



STUDY ASSISTANT

Study Management

Software Version: 13.01

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Study Management

Introduction

Study records in iRIS™ are comprised of two primary sections: Submissions and Study Management. Using these features both review board members and key study personnel can view and manage important study information. Additional sections may be available depending on your institution’s configuration, such as Animal Management, Subject Management, Post Award Management, etc.

The Study Management section enables access to many study items such as sponsors and subrecipients, drugs/devices/agents, enrollment criteria, the COI status of key personnel, and more.


This manual will provide a general overview of the tools available within this Study Management tab.

Accessing a Study

To view the Study Management tab, you must first open a study. One method to do this is to click the **View and Manage My Studies** button in the “Featured Study Operations” panel on the Study Assistant homepage. This will anchor the page down to the “My Studies” panel, displaying all studies that are associated to the logged in-user.

The screenshot displays the 'All Studies' tab in the Study Management section. It features a search bar at the top right and filter buttons for 'All', 'Draft', 'IACUC', and 'IBC Board'. Below the filters, it shows '57 result(s) found...' and a pagination control '1 - 5'. The main content is a table with the following columns: 'Click to open Study Dashboard', 'Study Status', 'Review Board', 'RB Number', 'RB Expiration', 'Study Title / Study Alias', 'Principal Investigator', and 'Actions'. The table lists five study entries with their respective statuses and actions.

| Click to open Study Dashboard | Study Status | Review Board | RB Number | RB Expiration | Study Title / Study Alias | Principal Investigator | Actions |
|-------------------------------|--|--------------|------------|---------------|--|------------------------|---|
| | Active | IRB | IRB-21-477 | 06/24/2022 | Malaria in Juveniles in South Africa Malaria in Juveniles | Investigator, John | Applications Documents Forms Hide Close Exempt Copy Delete Correspond |
| | Pending - Submitted for Initial Review | IRB | IRB-21-402 | | Risk Assessment Program (RAP) Registry Risk Assessment Program (RAP) Registry | Investigator, John | Applications Documents Forms Hide Exempt Copy Delete Correspond |
| | Open | IRB | IRB-21-478 | 06/28/2022 | Malaria in Juveniles Malaria in Juveniles | Investigator, John | Applications Documents Forms Hide Close Exempt Copy Delete Correspond |
| | Draft | IRB | IRB-21-470 | | Copy of NIH - FD - 00001- Multi-Site safety of masks over 52 weeks ... NIH - FD - 0001 | Investigator, John | Applications Documents Forms Hide Exempt Copy Delete Correspond |
| | Pending - Submitted for Initial Review | IRB | IRB-21-483 | 12/31/2021 | COVID 19 Complications in adults 55 and older COVID 19 Complications in adults 55 and older | Investigator, John | Applications Documents Forms Hide Exempt Copy Delete Correspond |














































Click the  icon to open a study record.

All Studies
Recently Used
Study Status

Search
⚙️

All
Draft
IACUC
IBC Board
▼

57 result(s) found... 1 - 5 ▶

| Click to open Study Dashboard | Study Status | Review Board | RB Number | RB Expiration | Study Title Study Alias | Principal Investigator | Actions |
|---|--|--------------|------------|---------------|---|------------------------|---|
| <i>Malaria in Juveniles in South Africa</i> | | | | | | | |
|  | Active | IRB | IRB-21-477 | 06/24/2022 | Malaria in Juveniles | Investigator, John |         |
| <i>Risk Assessment Program (RAP) Registry</i> | | | | | | | |
|  | Pending - Submitted for Initial Review | IRB | IRB-21-402 | | Risk Assessment Program (RAP) Registry | Investigator, John |         |
| <i>Malaria in Juveniles</i> | | | | | | | |
|  | Open | IRB | IRB-21-478 | 06/28/2022 | Malaria in Juveniles | Investigator, John |         |
| <i>Copy of NIH - FD - 00001- Multi-Site safety of masks over 52 weeks ...</i> | | | | | | | |
|  | Draft | IRB | IRB-21-470 | | NIH - FD - 0001 | Investigator, John |         |
| <i>COVID 19 Complications in adults 55 and older</i> | | | | | | | |
|  | Pending - Submitted for Initial Review | IRB | IRB-21-483 | 12/31/2021 | COVID 19 Complications in adults 55 and older | Investigator, John |         |

57 result(s) found... 1 - 5 ▶

By default, opening a study will redirect to the “Submissions” tab, as shown below.

