

The PPD Monitoring Schedule Report is used to track monitoring visits by PPD to Protocol Performance Sites for protocols done under IND and for protocols where PPD is selected as the Primary or Secondary Site Monitor. This report displays the following information fields per Protocol number:

- Protocol Number
- IND Number
- Protocol Title
- Protocol Status
- PPD Monitoring Schedule Info:
 - Site Name
 - Site PI
 - Monitor
 - Additional Monitors
 - Start Visit Date
 - End Visit Date
 - Protocol Close-Out Visit

- Received by FBS
- Date Received
-

Filters

- **Protocol Status**
 - Active (Enrollment Ongoing)
 - Completed
 - Enrollment Completed
 - Hold
 - Not Done
 - Pending
 - Terminated
 - Concept Approved
 - Concept Deferred
 - Concept Denied
 - Concept Proposed
 - Active/ Enrollment Completed/ Pending
- **DMID Regulatory Officer**
- **Study Close-out**
 - Done
 - Not Done
 - N/A

Cross-links

- Site Name – Cross-link to the Site Report, which provides information for that site.
- Site PI – Cross-link to the Users Report, which provides information for that Site PI.

2.6.5. Products

The Products menu for the Reports module will display links to the three reports that provide all available information regarding products and any associated protocols.

2.6.5.1. Inventory Report

The General Inventory Report displays the inventory information for products in the Fisher Repository. This report displays the following information fields per Label Name:

- Label Name
- Manufacturer
- Lot Number
- Unit Type
- Current Balance

2.6.5.2. Orders Report

The Orders Report provides a summary of the products ordered via HSROAD. This report displays the following information fields per Order Number:

- Order Number
- Order Date
- Order Status
- Approved Date
- Approved Name
- Items
- Unit Type
- Quantity

Filters

- **Approval Status**
 - Approved
 - Rejected
 - Pending

Cross-links

- Order Number – Cross-link to CARIM Order Form, which provides an electronic copy of the order form.

2.6.5.3. Products Report

The Products Reports shows the information on all products along with any associated protocols. This report displays the following information fields per product:

- Product Name
- Product Name Group
- Manufacturer
- Countries licensed other than US
- Product Category
- Vaccine Information
- Preservative Information
- Adjuvant Information
- Drug Information
- Distribution and Labeling by
- Formulation
- Comments
- Protocol Numbers and Titles

Filters

- **Product Groups**
- **Product Category**
- **Manufacturer**

Cross-link

- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.

2.6.6. Project Management

The Project Management menu for the Reports module will display links to the various reports that provide information regarding projects such as Auditing Schedule, Drafts Final Due Dates, General Contracts, etc.

2.6.6.1. Auditing Schedule Report

The Auditing Schedule report displays the schedule for audit visits to manufacturer or audit sites. This report displays the following information fields per Manufacturer/Audit Site:

- Start Visit Date/ End Visit Date
- Project
- Audit Type
- Auditing Company
- Auditors
- Manufacturer/ Audit Site
- Individuals Accompanying Auditor
- ORA Individuals Accompanying Auditor

Filters

- **Manufacturer/ Audit Site**
- **Project**

2.6.6.2. Auditor Area of Expertise Report

The Auditor Area of Expertise report displays credential information for auditors. This report displays the following information fields per auditor:

- Auditor
- Company Name
- Area of Expertise

Filters

- Company

Conditions

- Report only displays auditors.

2.6.6.3. Audit Request Report

The Audit Request report lists all information for audits requested. This report displays the following information fields per Requested Task Start Date:

- Task Start Date/ Task End Date
- Project

- Audit Type Requested
- Manufacturer/ Audit Site
- Request Form

Filters

- **Project**

Cross-link

- Request Form Download – Cross-link to electronic copy of DMID Request Form for Consultants/Auditors.

2.6.6.4. Auditors/Consultants Contact Report

The Auditors/Consultants Contact report displays the contact information for Auditors/Consultants. This report displays the following information fields per Contact Name:

- Auditor/Consultant Name
- Company
- Address
- Country
- Phone Number
- Cell Phone
- Fax Number

Filters

- **Company**

2.6.6.5. Conflicts Report

The Conflicts Report displays company conflicts encountered. This report displays the following information fields by Company Name:

- Company
- Contact
- Conflicts

2.6.6.6. Contact Office Submissions Report

The Contract Office Submissions report displays the contract documents submitted to FBS CO and Government Offices. This report displays the following information fields per document by Date Submitted to FBS CO:

- Author
- Type of Contract Document
- Date Submitted to FBS CO
- Date to Follow-up with FBS CO
- Date Revisions Sent to FBS CO

- Date Submitted to Govt. CO
- Date Revisions Submitted to Govt. CO
- Outcomes
- Date COA Executed
- Date COA/ Executable Received
- Comments

Filters

- **Authors**

2.6.6.7. Draft Final Due Dates Report

The Draft Final Due Dates report displays the due dates for Draft of Final Reports. This report displays the following information fields per Audit Visit by Start Visit Date:

- Start Visit/ End Visit Date
- Auditing Company
- Auditors
- Manufacturer/ Audit Site
- Draft Report Due Date
- Date Draft Audit Report Received
- Date Final Audit Report Received

Filters

- **Manufacturer/ Audit Site**
- **Project**

2.6.6.8. General Contracts Report

The General Contracts report displays contracts between Fisher BioServices and Subcontractors\Consultants. This report displays the following information fields per Contract Number:

- Contract Number
- Subcontractor/ Consultant
- Title
- Contract Type
- Period of Performance
- Contract Status
- Contract Ceiling
- Comments

Filters

- **Contract Type**
- **Contract Status**
- **Contract Number**

2.6.6.9. General Contract Summary Report

The General Contract Summary Report provides a summary of the contract information of contracts between Fisher BioServices and Subcontractors/Consultants. This report displays the following information fields per Contract Number:

- Contract Number
- Contract Name
- Title
- Contract Type
- Brief Description of SOW
- Status of Contract
- Date Fully Executed
- Description
- Period of Performance Start Date/ End Date
- Effective Date
- Amount Funded
- Contract Ceiling
- Comments

Filters

- **Contract Type**
- **Contract Status**

2.6.7. Protocols

The Protocols menu for the Reports module will display links to the various reports that provide information pertaining protocols.

2.6.7.1. Agreements Report

The Protocol Agreements Report displays any agreements currently assigned to protocols. This report displays the following information fields per Protocol number:

- Protocol Number
- Protocol Champion
- Agreement Type
- Agreement Parties (1-4)
- Agreement Date

Filters

- **Agreement Type**
 - CMSA
 - CRADA
 - CTA
 - DIR
 - MTA

- VRC

Conditions

- The agreement must be associated with the Main Study Design of the Protocol.

Cross-links

- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.
- Protocol Champion – Cross-link to the Users Report, which provides information for that Protocol Champion.
- Agreement Parties – Cross-link to the Site Report, which provides information for these sites.

2.6.7.2. BioDefense Report

The BioDefense report lists protocols conducted for BioDefense. This report displays the following information fields per Protocol number:

- Protocol Number
- Protocol Title
- IND Number
- Program Code - Protocol Champion
- Protocol Status
- Disease 1/ Disease 2
- PPC
- Targeted Population

Filters

- **Protocol Status**
 - Active (Enrollment Ongoing)
 - Completed
 - Enrollment Completed
 - Hold
 - Not Done
 - Pending
 - Terminated
 - Concept Approved
 - Concept Deferred
 - Concept Denied
 - Concept Proposed
- **Priority Pathogen Category**
- **Diseases**

Conditions

- Report only presents protocols conducted for BioDefense

Cross-link

- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.

2.6.7.3. By Program Codes Report

The Protocols by Program Codes Report lists all Program Codes and the protocols associated with each. This report displays the following information fields per Program Code:

- Program Code
- Program Name
- Protocol Number
- Protocol Title
- Protocol Status
- Protocol Status Date
- Award Number

Filters

- **Program Code**

Cross-Links

- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.
- Award Number – Cross-link to the Awards Report, which provides information for that award.

2.6.7.4. Domestic/Non-US Report

The Domestic/Non-US Report displays information on protocols based on their performance sites and their location. This report displays the following information fields per Award Number:

- Country
- Award Number
- Protocol Number
- Protocol Title
- Lead PI
- Number of Registered Sites
- Number of Subjects Planned

Filters

- **Sites**
 - Non-US
 - Domestic
 - Both
 - None
- **Phases**

- II/ IIA
- IIA
- N/A
- Phase 1
- Phase 1 Challenge
- Phase 1/ Phase 2
- Phase 2
- Phase 2/ Phase 2A
- Phase 2/ Phase 3
- Phase 2A
- Phase 2B
- Phase 3
- Phase 3B
- Phase 4
- Phase II Challenge
- Phase III Challenge
- **Protocol Status**
 - Active (Enrollment Ongoing)
 - Completed
 - Enrollment Completed
 - Hold
 - Not Done
 - Pending
 - Terminated
 - Concept Approved
 - Concept Deferred
 - Concept Denied
 - Concept Proposed

Conditions

- The report displays all protocols with the number of registered sites, countries for those sites, and planned number of subjects for the study.

Cross-links

- Award Number – Cross-link to the Awards Report, which provides information for that award.
- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.
- Lead PI – Cross-link to the Users Report, which provides information for that Lead PI.

2.6.7.5. Initiation Letters Report

The Protocol Initiation Letter Report is used to track Protocol Initiation Letters by IND. This report displays the following information fields per IND number:

- IND Number
- Protocol Number
- Protocol Title

- DMID Regulatory Officer
- Protocol PI
- Site Name
- Date Letter Sent to PI
- Letter Status

Filters

- **IND Status**
 - Active
 - Hold
 - Inactive
 - Pending
 - Terminated
 - Transferred
 - Withdrawn
 - Active/ Pending/ Hold
 - Inactive/ Withdrawn/ Terminated
- **DMID Regulatory Officer**
- **Letter Status**
 - Done
 - N/A
 - Not Done
 - Pending

Cross-link

- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.

2.6.7.6. Personnel Report

The Personnel Report displays credential information for personnel involved with any protocols. This report displays the following information fields per Personnel Name:

- Personnel Name
- Protocol Number
- Sites
- Date of CV
- CV Received
- Financial Disclosure Date Signed
- Ethics Training Date
- Ethics Received by Fisher
- License State/ Type
- License Expiration Date
- License Received By Fisher
- Last Update

Filters

- **Protocol Number**
- **CV Received**

- Yes
- No
- N/A
- **License Received**
 - Yes
 - No
 - N/A
- **Ethics Training Received**
 - Yes
 - No
 - N/A
- **Financial Disclosure Received**
 - Yes
 - No
 - N/A

Cross-links

- Sites – Cross-link to the Site Report, which provides information for that site

2.6.7.7. Phase Report

The Phase Report displays information on protocols based on their phase and primary disease. This report displays the following information fields by Phase per Protocol Number:

- Disease 1
- Award Number
- IND Number
- Protocol Number
- Protocol Title
- Trial Phase
- Lead PI/ Protocol Champion
- Registered Sites
- Subjects Planned

Filters

- **Sites**
 - Non-US
 - Domestic
 - Both
- **Phases**
 - II/ IIA
 - IIA
 - N/A
 - Phase 1
 - Phase 1 Challenge
 - Phase 1/ Phase 2
 - Phase 2
 - Phase 2/ Phase 2A
 - Phase 2/ Phase 3

- Phase 2A
- Phase 2B
- Phase 3
- Phase 3B
- Phase 4
- Phase II Challenge
- Phase III Challenge
- **Protocol Status**
 - Active (Enrollment Ongoing)
 - Completed
 - Enrollment Completed
 - Hold
 - Not Done
 - Pending
 - Terminated
 - Concept Approved
 - Concept Deferred
 - Concept Denied
 - Concept Proposed

Cross-Links

- Award Number – Cross-link to the Awards Report, which provides information for that award.
- IND Number – Cross-link to the IND by Number report, which provides information for that protocol.
- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.

2.6.7.8. PPD Data Transfer Report

The PPD Data Transfer report is used by the CTi system administrator to upload XML files imported from PPD's website. The XML files contain information regarding new and existing protocols and their associated awards. Users no longer have the option to create new protocols through HSROAD. CTi uploads new XML files every night.

2.6.7.9. Protocol Details Report

The Protocol Details Report lists all protocols and allows the user to view the details information on a protocol by clicking on the protocol number. This report displays the following information fields per Protocol number:

- Protocol Number
- IND Number
- Protocol Short Name
- Protocol Title
- Archived

Filters

- **Sites**
 - Non-US
 - Domestic
 - Both
 - None
- **Phases**
 - II/ IIA
 - IIA
 - N/A
 - Phase 1
 - Phase 1 Challenge
 - Phase 1/ Phase 2
 - Phase 2
 - Phase 2/ Phase 2A
 - Phase 2/ Phase 3
 - Phase 2A
 - Phase 2B
 - Phase 3
 - Phase 3B
 - Phase 4
 - Phase II Challenge
 - Phase III Challenge
- **Protocol Status**
 - Active (Enrollment Ongoing)
 - Completed
 - Enrollment Completed
 - Hold
 - Not Done
 - Pending
 - Terminated
 - Concept Approved
 - Concept Deferred
 - Concept Denied
 - Concept Proposed

Conditions

- The report displays an IND number if there is one associated with the protocol.

Cross-Links

- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.

2.6.7.10. Protocol General Report

The Protocol General Report displays general information on all protocols. This report displays the following information fields per Protocol number:

- Protocol Number
- Award Number
- Version Numbers/ Version Dates
- IND Number
- IRB Approval Date
- Safety Monitor

Filters

- **Sites**
 - Non-US
 - Domestic
 - Both
- **Phases**
 - II/ IIA
 - IIA
 - N/A
 - Phase 1
 - Phase 1 Challenge
 - Phase 1/ Phase 2
 - Phase 2
 - Phase 2/ Phase 2A
 - Phase 2/ Phase 3
 - Phase 2A
 - Phase 2B
 - Phase 3
 - Phase 3B
 - Phase 4
 - Phase II Challenge
 - Phase III Challenge
- **Protocol Status**
 - Active (Enrollment Ongoing)
 - Completed
 - Enrollment Completed
 - Hold
 - Not Done
 - Pending
 - Terminated
 - Concept Approved
 - Concept Deferred
 - Concept Denied
 - Concept Proposed

Conditions

- Report displays all protocols and related information from the Main Study Design.

Cross-Links

- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.

- Award Number – Cross-link to the Awards Report, which provides information for that award.
- IND Number – Cross-link to the IND by Number report, which provides information for that protocol.