My Workspaces

IRB Number: **IRB-21-478**
 PI: Investigator, John

Study Assistant
Submissions
 Back

Study Status: Open

IRB Number : IRB-21-478

Study Title : Malaria in Juveniles

IRB Expiration Date: 06/28/2022

Submissions
Study Management
Subject Management

Close Exempt Study
Current Approval Packet

Protocol Items

- Study Application
- Informed Consents ▶
- Other Study Documents ▶
- Contract Documents

Protocol Items

- Reportable Event Form

- Submissions History
- Study Correspondence

Outstanding Submission(s)

| Track Location | Ref Number | Request Type | Process Submission |
|---------------------------------------|------------|--------------|--------------------|
| There are no outstanding submissions. | | | |

Regulatory Forms

Regulatory Submission Forms

- Continuing Review Submission Form
- Study Amendment Form
- Study Closure Form
- Unanticipated Events Form
- Yearly Check-in Form

For more information on the “Submissions” tab, see the *Study Assistant – Submissions manual*.

Study Information Header

Displayed at the top of every study record is an information header, an example of which is shown below.

My Workspaces

IRB Number: **IRB-21-478**
 PI: Investigator, John

Study Assistant
Study Management
 Back

Study Status: Open

IRB Number : IRB-21-478

Study Title : Malaria in Juveniles

IRB Expiration Date: 06/28/2022

The upper row of the header contains the **Study Number** and **PI** name. The example above is an IRB study, so the IRB Number is displayed.

Below this is the Study Status, Study Number, Review Board Expiration Date (if it exists), and Study Title.

The information in the header will update dynamically as changes to the study occur.

Study Management

Navigate to the Study Management section by clicking the “Study Management” tab.

The screenshot displays the Study Management interface. At the top, there is a header bar with 'My Workspaces' (with a dropdown arrow), 'IRB Number: IRB-21-478', 'PI: Investigator, John', 'Study Assistant', 'Study Management', and a 'Back' button. Below the header, there is a summary section with 'Study Status: Open' (in a green box), 'IRB Number: IRB-21-478', 'Study Title: Malaria in Juveniles', and 'IRB Expiration Date: 06/28/2022'. The main content area has three tabs: 'Submissions', 'Study Management', and 'Subject Management'. The 'Study Management' tab is active, showing a list of study-related tasks and categories. The categories are: Study Details (Study Summary/Profile, Screen Access, Key Personnel, External Personnel, COI Status, Review Board Selection, Department Access, Associated Projects, Activity Log / Negotiation History, Associated Studies), Study Tasks (Study Notebook), Sponsors & Subrecipients (Sponsor, Subrecipients, Study Umbrella), Drugs, Devices and Agents (Drug/Biologic/Chemical agents), Finance Set-up (Construct Study Plan, Study Plan Timeline, Study Accounts, Budget Management, Milestone Management), Finance Tracking (Subject on Study Financial Tracking, Invoice Management, General Ledger), and Miscellaneous (Study Monitor CRF (Case Report Forms), Study Advertising, Equipment).

Study Management contains study-specific information primarily originating from the initial study application. Certain data values included in the application form connect directly to the links on the Study Management page (*see the Study Assistant – Add a Study manual for more information*).

Study Details

The first section in Study Management is Study Details. Study Details contains links to different study core fields such as study summary information as set by the review board, personnel screen access, personnel on the study, and departments on the study.

Study Summary/Profile

The Study Summary will display the current status information related to the study. Any review board updates to these fields will be reflected here.

My Workspaces ▾
IRB Number: **IRB-21-476**
PI: Investigator, John
Study Assistant

Study Summary

⏪ Back

Study Status: Active

IRB Number : IRB-21-476

Study Title : Malaria in Juveniles

IRB Expiration Date: 06/24/2022

Print Friendly Save Changes

| | |
|-----------------------------------|---|
| Study Title: | Malaria in Juveniles |
| Status: | Active |
| Study Alias: | Malaria in Juveniles |
| Use Subject Tracking: | <input checked="" type="radio"/> Yes <input type="radio"/> No |
| Use Electronic Data Capture(EDC): | <input type="radio"/> Yes <input checked="" type="radio"/> No |
| Animal Research: | <input type="radio"/> Yes <input checked="" type="radio"/> No |

⊞ Study Department(s)

| Name | Is Primary |
|-------------------------------|------------|
| GHW - 7543 - General Hospital | Yes |

⊞ Study Personnel

| | |
|------------------------------------|----------------------------------|
| Principal Investigator: | John Investigator |
| Contact: | Betty Smith |
| Co-Investigator: | Tom Jefferson |
| Study Author: | John Investigator |
| Department Administrator: | Jeff Sykes |
| Nurse: | George Jefferson Nathan Mossman |
| Additional Principal Investigator: | Sean Coordinator |

This page is broken up into several sections. The first section displays basic study information and may appear differently in your system, depending on your system configuration. Always displayed are the Study Title, Status, and Study Number. The Status field is the current Study Status.

The additional sections provide more specific study information. These may be expanded or collapsed by clicking on the or the icons.

You can also open a view of this page to print out for your records by clicking on the **Print Friendly** button.

Study Departments


The first section of the Study Summary lists current departments associated to the study (as defined in section 3.0 of the Study Application).

| Study Department(s) | | |
|-------------------------------|--|------------|
| Name | | Is Primary |
| GHW - 7543 - General Hospital | | Yes |

Study Personnel

Study Personnel displays the names and roles of the current Study Personnel that are associated with the study (as defined in section 2.0 of the Study Application).

| Study Personnel | |
|---|---|
| Principal Investigator: |  John Investigator |
| Contact: |  Betty Smith |
| Co-Investigator: |  Tom Jefferson |
| Study Author: |  John Investigator |
| Department Administrator: |  Jeff Sykes |
| Nurse: |  George Jefferson  Nathan Mossman |
| Additional Principal Investigator: |  Sean Coordinator |

A user’s profile can be viewed by clicking on the  icon next to their name. This opens the User Information pop-up window shown below.

User Information - John Investigator

Contact Information

| | |
|---|--|
| <p>Last Name: Investigator</p> <p>Suffix:</p> <p>Job Title:</p> <p>Degree:</p> <p>Employee ID: 020017109</p> <p>Specialty:</p> <p>Relationship to the Institution <input type="radio"/> Affiliated <input checked="" type="radio"/> Non-Affiliated</p> <p>Department(s)</p> <ul style="list-style-type: none"> • GHW-General Hospital • GUR-Pediatric | <p>First Name: John Middle Name:</p> <p>Contact Information:</p> <p>Email Address:</p> <p>Primary Number: 909-111-2222</p> <p>Cell Number: 909-222-4444</p> <p>Pager Number:</p> <p>Fax Number:</p> <p>Street 1: 446 Missouri Ct</p> <p>Street 2:</p> <p>City: Redlands</p> <p>County/Parish: California</p> <p>State: CA: California</p> <p>Province: California</p> <p>Country: USA: UNITED STATES</p> <p>ZIP/Postal Code: 92373-1212</p> |
|---|--|

Training History

| Training Group | Course | Course Date | Course Expiration | Score |
|----------------|---|-------------|-------------------|-------|
| | Animal Handlers Course | 03/03/2020 | | |
| | AVMA Guidelines for the Euthanasia of Animals: 2020 Edition | 03/02/2020 | 07/07/2021 | |
| | Basic Course | 01/01/2020 | 06/01/2021 | |

This window will list contact information as defined in the user’s account, training records defined under the Education History group, and any Medical Licenses and CVs uploaded.