2.6.7.11. Protocol Status Report

The Protocol Status Report is used to track the status of protocols by Protocol Number. This report displays the following information fields per Protocol Number:

- Protocol Number
- Protocol Title
- Protocol PI
- Protocol Champion
- Protocol Status

Filters

- **Protocol Status**
 - Active (Enrollment Ongoing)
 - Completed
 - Enrollment Completed
 - Hold
 - Not Done
 - Pending
 - Terminated
 - Concept Approved
 - Concept Deferred
 - Concept Denied
 - Concept Proposed
 - Active/ Enrollment Completed/ Pending
- **Protocol Champion**

Cross-Links

- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.

2.6.7.12. Protocols by Site Report

The Protocols by Site Reports lists all sites with their associated protocols. Only sites with protocols are listed. The report displays the following information fields per Site:

- Site Name
- Address
- Protocol Number
- Protocol Title
- Current Status
- Last Status Update
- IND Number

- IND Title

Filters

- **Site Category**
 - Award
 - Clinical
 - Laboratories
 - Data Centers
 - Non-US
 - Domestic
- **Protocols Under Active INDs**

Conditions

- Site must be classified as a Protocol Award Site.

Cross-links

- View all site information – Cross-link to the Site Information report, which provides information for that protocol site in addition to the displayed address.
- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.
- IND Number – Cross-link to the IND by Number report, which provides information for that protocol.

2.6.7.13. Protocols (under Contracts or Grants) Report

The Protocols (Under Contracts or Grants) Report lists all protocols done under contracts or grants by phase. The purpose of the report is to track protocols in the Contracts or Grants portfolio that may need to be audited or monitored. This report displays the following information fields per Protocol:

- Trial Phase
- Protocol Number
- Protocol Title
- Status
- IND Number
- Protocol Champion
- DMID Regulatory Officer
- Awards
- Study Type (NLM)

Filters

- **Type of Study**
 - Interventional
 - Observational
 - Blank
- **Protocol Champion**
- **DMID Regulatory Officer**
- **Phases**
 - II/ IIA

- IIA
- N/A
- Phase 1
- Phase 1 Challenge
- Phase 1/ Phase 2
- Phase 2
- Phase 2/ Phase 2A
- Phase 2/ Phase 3
- Phase 2A
- Phase 2B
- Phase 3
- Phase 3B
- Phase 4
- Phase II Challenge
- Phase III Challenge

2.6.7.14. Protocols (under IND) by Date Report

The Protocols (under IND) by Date report displays protocols and their creation dates, which is the date the protocol record was created in the database system. The report displays the following information fields per Protocol Number:

- Protocol Number
- Protocol Title
- IND Number
- DMID Regulatory Officer
- Date Protocol was Created
- Protocol Status/ Status Date

Filters

- **Protocol Status**
 - Active (Enrollment Ongoing)
 - Completed
 - Enrollment Completed
 - Hold
 - Not Done
 - Pending
 - Terminated
 - Concept Approved
 - Concept Deferred
 - Concept Denied
 - Concept Proposed
- **DMID Regulatory Officer**
- **IND Status**
 - Active
 - Hold
 - Inactive
 - Pending
 - Terminated
 - Transferred

- Withdrawn
- Active/ Pending/ Hold
- Inactive/ Withdrawn/ Terminated

Condition

- Protocols created prior to January 1, 2001 will not be listed with a creation date.

Cross-links

- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.

2.6.7.15. Protocol Updates Report

The Protocol Updates report tracks protocols by Protocol Champions in order to provide them with a listing of protocols in their portfolio. This report displays the following information fields per Protocol by Program Code:

- Protocol Champion
- Program Code
- Awards
- Award PI
- Protocol Number
- Protocol Title
- Protocol Status
- Type of Study

Filters

- **Protocol Status**
 - Active (Enrollment Ongoing)
 - Completed
 - Enrollment Completed
 - Hold
 - Not Done
 - Pending
 - Terminated
 - Concept Approved
 - Concept Deferred
 - Concept Denied
 - Concept Proposed
 - Active/ Enrollment Completed/ Pending
- **Protocol Champion**
- **Type of Study**
 - Interventional
 - Observational
 - Blank

Conditions

- Report does not show protocols associated with INDs that have been transferred or archived protocols.

Cross-links

- Program Code – Cross-link to the Protocols by Program Codes report, which provides information for that protocol.
- Award Number – Cross-link to the Awards Report, which provides information for that award.
- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.

2.6.7.16. Violations/Deviations Report

The Protocol Violations/Deviations report lists details of all violations/deviations associated with each protocol, if any. This report displays the following information fields by Protocol Number:

- Protocol Number
- Protocol Title
- Protocol PI
- Site Name
- Description
- PID
- Date
- Received by Fisher
- Comments

Cross-links

- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.
- Site PI – Cross-link to the Users Report, which provides information for that Site PI.
- Site Name – Cross-link to the Site Report, which provides information for that site.

2.6.8. Shipping for CARIM

The Shipping for CARIM menu for the Report module will display links to reports that provide information regarding shipments of orders using information from the CARIM database.

2.6.8.1. DMID IND/IND for Human Use Report

The DMID IND/IND for Human Use report lists all DMID IND/IND for Human Use shipments along with their information. This report displays the following information fields per Shipping Number:

- Shipping Number

- Confirm Date
- Protocol/ IND
- PI- Performance
- Label Name
- Lot Number
- Units Shipped
- Units Type

2.6.8.2. NON-DMID IND/NON-IND for Human Use Report

The Non-DMID IND/Non-IND for Human Use report lists all Non-DMID IND/Non-IND for Human shipments along with their information. This report displays the following information fields per Shipping Number:

- Shipping Number
- Confirm Date
- Protocol/ IND
- PI- Performance
- Label Name
- Lot Number
- Units Shipped
- Units Type

2.6.8.3. Not for Human Use Report

The Not for Human Use report lists all Not for Human Use shipments along with their information. This report displays the following information fields per Shipping Number:

- Shipping Number
- Confirm Date
- Protocol/ IND
- PI- Performance
- Product Number
- Label Name
- Lot Number
- Units Shipped
- Units Type

2.6.8.4. Return Report

The Return report lists all DMID shipment returns along with their information. This report displays the following information fields per Returned Shipment Number:

- Returned Shipment Number
- Confirm Date
- Protocol/ IND
- Product Number
- Label Name

- Lot Number
- Manufacturer
- Units Returned
- Units Rejected
- Units Type

2.6.9. Sites Information Report

The Site Information Report lists all sites with their contact information and type of site. The report displays the following information fields by Site Name:

- Site Name
- Department
- Address
- Country
- Continent
- Phone Number
- Fax Number
- Type of Site
- Comments

Filter

- **Site Category**
 - Award
 - Clinical
 - Laboratories
 - Data Centers
 - Non-US
 - Domestic

Cross-Links

- See site Protocols – Cross-link to the Protocols by Site report, which lists all protocols associated to that site.
- See site Personnel – Cross-link to the Personnel Report, which lists all personnel associated to that site.

2.6.10. System

The System menu for the Report module will display links to history reports for the various components of the system.

2.6.10.1. Awards History Report

The Awards History Report shows the changes made to the records in the Awards table and who made those changes. Upon choosing this report, the user is given a list of

Awards in the history table, and clicking on an Award Number will show them the history for that record. This report displays the following information fields per Award number:

- Award Number
- Award Title
- Modified By
- Date Modified

Conditions

- Report displays changes made to an Award within the current year.

Cross-Links

- Award Number – Cross-link to the Awards Report, which provides information for that award.

2.6.10.2. Protocols History Report

The Protocols History Report shows the changes made to the records in the Protocols table and who made those changes. Upon choosing this report, the user is given a list of Protocols in the history table, and clicking on a Protocol Number will show them the history for that record. This report displays the following information fields per Protocol number:

- Protocol Number
- Protocol Title
- Modified By
- Date Modified

Conditions

- Report displays changes made to a Protocol within the current year.

Cross-Links

- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.

2.6.10.3. Study Design History Report

The Study Design History Report shows the changes made to the records in the Study Design table and who made those changes. Upon choosing this report, the user is given a list of Protocols with Study Design history, and clicking on a Protocol Number will show them the history for that record. This report displays the following information fields per Protocol number:

- Protocol Number
- Protocol Title
- Study Design Extension
- Modified By
- Date Modified

Conditions

- Report displays changes made to a Study Design within the current year.

Cross-Links

- Protocol Number – Cross-link to the Protocol Details report, which provides information for the protocol including cross-links to the Main, Performance Sites, Products, Study Design, and Documents information of that protocol.

2.6.10.4. Users Report

The Users Information Report shows the information on all the users currently in the system. This report displays the following information fields per User's Last Name:

- Last Name
- First Name
- Email Address
- Salutation
- Title
- Site
- Department
- Address
- Country
- Phone Number
- Fax Number
- Location
- Role
- Type of ID
- Type of Investigator
- Group Affiliation
- International Monitoring Group
- Group Name
-

Filters

- **Roles**
- **Types**
- **Groups**

2.6.10.5. Users Login History Report

The Users Login History Report displays the historical login information for all users that have entered the system. This report displays the following information fields per User Name:

- First and Last Name
- Role
- Total Login
- Last 30 days Login
- Last 5 Logins

- Avg. Overall Percentage

Filters

- **Month**
- **Year**

Cross-link

- User Profile – Cross-link to the Users Report, which provides information for that User.

2.6.10.6. IMPAC Upload Report

The IMPAC Upload Report is used to track the IMPAC Uploads. Uploads are done on a weekly basis for Award data. The report lists the status of the upload. If an error occurs in the upload process of data associated with an award, an error message will appear on the report. The System Administrator must correct the error prior to the next upload. This report displays the following information fields per Award number:

- Award Number
- Message Description
- Date Upload

2.6.10.7. PPD CTM Upload Report

The PPD CTM Upload report lists only the details of the XML files transferred the night before. If there is a warning regarding any of the files transferred, the database is updated, but the value in question might not be listed in HSROAD. If there is an error, the database is not updated, and has to be fixed before the next update. If it is a technical error CTi will try to fix it, however, it is a data error then Fisher BioServices or CTi will contact PPD to resolve the error. This report displays the following information fields by previous night upload:

- Message Type
- Comments

Filters

- **Error**
- **Message**
- **Warning**

2.6.10.8. PPD CTM History Report

The PPD CTM History report tracks all the history for each data transfer for the past year only. Upon choosing this report, the user is presented with a list of all files transferred, and clicking on a file name will display the history for that file. This report displays the following information fields per file name:

- File Name

- Original File Name
- Uploaded by
- Date Processed
- Message Type
- Comments

Cross-link

- File Name – Cross-link to PPD Upload History report, which provides all the details for that XML file.

2.6.10.9. PPD CTM Mapping Report

The PPD CTM Mapping report maps the lookup values between HSROAD and PPD. This report displays the following information fields per Value:

- Schema Element
- Table Name
- HSROAD ID
- HSROAD Value
- CTM ID
- CTM Value

Filters

- **Schema Element**
- **Table Name**

2.6.10.10. PDF Compressor Report

The PDF Compressor report tracks only the PDF files that were compressed the night before. The PDF Compressor compresses PDF files uploaded into smaller file sizes. This report displays the following information fields by previous night activity:

- Doc ID – Title
- Message Type
- Comments

Filters

- **Errors**
- **Message**
- **Warning**

2.7. System Administration Module

The System Administration module is used for the administration of the system. Only users with administrative access level will be presented with the options to view, create, modify, or delete information regarding users, documents, utilities, system tables, etc.

This module can be entered from the HSROAD Main Menu by users with administrative access level. The user will be presented with a menu on the left-hand side with links to each of the individual sub-modules for the system administration area.

2.7.1. User Information

The User Information module will display links to the three sub-modules that compose this area that help administer user/group accounts and roles.

2.7.1.1. User Accounts

The User Account module is used to setup or modify all information pertaining to the users in the system. This module can be entered from the System Administration module for users with administrative access level. Upon entering the User Accounts module, the administrator will be presented with a table listing all the available users in the system. The table can be sorted by the user ID, last name, first name or role name by clicking on the column header or the administrator can search for a user by entering a portion of their first or last name in the search box. Options will be presented to create, modify or delete user information.

Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Support | Log Out Donna (System Administrator) ?

Order It | Protocols | Protocol Support | Project Management | Agreements | Reports | System Administration

▼ User Information
 User Accounts
 Group Accounts
 Roles
 ▶ Documents
 ▶ Utilities
 ▶ Data Dictionary
 ▶ NLM Administration
 ▶ Order It Access
 ▶ Custom Data Mapping

User Accounts

Select a user below or enter a User ID in the search to view or modify a user record.
Click the 'Create a User' link to create a new user.

✚ Create a User

First and/or Last Name:

✎ = Edit ✎ = Delete

Actions	User ID	Last Name	First Name	Role Name	Archived
✎ ✕	0suser	0	suser	Site user	
✎ ✕	0suser0	Rangu	Suneetha	Site user	•
✎ ✕	10suser10	10	suser10	Site user	
✎ ✕	111drm	site	user	Site user	
✎ ✕	11suser11	11	user11	Site user	
✎ ✕	1suser	1	suser	Site user	
✎ ✕	1suser1	1	suser1	Site user	
✎ ✕	1vvsuser	suser	1vv	Site user	
✎ ✕	2suser	2	suser	Site user	
✎ ✕	2suser2	2	suser2	Site user	
✎ ✕	2vvsuser	2vv	suser	Site user	

Figure 39: User Accounts module

In addition, note that the field names with the red dot denote the “required” or “mandatory” fields. These fields must be filled before the user record can be saved.

Inactive users will be indicated by a red dot in the Archive column and will not have access to the system. These users can be permanently deleted from the system if desired.

2.7.1.2. Group Accounts

The Group Accounts module is used to set up and edit user groups. This module can be entered from the System Administration module for users with administrative access. Upon entering the Group Accounts module, the administrator will be presented with a table listing all the available groups in the system. The table can be sorted by group Id, group name, program officer, objective or numbers of users in the group or the administrator can search for a group by entering a portion of the group name or objective in the search box. Options will be presented to create, modify or delete a group. When creating or modifying a group, the administrator will also be able to assign or un-assign users to a group.

Group Accounts

Select a group below or enter a Group Name in the search to view or modify a group record. Click the 'Create a Group' link to create a new group.

[Create a Group](#)

= Edit = Delete

Search criteria: All Groups

Action	Group ID	Group Name	Program Officer	Objective	Users per Group
	148	DDD	FName-DemoAdmin LName-Doc	DocDemo-Objective	0
	87	Gambia	George Corbin	Gambia	3
	141	HRTD	Contact Sys Admin Net Listed		0
	34	M21	Rory Duncan	Micrology Program	7
	35	M22	James Meegan	Acute Viral Diseases	9
	36	M23A	James Meegan	Acute Viral Diseases Program	7
	37	M23B	Pat Repp	Emerging Viral Disease Program	8
	38	M23C	Mark Chelberg	Protein and Other Acute Viruses Program	7
	39	M23a	Col Jacobs	Born Microbiology, Diagnostics, Small Business	14

Figure 40: Group Accounts module

Note: The field names with the red dot denote the “required” or “mandatory” fields. These fields must be filled before the group account can be saved.

A group account can be permanently deleted from the system if desired.

2.7.1.3. Roles

The Roles module is used to set up and edit user roles for assigning access to the various modules and sub-sections of the application. This module can be entered from the System Administration module for users with administrative access level. Upon entering the Roles module, the administrator will be presented with a table listing all the available roles in the system. The table can be sorted by role id, name, and number of users assigned to that role or the administrator can search for a role by entering a portion of the role name in the search box. Options will be presented to create, modify or delete a role.

Action	Role ID	Role Name	Users per Role
	10	Barcode User	1
	1	Not Assigned	2012
	8	PPD Monitor	45
	9	PPD Read-Only	21

Figure 41: Roles module

Note: The field names with the red dot denote the “required” or “mandatory” fields. These fields must be filled before the role record can be saved. Also, only roles with no users assigned may be deleted.

The following permissions may be assigned through the Roles Module:

- System Administration (all system administration rights)
- Reports (must be given access to reports to view any reports)
 - Report Sub-Menu (to assign which specific reports this role has access to)
 - Awards
 - Expired Awards
 - Book Inventory
 - Documents
 - Annual Report Status
 - Annual Report
 - IND By Disease
 - IND By Number
 - IND Regulatory
 - IND Short Summary
 - IND Summary
 - Investigator’s Brochures
 - Old IND Summary
 - Pre-IND Short Summary
 - Pre-IND Summary
 - Products By IND
 - Signature Block
 - Clinical Monitoring
 - Foreign PPD Monitoring
 - International Monitoring Contact List
 - Monitoring By Site
 - Monitoring Report
 - PPD Monitoring Schedule
 - Inventory/Shipping for CARIM
 - Orders
 - Products
 - Audit Request Form

- Auditing Schedule
- Auditor Area of Expertise
- Auditors/Consultants Contact
- Conflicts Reports
- Contract Office Submissions
- Draft Final Due Dates
- General Contracts/General Contract Summary
- Agreements
- BioDefense
- By Program Code
- Domestic/Non-US
- Initiation Letters
- NLM
- NLM Summary
- Personnel
- Phase
- PPD Date Transfer
- Protocol Details
- Protocol General
- Protocol Status
- Protocol By Site
- Protocols (Under Contracts or Grants) By Phase
- Protocols (Under IND) By Date
- Protocol Updates
- Protocol Violations
- Site Information
- Award History
- Protocol History
- Study Design History
- Users
- User Login History
- Protocol (Create, modify, delete)
 - Protocol Sub-Menu (defines access to specific fields on the Protocol form)
 - Award Short name
 - Protocol Champion
 - Study Director (Lead PI)
 - Program Access Group
 - Program Code
 - Group Affiliation
 - DMID Held IND
 - IND Sponsor
 - Monitoring Fields
 - See All Protocols (gives this role access to view all protocols, not just ones they have access to)
- Performance Sites (Create, modify, delete)
 - Performance Sites Sub-Menu (defines access to specific fields)
 - Form FDA1572
 - PI Curriculum Vitae
 - Protocol Initiation Letter Date
 - Protocol Initiation Letter Status

- Regulatory Documents
- Products (Create, modify, delete)
 - Products Sub-Menu (defines access to specific fields)
 - Lot Number
 - Expiration Date
- Holds (Create, modify, delete)
- Study Design – Agreements (Create, modify, delete)
 - Study Design Submenu (defines access to specific fields on the Study Design form)
 - Study Category
 - Control Category
 - Complexity Assessment
 - Complexity Assessment Reason
 - Type of Study
- Inclusion/Exclusion (Create, modify, delete)
- Create Sub-protocol (defines access to create Protocol Extensions)
- Sites (Create, modify, delete)
- IND Submissions (Create, modify, delete)
- Products (Create, modify, delete)
- Schedule PPD Monitoring (Create, modify, delete)
- Order it Module (Create, Modify, Delete, Approve/Reject)
- Auditing Schedule Info (Create, modify, delete)
- Contract Office Submissions (Create, modify, delete)
- General Contracts (Create, modify, delete)
- MTA (Create, modify, delete)
- DocuTrak
 - Barcode & Tracking
 - Delete Barcodes
 - Ipaq
 - Scan
 - HSROAD
 - Documents Admin
 - Attachments
 - View Documents

Note: The field names with the red dot denote the “required” or “mandatory” fields. These fields must be filled before the role information can be saved.

A role can be permanently deleted from the system if desired.

2.7.2. Documents

The Documents module is used to add, view, or delete documents available in the system. This module can be entered from the System Administration module for users with administrative access level. Upon entering the Documents module, the administrator will be presented with a table listing all documents and their respective information. The table can be sorted by doc ID- title, document type, source, protocol number, or IND by clicking on the column headers or the administrator can search for a

document by entering a portion of the document title, protocol number, or IND in the search box.

A document can be permanently deleted from the system if desired.

2.7.3. Utilities

The Utilities module is used to edit the Lookup tables for the application as well as deleting Protocols from the system. This module can be entered from the System Administration module for users with administrative access level. Upon entering the Utilities module, the administrator will be presented with a table listing all the available lookup tables in the system. The table can be sorted by the table name or description, or the user can search for a table by entering a portion of the table description in the search box. Upon choosing a lookup table, the user will then have the option to edit, delete, or add records to the table.

Please note that the LuTables (Look-Up tables) performs a different function. Adding or editing the records in this table will affect the tables that are displayed in the Utilities module. Edits made here will only affect the Utilities module, and will not remove or change the table name in the database.

The Protocols table does not allow any creation or editing of records, but is used merely to delete inactive protocols from the system. Deleting protocols in the Utility module is permanent, as they will be removed from the database.

2.7.4. Data Dictionary

The Data Dictionary menu will display links to the sub-modules which give administrators access to the database information. The administrators will have access to all the tables, stored procedures, and triggers for the system. For more details on database information please refer to section 4 of this document.

2.8. Awards/IMPACII

The Awards module is no longer an option on the HSROAD main menu. However, awards information is still available for viewing on HSROASD under the Reports module. The Awards reports will display all awards and their information along with any associated protocols. The award information is transferred from IMPAC on a weekly basis to HSROAD. IMPACII is the application that transfers all award data from the IMPAC database to the IMPAC table, which then uses the data captured to populate the Awards section on HSROAD.

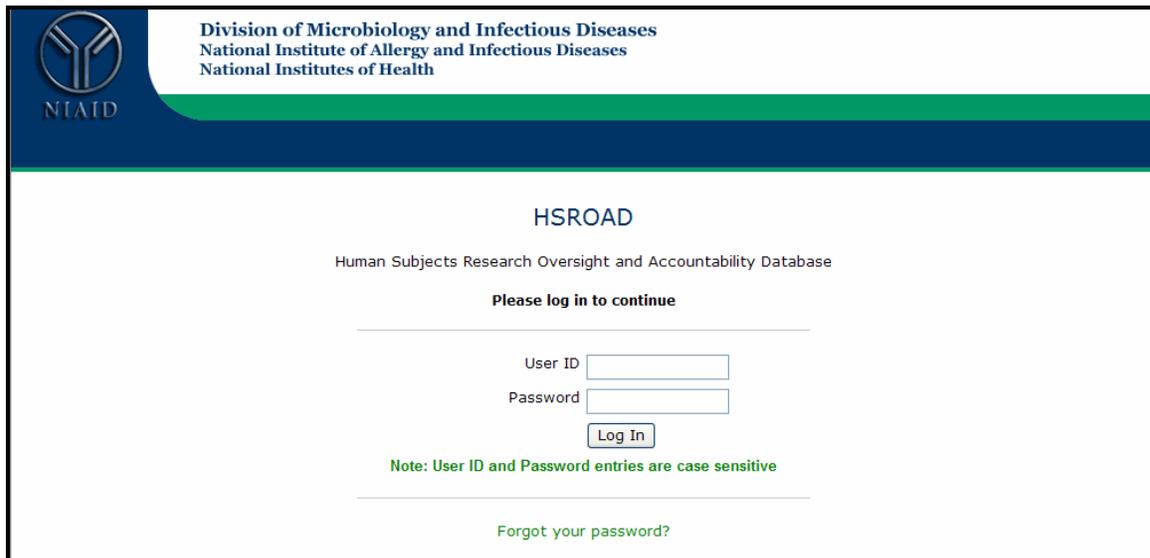
3. Methods for Ensuring Security

Three levels of control for permissions and access have been implemented to the HSROAD system. These levels are: 1) access into the system; 2) access to each module of the system; and 3) access to certain records provided in each module.

These levels of access control grant users with proper **id** and **password** permission into the system. Once having access into the system, the user is given access to each of the modules in the system based on the **role** assigned to the **id**. Finally, the user access to certain records within the module based on the **business rules** established for each. Below we describe each level and, where appropriate, provide an example.

3.1. Login

When the user accesses the system from their browser, they are presented with a login screen. If an account has been established, the user will use that account **id** and **password** to gain access to the system. If no account has been provided, a user will not gain access to the application.



Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health

NIAID

HSROAD

Human Subjects Research Oversight and Accountability Database

Please log in to continue

User ID

Password

Log In

Note: User ID and Password entries are case sensitive

[Forgot your password?](#)

Figure 42: HSROAD Login Screen

3.2. Roles

Once a user has successfully gained access, the system will control which modules will be available based on the **role** defined for the user. The user's role description will be displayed next to his/her name on the green bar. The role defined for the user will also determine what options and links are available on the home page. Some users will have links to the Order It and to the Create/View Audit Requests modules. Users with the

permission to approve orders will also see a link indicating that there are orders pending for approval.

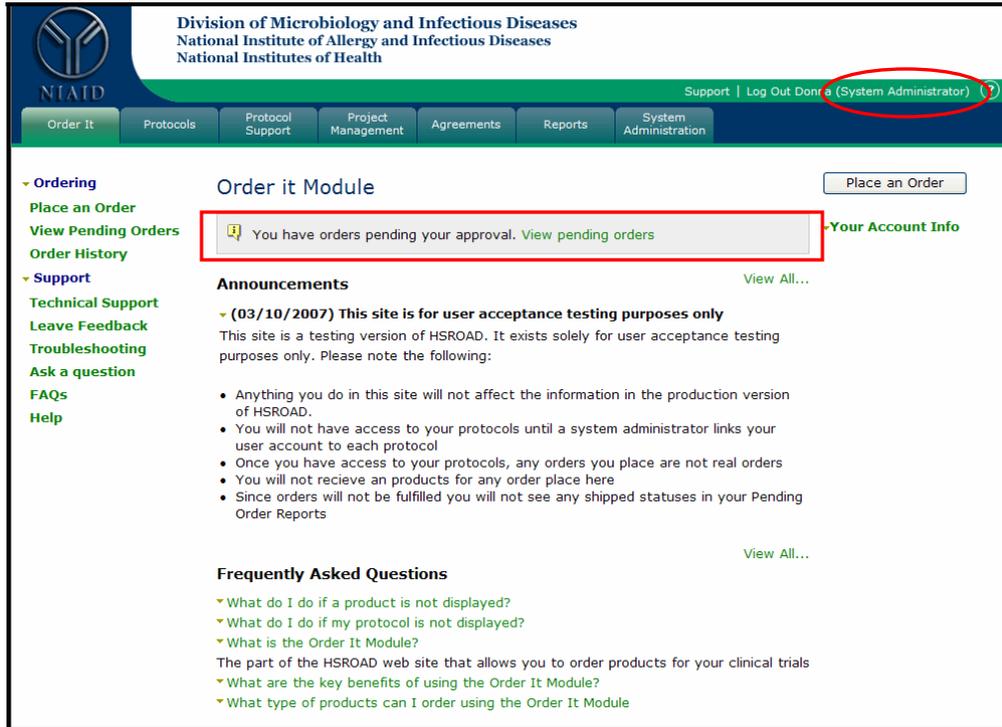


Figure 43: HSROAD Home Page

Under the System Administration's option, a user can find a module called "Roles" for the creation and management of roles. A user with "System Administrative" access level can create the definitions of each role. Each role is defined as having "Create", "Modify", and "Delete" action available within each module.

For instance, a user with a Role of "Program/Project Officer" is defined as having at least "Create" and "Modify" rights for Protocols, Product, and Project Management modules in the system.