Close this window to return to the Study Summary page.

Review Boards

All review boards associated with the study that have reviewed the submission in question will be displayed as a section on the Study Summary page. These sections contain important review board attributes and study information such as approval dates, expiration dates, closure information, the risk assigned to the study, and more. Information that is updated by the review board will be updated on this page as well.

| IRB | |
|--|---|
| IRB Number: | IRB-21-476 |
| IRB of Record: | Yes |
| Please Select the Type of Review Notification that Must be Sent: | Email with Home Screen Task and Continuing Review |
| Committee of Record: | --none-- |
| IRB Initial Approval: | 06/24/2022 |
| Review Cycle: | 12 Months |
| IRB Expiration Date: | 06/24/2022 |
| Last Continuing Review Approved: | |
| Days Prior to IRB Expiration: | 60 days prior exp |
| Continuing Review Due: | 04/25/2022 |
| Study Closure: | |
| Temporary Closed: | No |

Depending on system settings, and the review boards that are associated to the study, the information that displays on this page may differ.

If more than one review board is associated to the study, each review board is listed separately in different groups. In the example above, only one review board, IRB, has been assigned to this study, so only this section appears on the Study Summary screen.

Study Details

This area of the Study Summary will provide an overview of other items in the study record such as Sponsors, Drugs, Devices, and Enrollment Criteria. If information has been associated to the study in any of these groups, they will display in this area along with any accompanying details.

Sponsors on the study will display in this section. You can click on the **Sponsor** link to obtain additional information.

Study Details:

Sponsor

| | |
|----------------|---------------------|
| Sponsor | |
| Sponsor Name: | 3-M Pharmaceuticals |
| Sponsor Type: | Pharmaceutical |

Funding

ALL STUDIES

Add funding source(s) below: Federal, Sponsor, or Other. Select "Original Development by Applicant(s)" above if there is no funding for the study.

IF SPONSOR(S)

Please provide contact information below for the IRB Fee billing purposes.
NOTE: * Denotes mandatory field.

Contact Name: *

Contact Title: *

Mailing Address: *

City: *

State: *

Zip Code: *

Contact's Phone Number: *

Contact's Fax Number: *

Study Drugs and Devices will also display, along with the details for each item on the study. You can click on the link for either **Study Drug/Biologic/Chemical** agents or **Study Devices** for additional information.





Study Drug/Biologic/Chemical agents

| | |
|----------------------------|----------------|
| Drug List | |
| Trade Drug Name: | Amoxicillin |
| Generic Drug Name: | Amoxicillin A1 |
| Investigational Drug Name: | |
| IND Number: | |
| Dose Range: | |

Protocol Information: Drugs and Biological Products

| | |
|--|---|
| Does your study involve INVESTIGATIONAL drugs, reagents, or chemicals? | Has this study been submitted to the Institutional Biosafety Committee (IBC) review? The IRB requires documentation of IBC approval before final approval of the study can be granted. <input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> N/A |
| | Investigational New Drug Application (IND)# <input type="text" value="554689"/> |
| | Is the drug provided free of charge? <input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> N/A |

This Study Details section also displays any Inclusion or Exclusion Criteria added to the study with clickable links for additional details.

-  **Inclusion Criteria** No Inclusion criteria have been associated.
-  **Exclusion Criteria** No Exclusion criteria have been associated.
-  **Treatment Criteria** No Treatment criteria have been associated.
-  **Workup Criteria** No Workup criteria have been associated.

When you are finished viewing the Study Summary, click the **Back** button to return to the Study Management tab.

Screen Access

Screen Access enables users to customize access to study screens for certain KSP. By default, if a user is assigned a role on the study, their study access will be determined by the Study Role Access configuration within System Administration (see the System Administration – System Setup manual for more information). This “Screen Access” page allows users to further customize the areas of a study that KSP have access to.

My Workspaces ▾ IRB Number: **IRB-21-476** Study Assistant **Study - Screen Access** Back
 PI: Investigator, John

Study Status: **Active** IRB Number : IRB-21-476 Study Title : Malaria in Juveniles
 IRB Expiration Date: 06/24/2022

Save Changes

| Screen Name | John Investigator | | Betty Smith | | Tom Jefferson | | Jeff Sykes | | George Jefferson | |
|-------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
| | Read | Write | Read | Write | Read | Write | Read | Write | Read | Write |
| Submissions | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Application | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Grant Application | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Informed Consent | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Other Study Documents | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Study Correspondence | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Submissions History | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Contract Documents | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Study Notebook | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Study Management | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Study Summary/Profile | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Screen Access | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Key Personnel | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |

The leftmost column of this table lists all available screens for this specific study. The columns on the right correspond to each KSP on the study. Within each user column are checkboxes that represent whether or not that user can access a particular screen.

There are two checkboxes for each user/screen combination: “Read” and “Write”. Checking “Read” give the user read-only access to that screen, while checking both “Read” and “Write” gives the user full read/write screen access.

Depending on the number of users on the study, vertical and horizontal scroll bars may display so you can view roles and screens that may extend beyond the boundaries of the browser window.

After making the desired changes to this screen, click the **Save Changes** button and then the **Back** button to return to the main Study Management screen.

Key Personnel

This link will open a screen similar to the one found in Section 3.0 of the Study Application. Listed on this page is all current personnel on the study. In order for this study record to display in a user’s **My Studies** panel on the Study Assistant homepage, they must be listed as Key Study Personnel here.

Your system may or may not display all the roles shown below, depending on how your system is configured.

Depending on the Study Status, this page may be locked to any changes in personnel. In this case, any KSP modifications must be submitted to the review board for approval. See the Submissions manual for information on submitting change requests.

If the Study Status allows for Personnel changes, the page will not be locked, and you will be able to add and remove users from the Study, as shown in the screen below.

My Workspaces
IRB Number: **IRB-21-476** Study Assistant
Define Study Access Back

Study Status: **Active**

IRB Number : IRB-21-476

Study Title : Malaria in Juveniles

IRB Expiration Date: 06/24/2022

Save Access to the Study

3.0 Assign key study personnel (KSP) access to the study

[Click Here to Setup Study Personnel](#)

3.1 * Please add a Principal Investigator for the study:

| Name | Role | Responsibility | Training Record |
|-------------------|------------------------|--|--------------------------------------|
| John Investigator | Principal Investigator | <None added> Add/Modify | View Training Record |

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

| Name | Role | Responsibility | Training Record |
|-------------------|--|---|--------------------------------------|
| Coordinator, Sean | <input type="text" value="Additional Principal Investigator"/> | Administrative Reviewer , Student training delivery Add/Modify | View Training Record |
| Jefferson, Tom | <input type="text" value="Co-Investigator"/> | <None added> Add/Modify | View Training Record |

B) Research Support Staff

| Name | Role | Responsibility | Training Record |
|-------------------|------------------------------------|--|--------------------------------------|
| Jefferson, George | <input type="text" value="Nurse"/> | <None added> Add/Modify | View Training Record |
| Mossman, Nathan | <input type="text" value="Nurse"/> | <None added> Add/Modify | View Training Record |

You may also be able to add and modify responsibilities for users and view/manage KSP training records depending on your role settings.

To add an additional user to this study, click the **Setup Study Personnel** at the top of the page then you can find the user or search the directory to add the user to the corresponding role, as seen in the image below.