As some new requirements have been defined and for the system to have the ability to handle them, new permissions have been created and some existing permissions have been removed. For example, under Protocols we no longer have "IND Submission" and "Investigational Use Only" listed as permissions. The access level of a role can range from limited to unrestricted. Below are listed all the current roles and their respective permissions:

Role: Barcode User

	Create	Modify	Delete	Action
Awards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocols	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
See All Protocols	<i>Enables users to see all protocols</i>			<input checked="" type="checkbox"/>
Performance Sites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Holds	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Study Design - Agreements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Inclusion/Exclusion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocol Support				
Sites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IND Submissions	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Old INDs / B&T	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Pre-IND Module	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Schedule PPD Monitoring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Order It Module	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	approve/reject <input type="checkbox"/>
Project Management				
Auditing Schedule Info	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Contract Office Submissions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
General Contracts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Agreements				
MTA	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Reports	<input checked="" type="checkbox"/>			
System Administration	<i>Enables all actions for Administration</i>			<input type="checkbox"/>
DocuTrak	<i>Document Management applications and HSROAD sections</i>			

Role: Not Assigned

	Create	Modify	Delete	Action
Awards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocols	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
See All Protocols	<i>Enables users to see all protocols</i>			<input type="checkbox"/>
Performance Sites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Holds	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Study Design - Agreements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Inclusion/Exclusion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocol Support				
Sites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IND Submissions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Old INDs / B&T	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pre-IND Module	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Schedule PPD Monitoring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Order It Module	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	approve/reject <input type="checkbox"/>
Project Management				
Auditing Schedule Info	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Contract Office Submissions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
General Contracts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Agreements				
MTA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Reports	<input type="checkbox"/>			
System Administration	<i>Enables all actions for Administration</i>			<input type="checkbox"/>
DocuTrak	<i>Document Management applications and HSROAD sections</i>			

Role: PPD Monitor

	Create	Modify	Delete	Action
Awards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocols	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
See All Protocols	<i>Enables users to see all protocols</i>			<input checked="" type="checkbox"/>
Performance Sites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Holdings	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Study Design - Agreements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Inclusion/Exclusion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocol Support				
Sites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IND Submissions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Old INDs / B&T	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pre-IND Module	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Schedule PPD Monitoring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Order It Module	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>approve/reject</i> <input type="checkbox"/>
Project Management				
Auditing Schedule Info	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Contract Office Submissions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
General Contracts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Agreements				
MTA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Reports	<input checked="" type="checkbox"/>			
System Administration	<i>Enables all actions for Administration</i>			<input type="checkbox"/>
DocuTrak	<i>Document Management applications and HSROAD sections</i>			

Role: PPD Read-Only

	Create	Modify	Delete	Action
Awards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocols	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
See All Protocols	<i>Enables users to see all protocols</i>			<input checked="" type="checkbox"/>
Performance Sites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Holdings	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Study Design - Agreements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Inclusion/Exclusion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocol Support				
Sites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IND Submissions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Old INDs / B&T	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pre-IND Module	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Schedule PPD Monitoring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Order It Module	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>approve/reject</i> <input type="checkbox"/>
Project Management				
Auditing Schedule Info	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Contract Office Submissions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
General Contracts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Agreements				
MTA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Reports	<input checked="" type="checkbox"/>			
System Administration	<i>Enables all actions for Administration</i>			<input type="checkbox"/>
DocuTrak	<i>Document Management applications and HSROAD sections</i>			

Note: Prin

Role: Program/Project Officer

	Create	Modify	Delete	Action
Awards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocols	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
See All Protocols	<i>Enables users to see all protocols</i>			<input type="checkbox"/>
Performance Sites	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Products	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Hold	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Study Design - Agreements	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Inclusion/Exclusion	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Protocol Support				
Sites	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
IND Submissions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Old INDs / B&T	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pre-IND Module	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Products	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Schedule PPD Monitoring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Order It Module	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	approve/reject <input checked="" type="checkbox"/>
Project Management				
Auditing Schedule Info	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Contract Office Submissions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
General Contracts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Agreements				
MTA	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Reports	<input checked="" type="checkbox"/>			
System Administration	<i>Enables all actions for Administration</i>			<input type="checkbox"/>
DocuTrak	<i>Document Management applications and HSROAD sections</i>			

Role: Project Manager

	Create	Modify	Delete	Action
Awards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocols	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
See All Protocols	<i>Enables users to see all protocols</i>			<input type="checkbox"/>
Performance Sites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Hold	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Study Design - Agreements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Inclusion/Exclusion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocol Support				
Sites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IND Submissions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Old INDs / B&T	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pre-IND Module	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Schedule PPD Monitoring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Order It Module	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	approve/reject <input type="checkbox"/>
Project Management				
Auditing Schedule Info	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Contract Office Submissions	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
General Contracts	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Agreements				
MTA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Reports	<input checked="" type="checkbox"/>			
System Administration	<i>Enables all actions for Administration</i>			<input type="checkbox"/>
DocuTrak	<i>Document Management applications and HSROAD sections</i>			

Role: Protocol Reports User

	Create	Modify	Delete	Action
Awards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocols	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
See All Protocols	<i>Enables users to see all protocols</i>			<input type="checkbox"/>
Performance Sites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Holdings	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Study Design - Agreements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Inclusion/Exclusion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocol Support				
Sites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IND Submissions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Old INDs / B&T	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pre-IND Module	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Schedule PPD Monitoring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Order It Module	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	approve/reject <input type="checkbox"/>
Project Management				
Auditing Schedule Info	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Contract Office Submissions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
General Contracts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Agreements				
MTA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Reports	<input checked="" type="checkbox"/>			
System Administration	<i>Enables all actions for Administration</i>			<input type="checkbox"/>
DocuTrak	<i>Document Management applications and HSROAD sections</i>			

Roles: Protocol User

A user with a Role of “Protocol User” has access to “Modify” in the Protocol module and limited to records as described in the business rules in the following section.

	Create	Modify	Delete	Action
Awards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocols	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
See All Protocols	<i>Enables users to see all protocols</i>			<input type="checkbox"/>
Performance Sites	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Products	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Holdings	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Study Design - Agreements	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Inclusion/Exclusion	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Protocol Support				
Sites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IND Submissions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Old INDs / B&T	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pre-IND Module	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Schedule PPD Monitoring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Order It Module	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	approve/reject <input type="checkbox"/>
Project Management				
Auditing Schedule Info	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Contract Office Submissions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
General Contracts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Agreements				
MTA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Reports	<input checked="" type="checkbox"/>			
System Administration	<i>Enables all actions for Administration</i>			<input type="checkbox"/>
DocuTrak	<i>Document Management applications and HSROAD sections</i>			

Roles: Reg. Officer/Barcode

	Create	Modify	Delete	Action
Awards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocols	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
See All Protocols	<i>Enables users to see all protocols</i>			<input checked="" type="checkbox"/>
Performance Sites	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Products	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Holds	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Study Design - Agreements	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Inclusion/Exclusion	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Protocol Support				
Sites	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
IND Submissions	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Old INDs / B&T	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Pre-IND Module	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Products	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Schedule PPD Monitoring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Order It Module	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	approve/reject <input type="checkbox"/>
Project Management				
Auditing Schedule Info	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Contract Office Submissions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
General Contracts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Agreements				
MTA	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Reports	<input checked="" type="checkbox"/>			
System Administration	<i>Enables all actions for Administration</i>			<input type="checkbox"/>
DocuTrak	<i>Document Management applications and HSROAD sections</i>			

Role: Regulatory Officer

	Create	Modify	Delete	Action
Awards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocols	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
See All Protocols	<i>Enables users to see all protocols</i>			<input checked="" type="checkbox"/>
Performance Sites	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Products	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Holds	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Study Design - Agreements	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Inclusion/Exclusion	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Protocol Support				
Sites	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
IND Submissions	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Old INDs / B&T	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Pre-IND Module	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Products	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Schedule PPD Monitoring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Order It Module	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	approve/reject <input checked="" type="checkbox"/>
Project Management				
Auditing Schedule Info	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Contract Office Submissions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
General Contracts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Agreements				
MTA	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Reports	<input checked="" type="checkbox"/>			
System Administration	<i>Enables all actions for Administration</i>			<input type="checkbox"/>
DocuTrak	<i>Document Management applications and HSROAD sections</i>			

Role: Report User

	Create	Modify	Delete	Action
Awards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocols	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
See All Protocols	<i>Enables users to see all protocols</i>			<input checked="" type="checkbox"/>
Performance Sites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Holds	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Study Design - Agreements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Inclusion/Exclusion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocol Support				
Sites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IND Submissions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Old INDs / B&T	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pre-IND Module	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Schedule PPD Monitoring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Order It Module	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>approve/reject</i> <input type="checkbox"/>
Project Management				
Auditing Schedule Info	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Contract Office Submissions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
General Contracts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Agreements				
MTA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Reports	<input checked="" type="checkbox"/>			
System Administration	<i>Enables all actions for Administration</i>			<input type="checkbox"/>
DocuTrak	<i>Document Management applications and HSROAD sections</i>			

Role: Site User

Users in this role have full access to the Order It Module. Access to a specific protocol is controlled at the Performance site level.

	Create	Modify	Delete	Action
Awards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocols	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
See All Protocols	<i>Enables users to see all protocols</i>			<input type="checkbox"/>
Performance Sites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Holds	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Study Design - Agreements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Inclusion/Exclusion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocol Support				
Sites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IND Submissions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Old INDs / B&T	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pre-IND Module	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Products	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Schedule PPD Monitoring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Order It Module	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<i>approve/reject</i> <input type="checkbox"/>
Project Management				
Auditing Schedule Info	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Contract Office Submissions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
General Contracts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Agreements				
MTA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Reports	<input checked="" type="checkbox"/>			
System Administration	<i>Enables all actions for Administration</i>			<input type="checkbox"/>
DocuTrak	<i>Document Management applications and HSROAD sections</i>			

Role: System Administrator

	Create	Modify	Delete	Action
Awards	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocols	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
See All Protocols	<i>Enables users to see all protocols</i>			<input checked="" type="checkbox"/>
Performance Sites	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Products	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Holds	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Study Design - Agreements	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Inclusion/Exclusion	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Protocol Support				
Sites	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
IND Submissions	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Old INDs / B&T	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Pre-IND Module	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Products	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Schedule PPD Monitoring	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Order It Module	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<i>approve/reject</i> <input checked="" type="checkbox"/>
Project Management				
Auditing Schedule Info	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Contract Office Submissions	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
General Contracts	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Agreements				
MTA	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Reports	<input checked="" type="checkbox"/>			
System Administration	<i>Enables all actions for Administration</i>			<input checked="" type="checkbox"/>
DocuTrak	<i>Document Management applications and HSROAD sections</i>			

With the use of Roles, we can now create any type of access levels needed for the different requirements at any given time. Records within each module will be available to a user/role according to the set of business rules in that module.

3.3. Business Rules

Business rules are defined as guidelines that indicate how the system will behave under certain conditions. In this case, the defined rules are as to how records are presented or made available to users in each module. This will provide the conditions assigned to the user's login and roles for which records the user may access within a module.

3.3.1. Protocol Rule

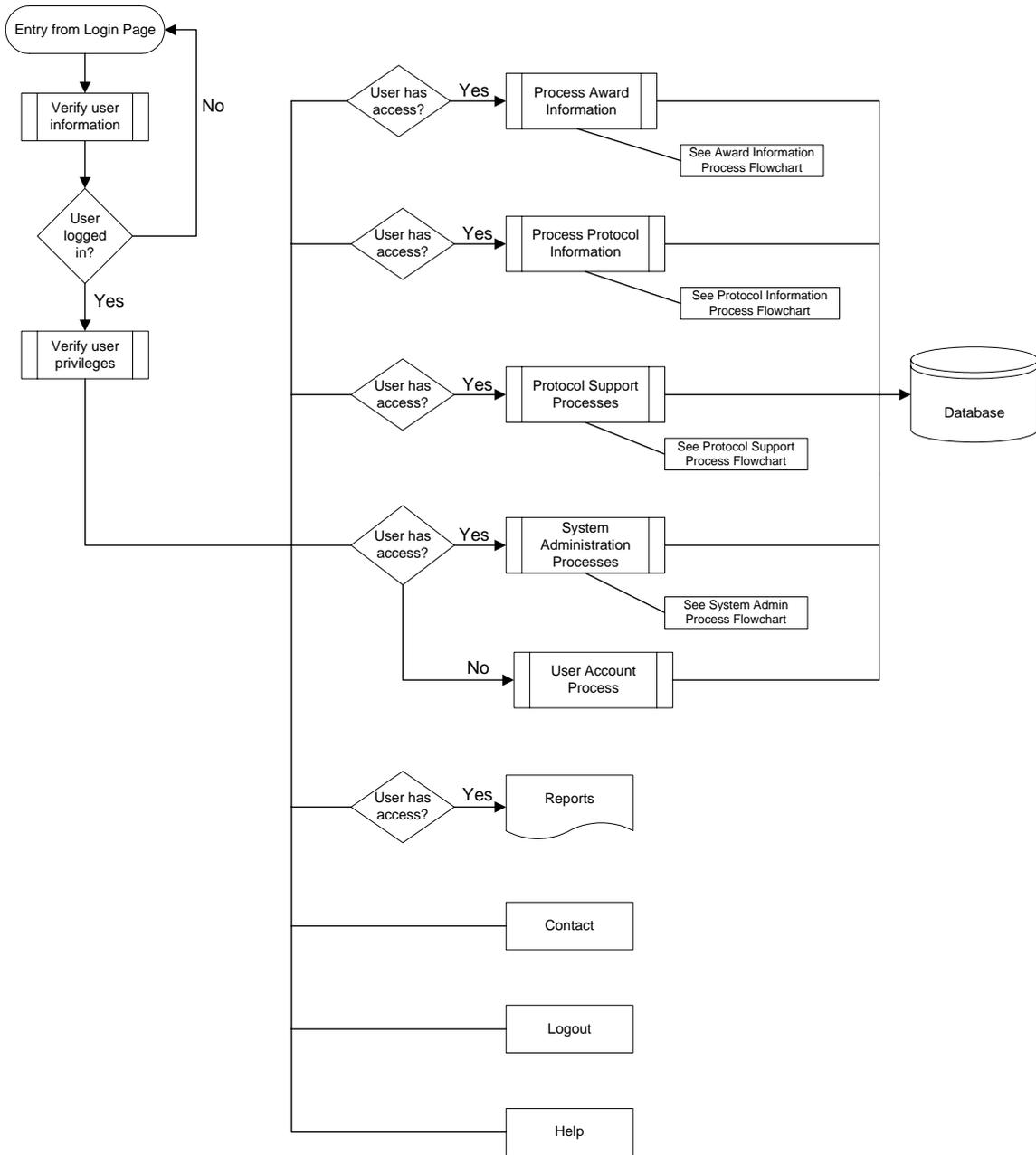
A Protocol Rule is defined as a user who:

- Created a protocol [*This is not used now as protocol comes from PPD*]
- Selected as the Protocol Champion for the protocol
- Selected as the RAS for the protocol
- Selected as the Lead PI(Study Director) for the protocol
- Selected as the Medical Monitor for the protocol

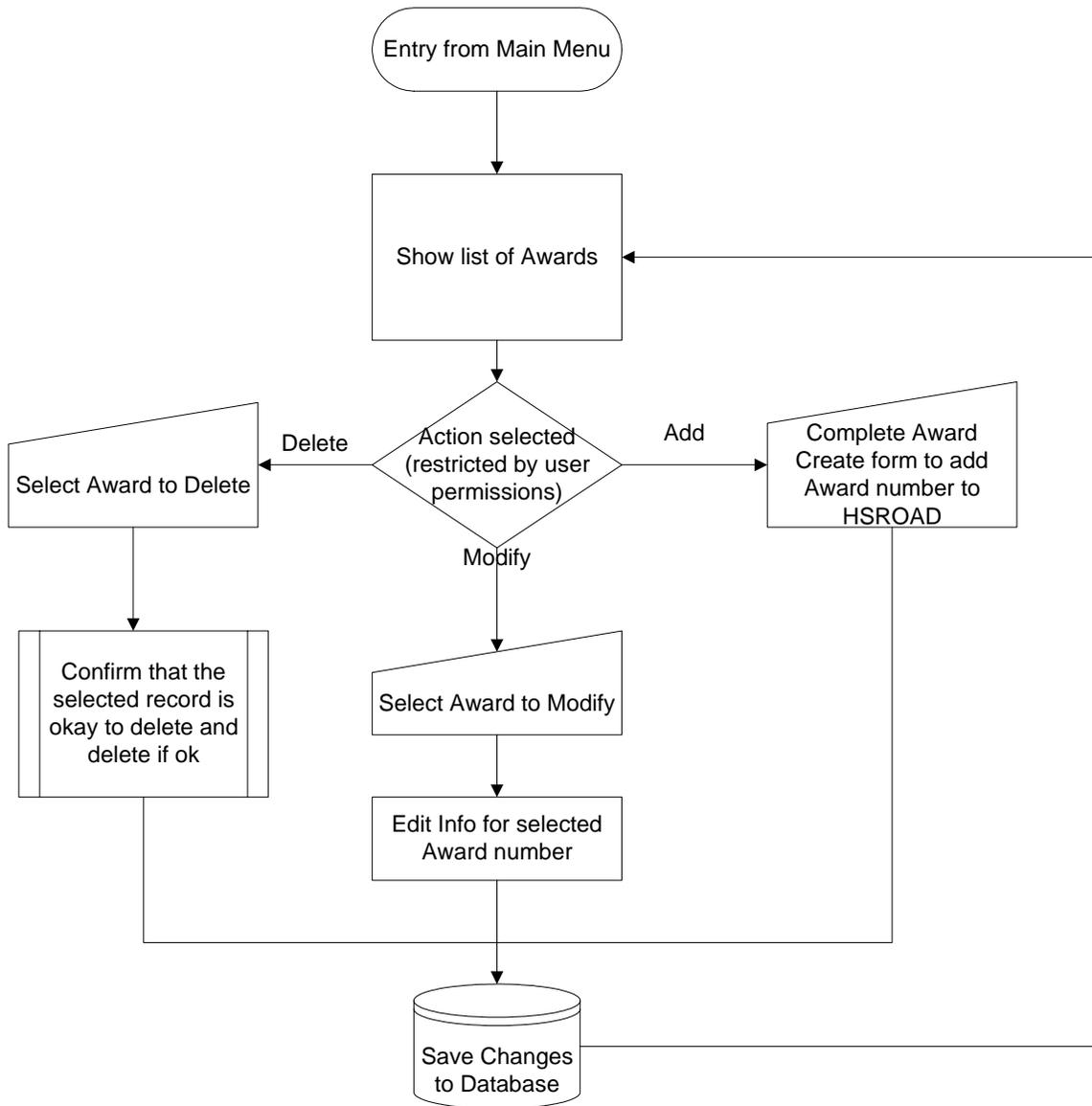
- Selected as the HSROAD contact for the protocol [*This is not in use yet*]
- Selected as the Protocol PI at the performance site that is associated with a protocol.
- Selected as the Site Coordinator at the performance site that is associated with a protocol.
- Selected as the Site User with Access to view reports or create orders.
- Selected as a member in the program access group (program code - groups)
- Selected as user where the user's site (user form) is the Data Collection Site of the protocol

4. Appendix – Functional Process Flowcharts

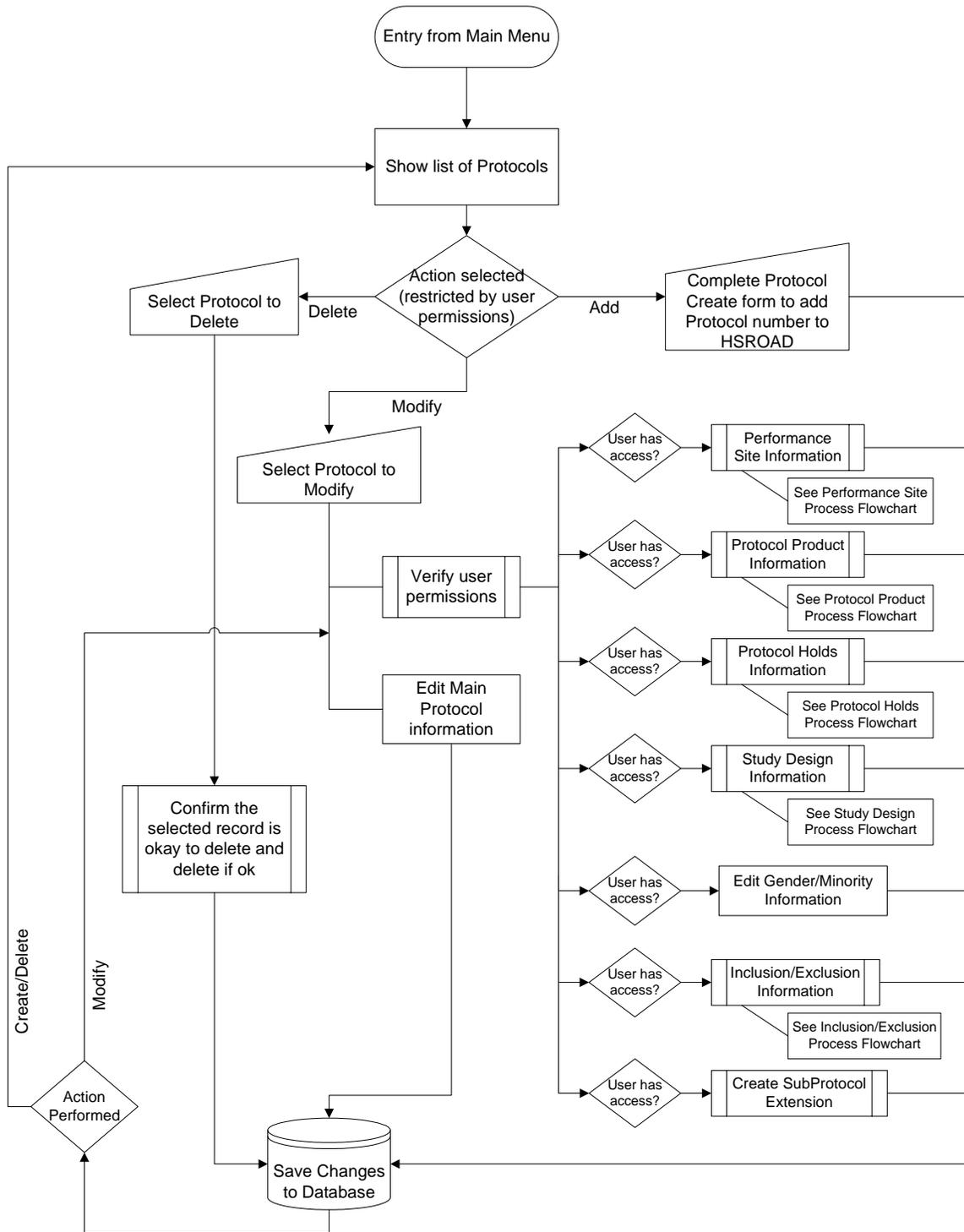
High Level System Flowchart



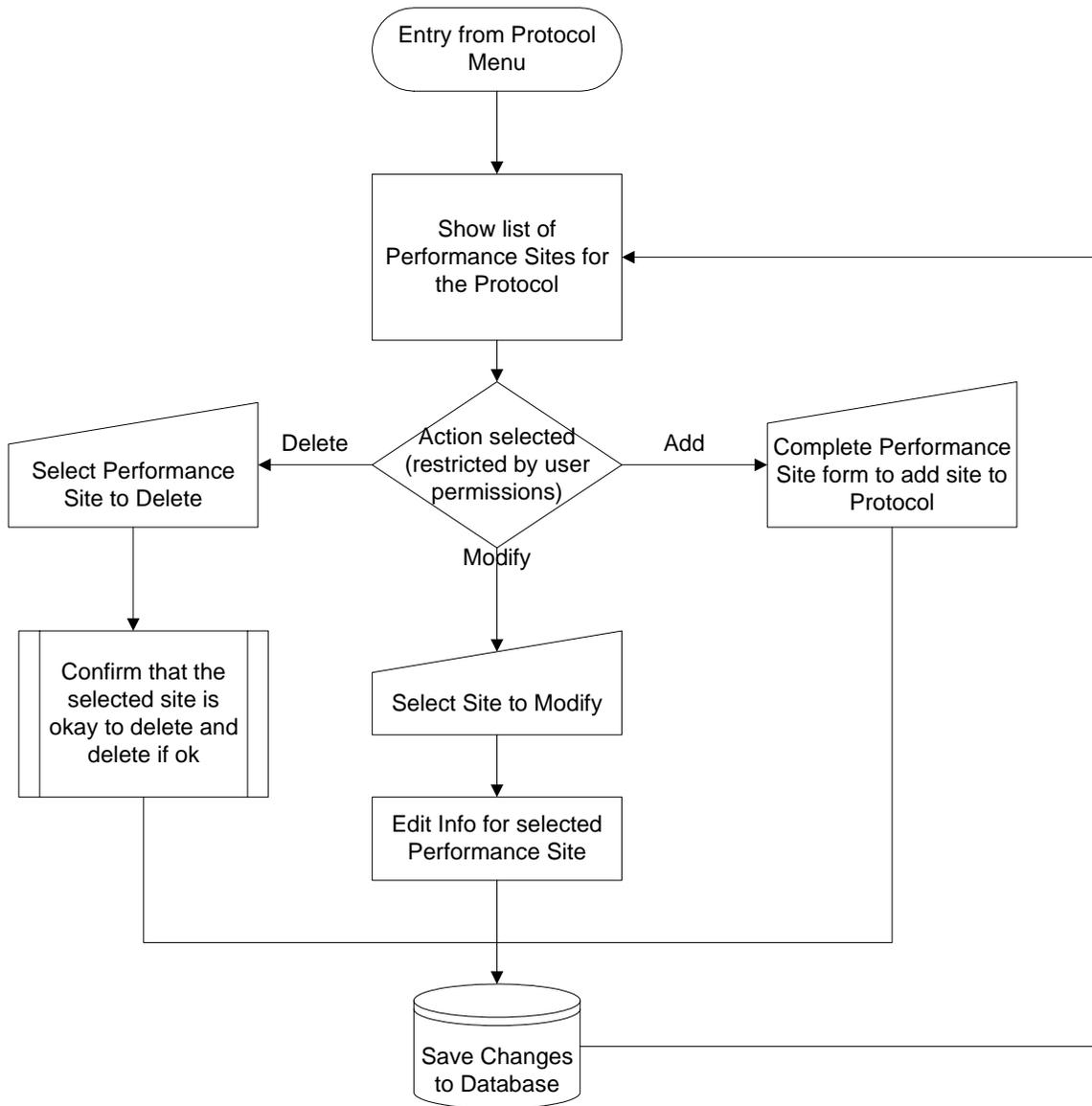
Awards Module



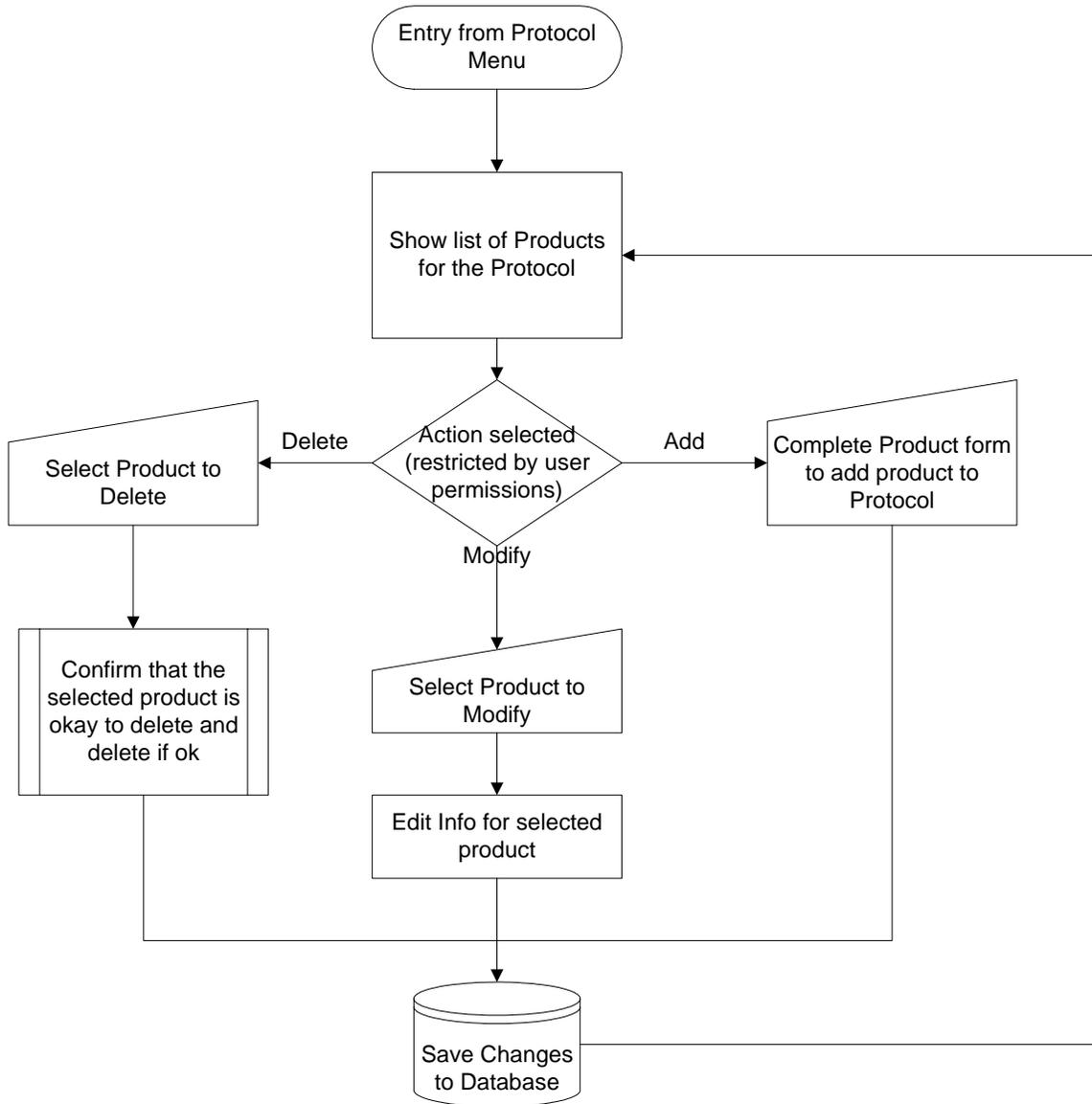
Protocols Module



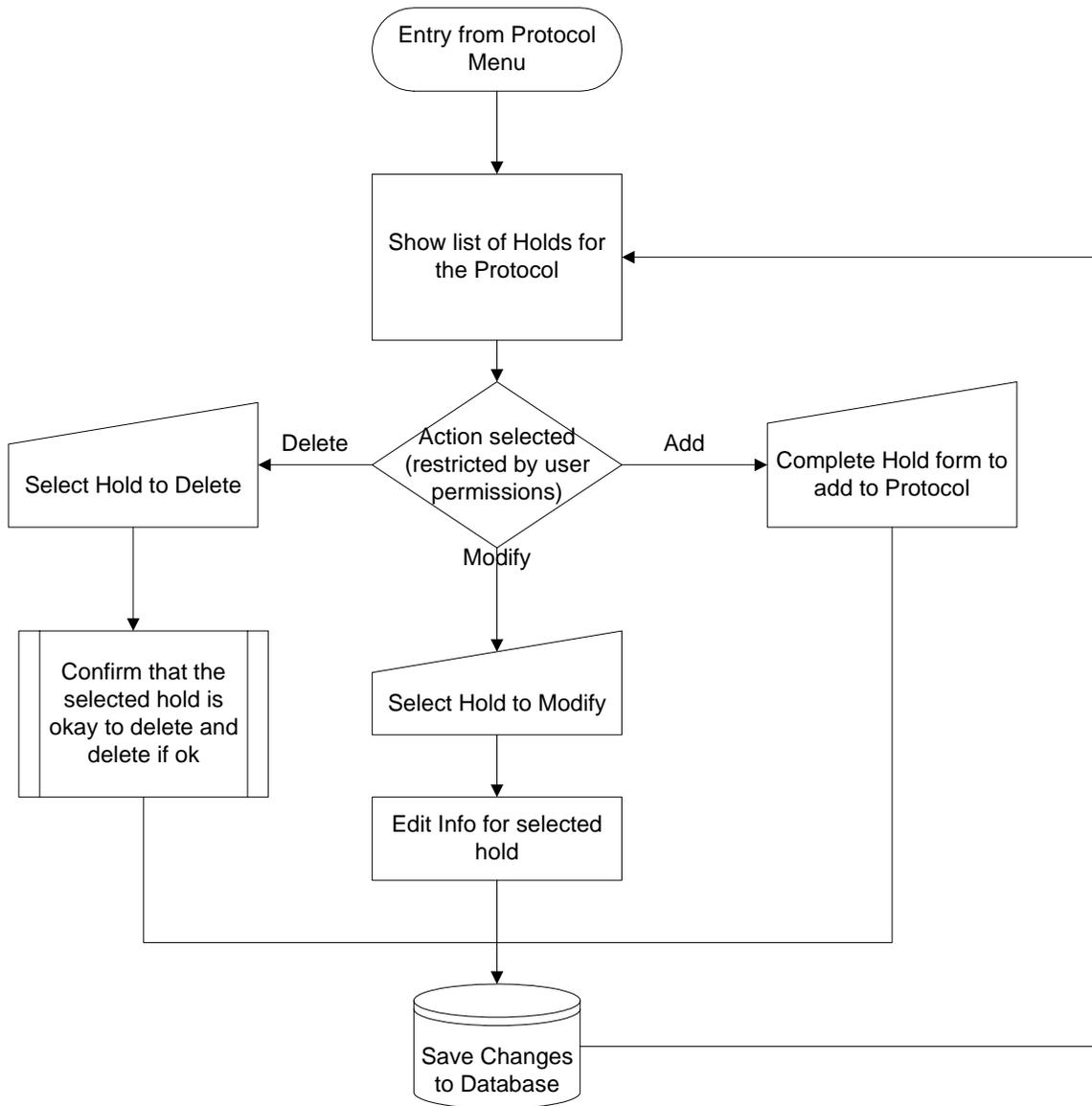
Performance Site Module



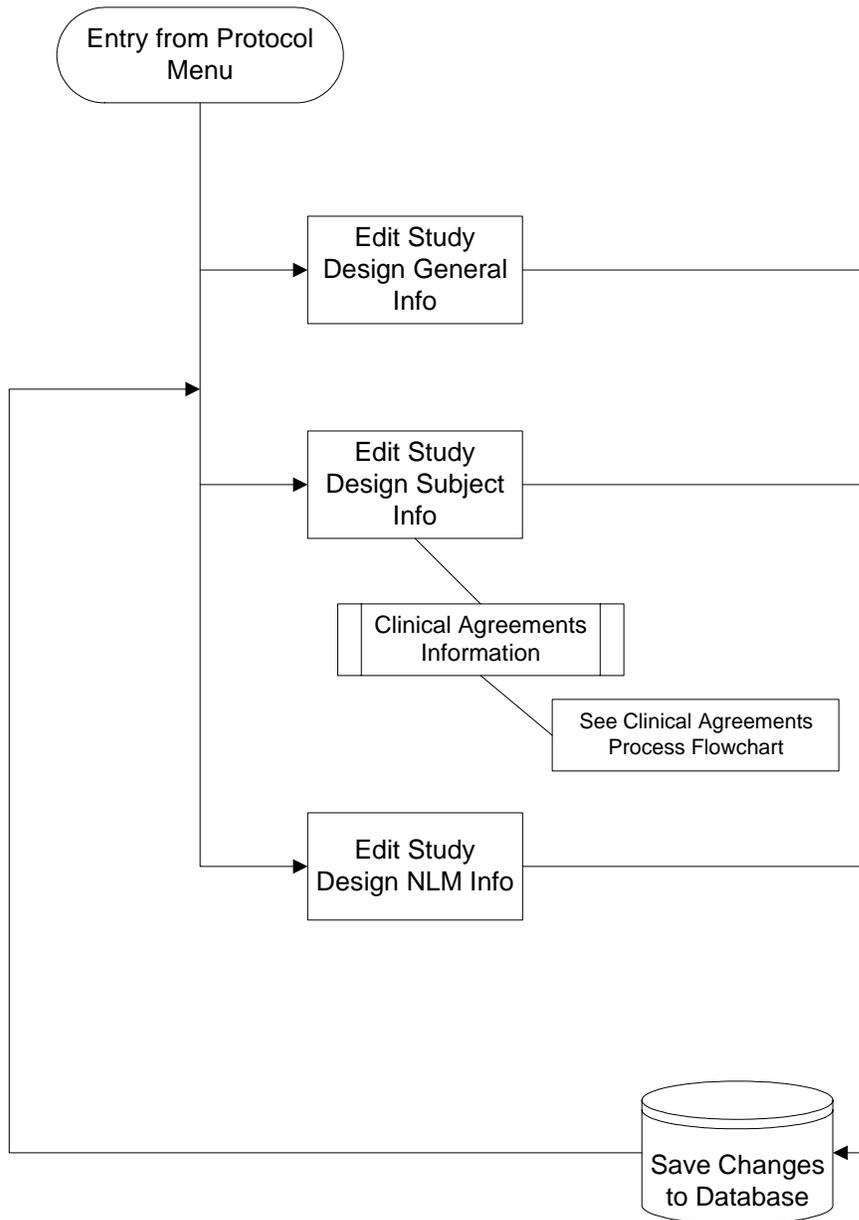
Protocol Products Module



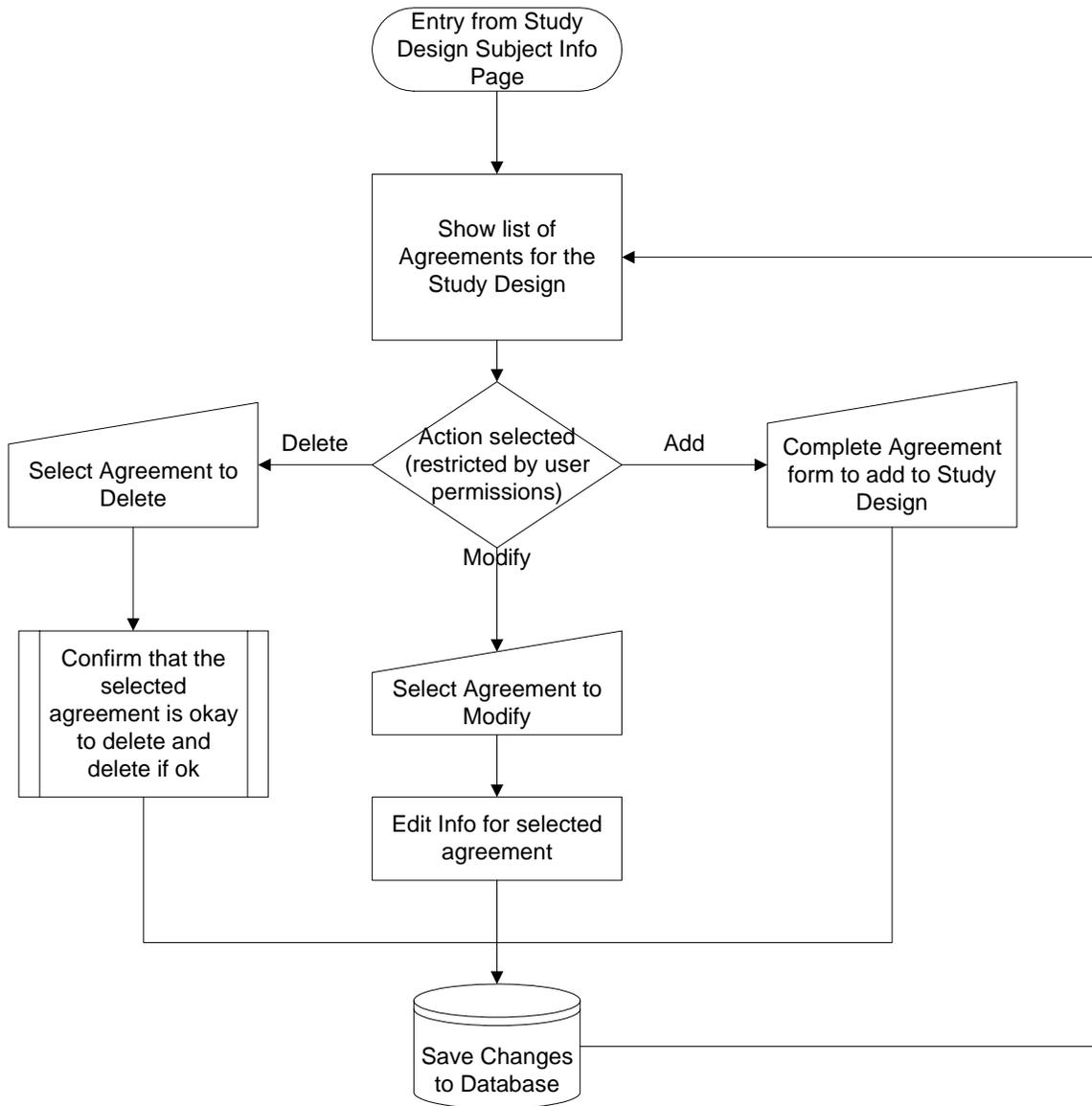
Protocol Holds Module



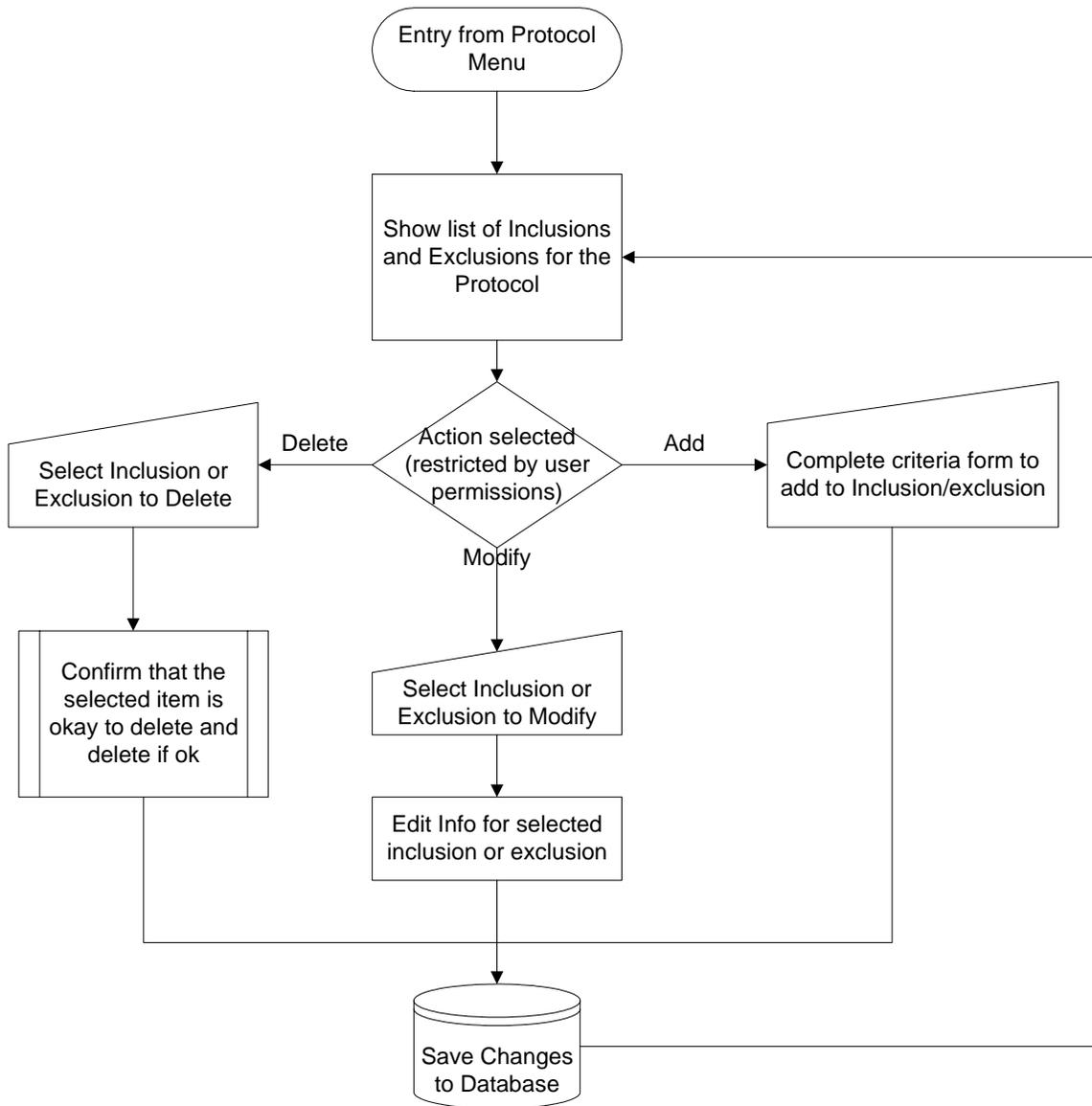
Study Design Module



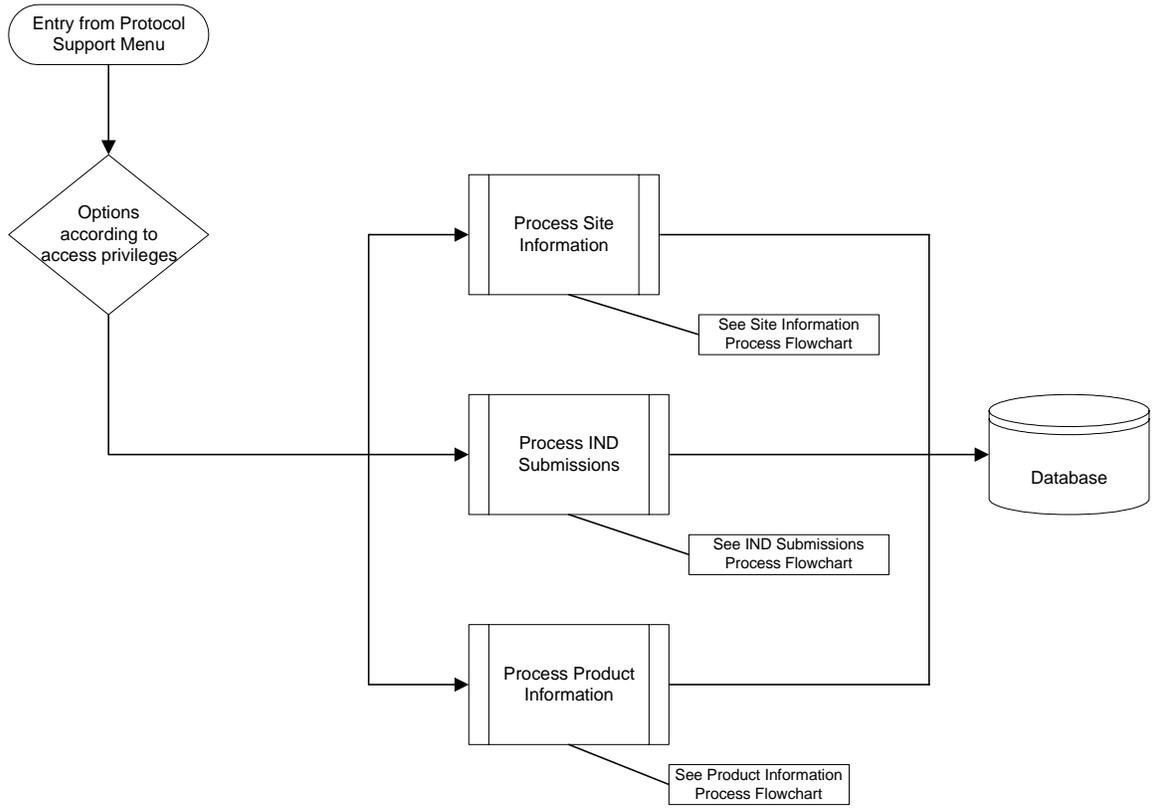
Clinical Agreements Module



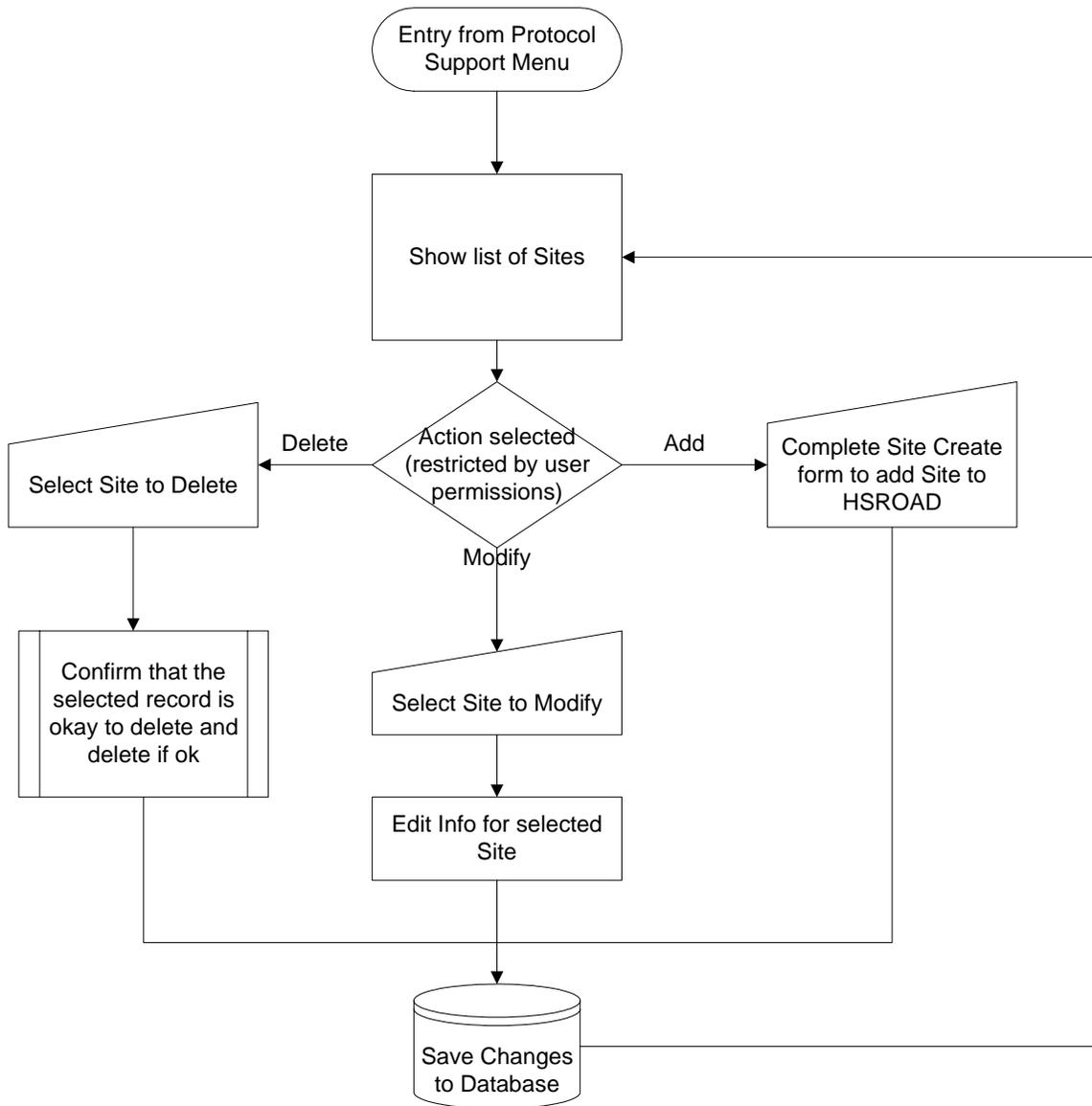
Inclusion/Exclusion Module



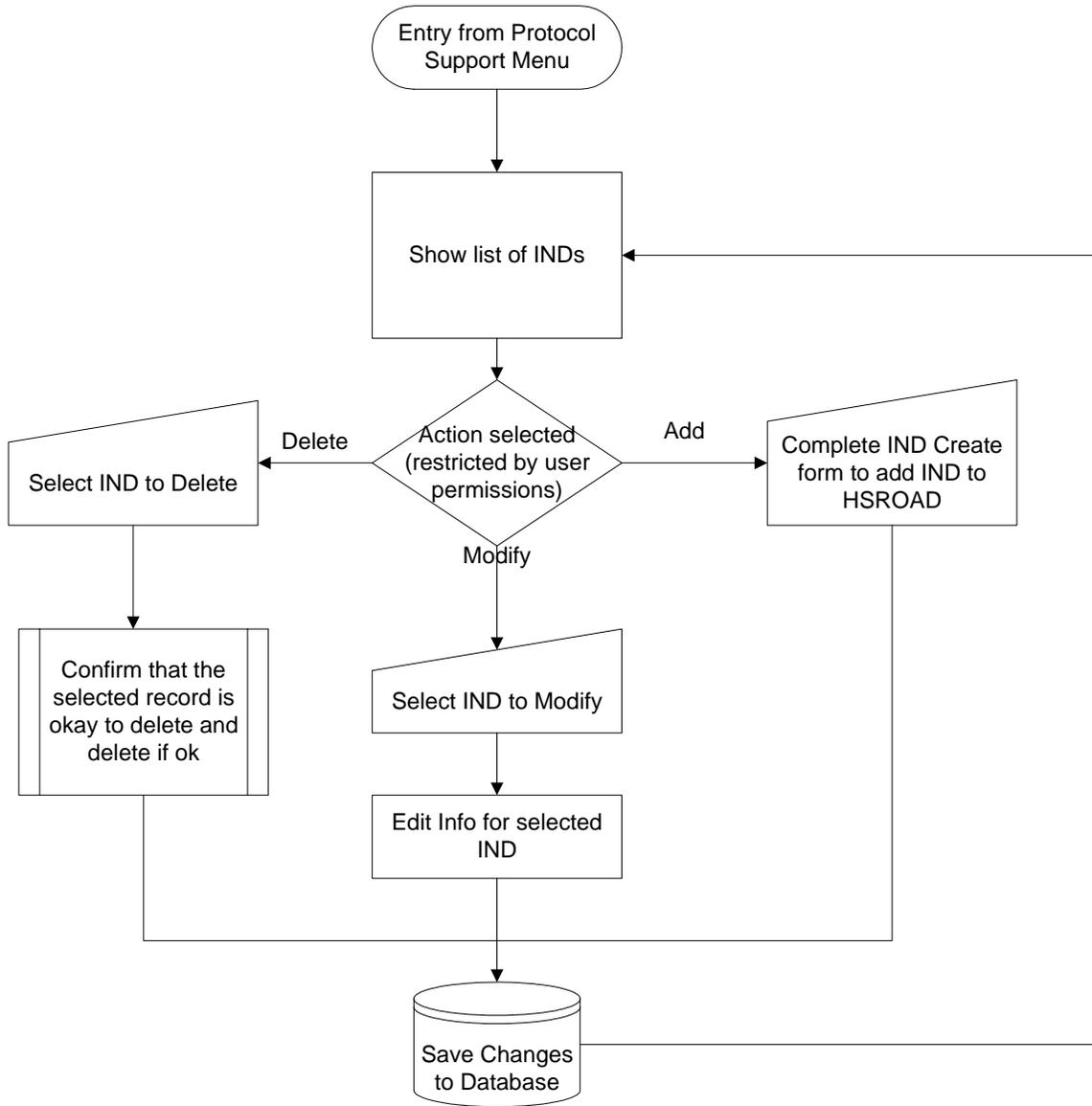
Protocol Support Module



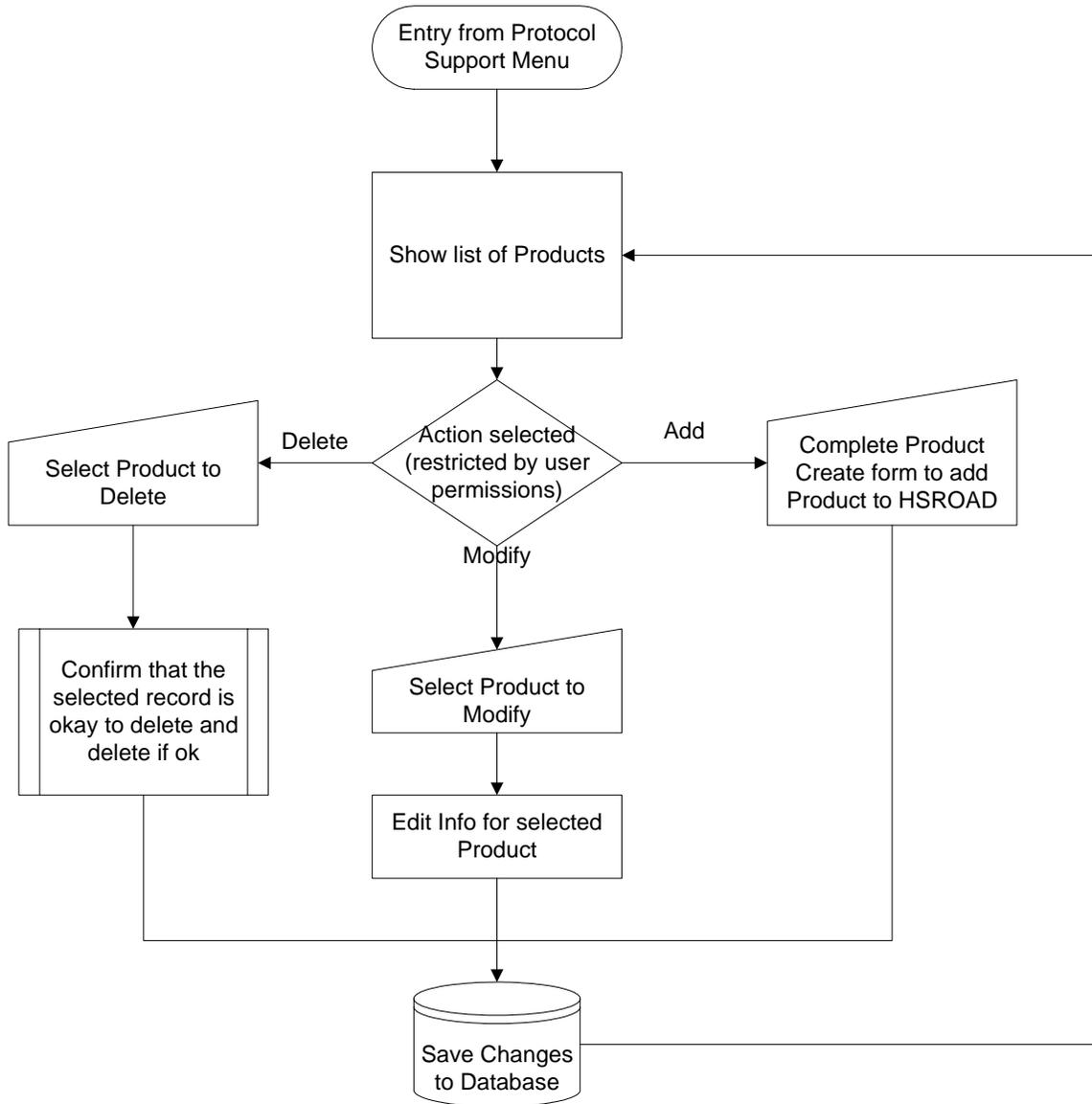
Site Information Module



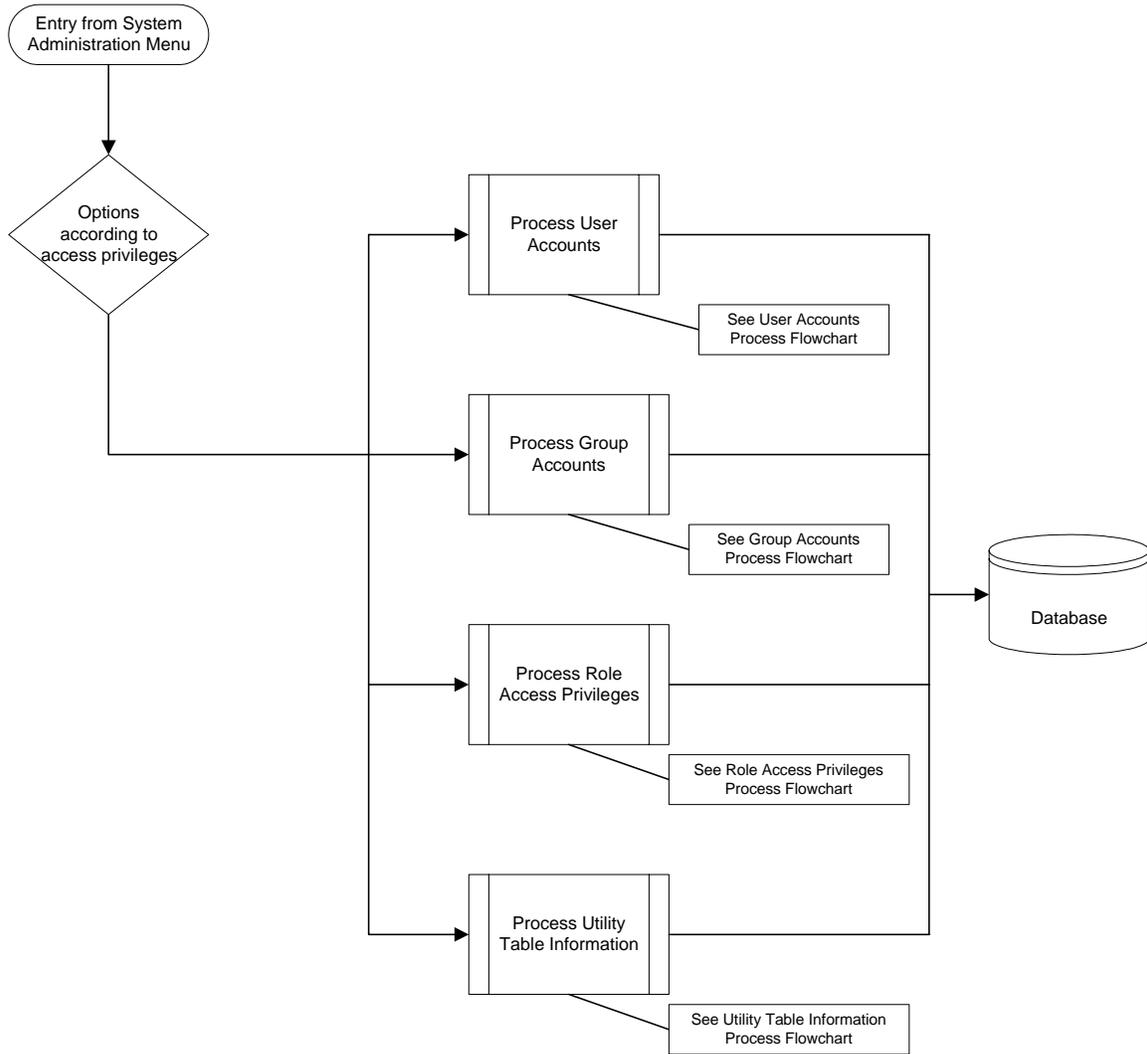
IND Submissions Module



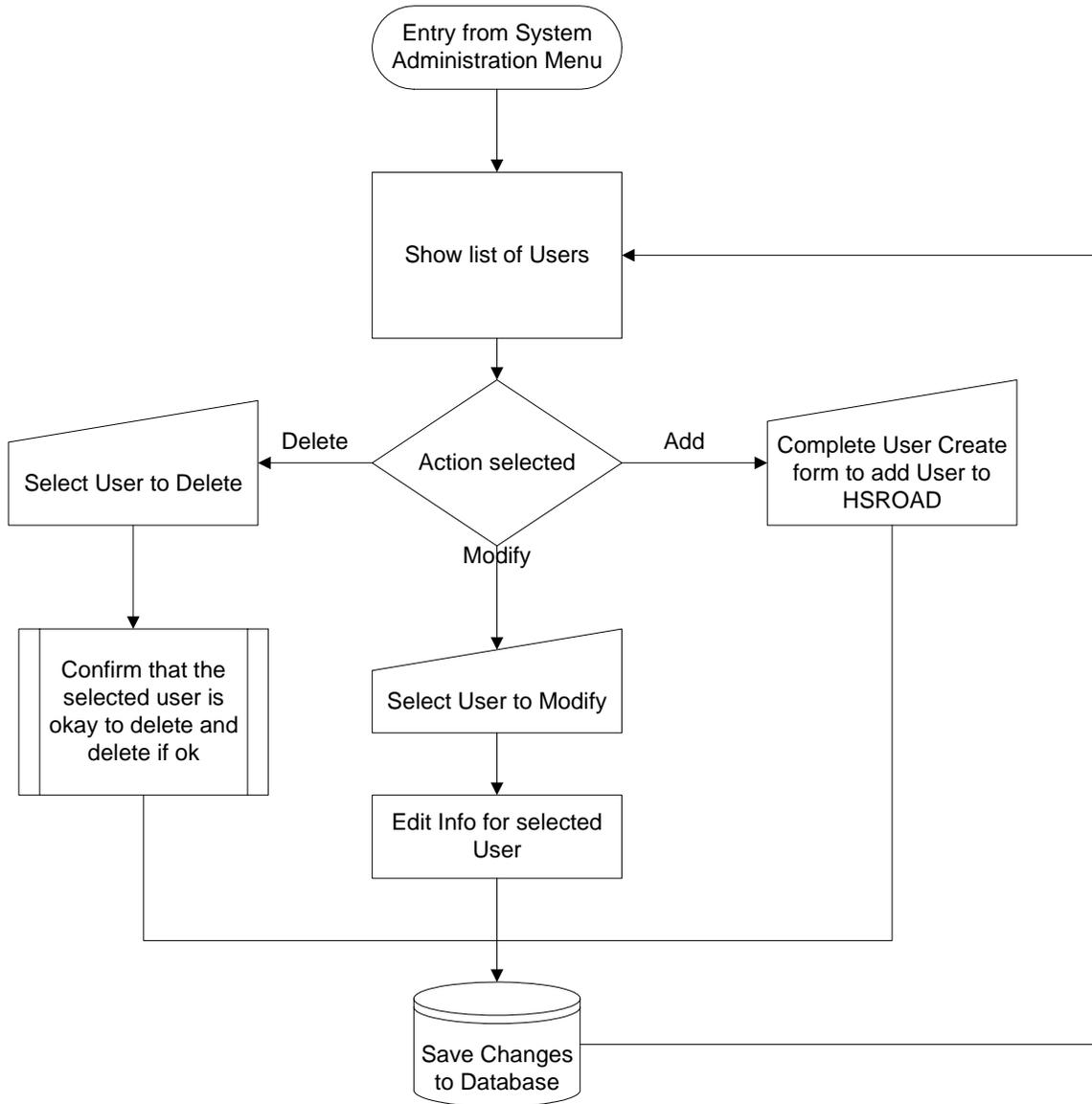
Products Module



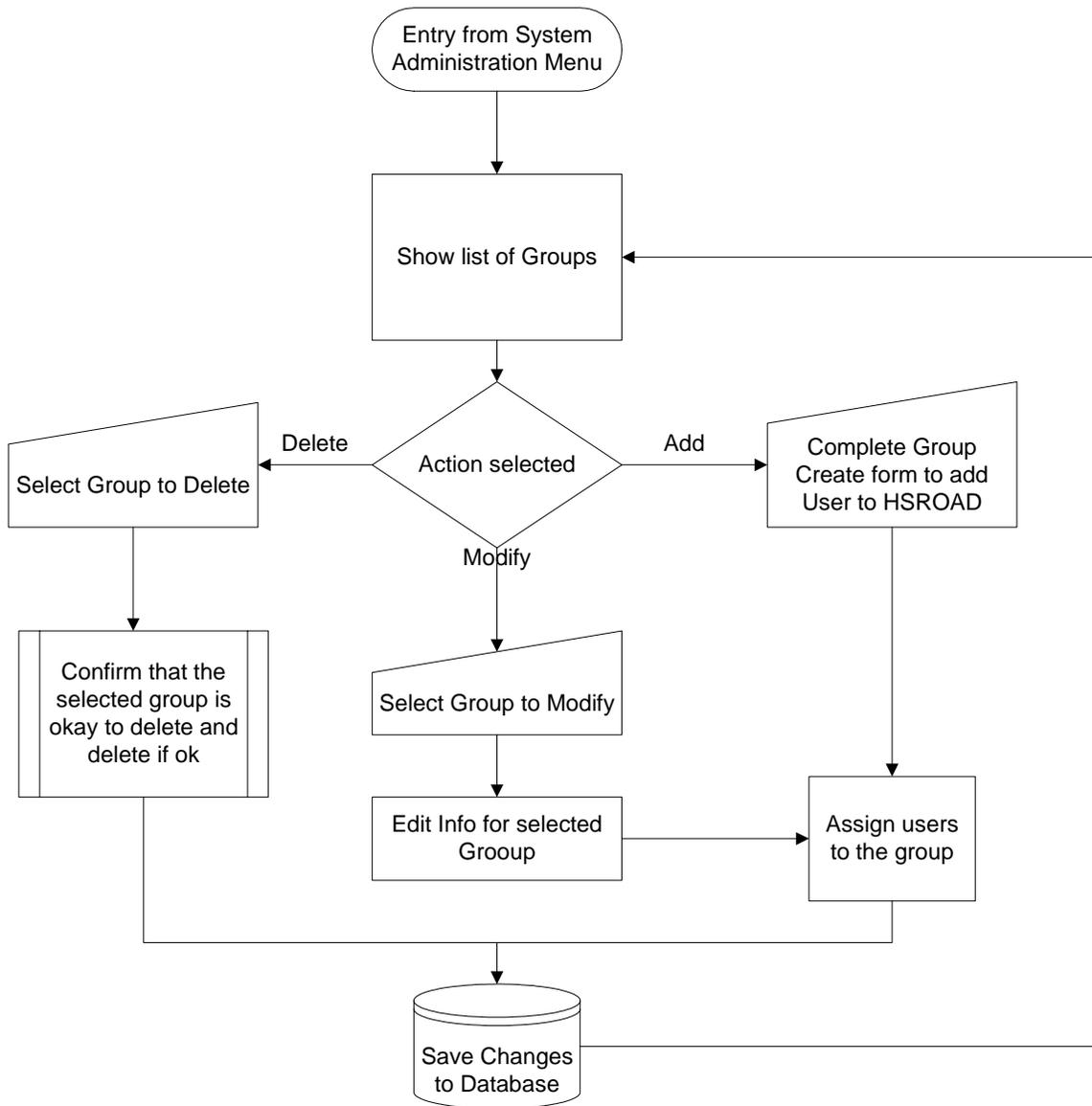
System Administration Module



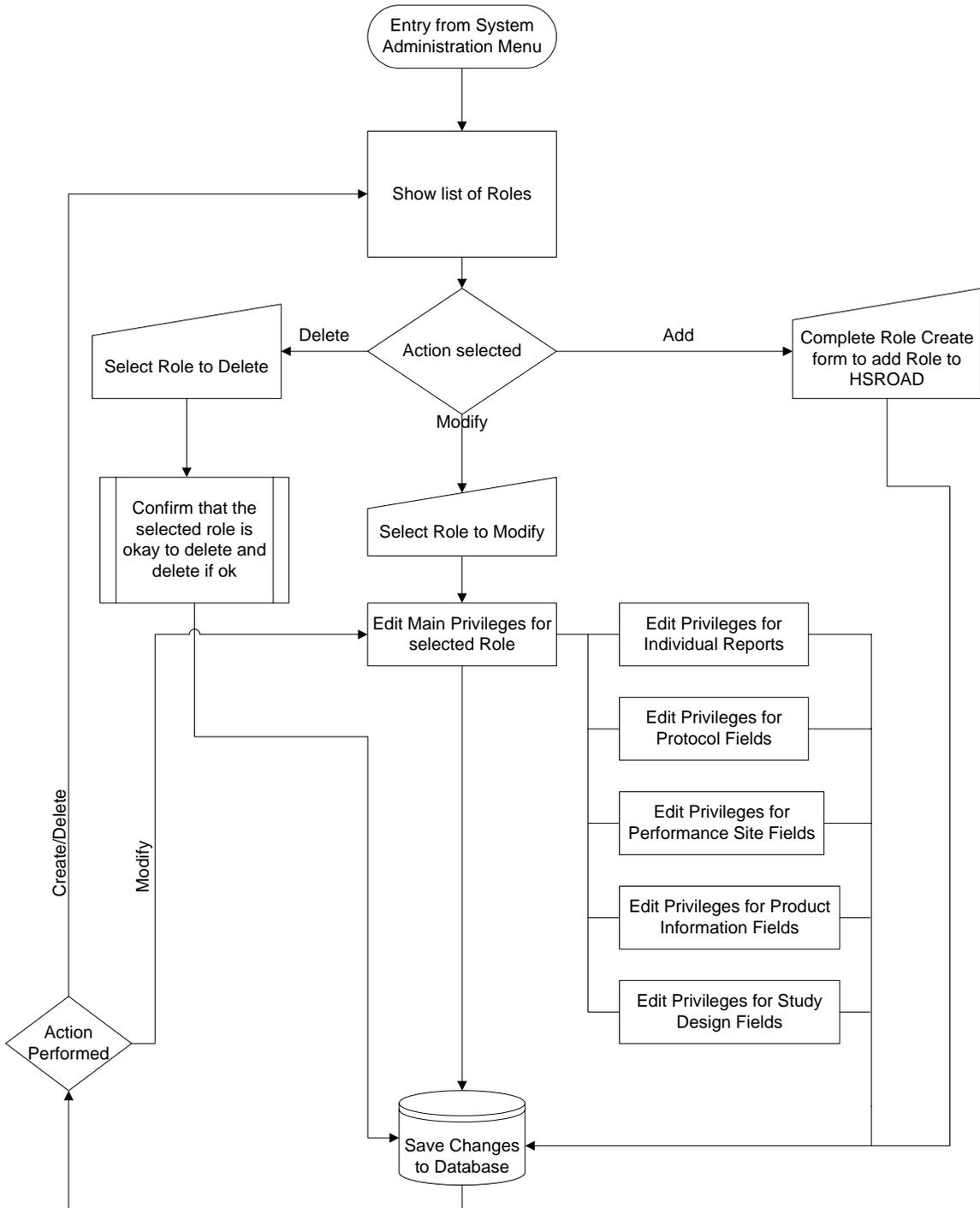
User Accounts Module



Group Accounts Module



Role Access Privileges Module



Utility Table Information Module