Setup Study Personnel X

| <div style="border: 1px solid gray; padding: 2px;"> User Search by Study Study Personnel Pool Create My Personnel Pool Update My Personnel Pool Delete My Personnel Pool </div> | Last Name: <input type="text"/> First Name: <input type="text"/> User Search by Study: All Departments Find User/Search Directory | | | | | | | | | | |
|--|---|-----------|------------|------------|-------|------------------|--|--|--|--|--|
| <div style="border: 1px solid gray; padding: 2px;"> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 5%;">Select</th> <th style="width: 5%;">Training?</th> <th style="width: 45%;">Name</th> <th style="width: 25%;">Department</th> <th style="width: 20%;">Email</th> </tr> </thead> <tbody> <tr> <td colspan="5" style="text-align: center;">No results found</td> </tr> </tbody> </table> </div> | Select | Training? | Name | Department | Email | No results found | | | | | |
| Select | Training? | Name | Department | Email | | | | | | | |
| No results found | | | | | | | | | | | |

Selected Study Personnel:

Principal Investigator

| Select | Name | Role | Responsibilities |
|-------------------------------------|--------------------|------------------------|------------------|
| <input checked="" type="checkbox"/> | Investigator, John | Principal Investigator | <None added> |

Additional Investigators

| Select | Name | Role | Responsibilities |
|-------------------------------------|-------------------|-----------------------------------|---|
| <input checked="" type="checkbox"/> | Coordinator, Sean | Additional Principal Investigator | Administrative Reviewer , Student training delivery |
| <input checked="" type="checkbox"/> | Jefferson, Tom | Co-Investigator | <None added> |

Research Support Staff

| Select | Name | Role | Responsibilities |
|-------------------------------------|-------------------|-------|------------------|
| <input checked="" type="checkbox"/> | Jefferson, George | Nurse | <None added> |

Clear Key Study Personnel Close Setup of Study Personnel

i This section is used to build the list of personnel on the study. User Search by Study allows you to search for a named person and associated them with a role on the study.

The Setup Study Personnel window allows you to search the user directory by First Name, Last Name, or Department. Enter all or part of the criteria and click the **Find User/Search Directory** button.

Setup Study Personnel X

| <div style="border: 1px solid gray; padding: 2px;"> User Search by Study Study Personnel Pool Create My Personnel Pool Update My Personnel Pool Delete My Personnel Pool </div> | Last Name: <input type="text" value="sykes"/> First Name: <input type="text"/> User Search by Study: All Departments Find User/Search Directory | | | | | | | | | | |
|--|---|-------------|---------------------------|------------|-------|--------------------------|--------------------------|-------------|---------------------------|--|--|
| <div style="border: 1px solid gray; padding: 2px;"> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 5%;">Select</th> <th style="width: 5%;">Training?</th> <th style="width: 45%;">Name</th> <th style="width: 25%;">Department</th> <th style="width: 20%;">Email</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td>Sykes, Jeff</td> <td style="text-align: center;">i General Hospital</td> <td></td> </tr> </tbody> </table> </div> | Select | Training? | Name | Department | Email | <input type="checkbox"/> | <input type="checkbox"/> | Sykes, Jeff | i General Hospital | | |
| Select | Training? | Name | Department | Email | | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | Sykes, Jeff | i General Hospital | | | | | | | | |

i This section is used to build the list of personnel on the study. User Search by Study allows you to search for a named person and associated them with a role on the study.

To select a user to add, click the icon. This opens the **Add to Personnel Role** window, where you can assign a role to the user.

Add Personnel Role X

Select the Role for **Jeff Sykes** :

Principal Investigator
 Additional Investigators --none--
 Research Support Staff --none--
 Contact
 Department Administrator --none--

Select any additional responsibilities to the named user: Add/Modify <None added>

Cancel Save

Select a role and then click the **Save** button. Once saved, the system will return to the **Setup Study Personnel** window where the newly added user has populated in the personnel table.

| Research Support Staff | | | |
|------------------------|-------------------|-------|------------------|
| | Name | Role | Responsibilities |
| (X) | Jefferson, George | Nurse | <None added> |
| (X) | Sykes, Jeff | Nurse | <None added> |

You may or may not see the same role options as presented in this document, depending on your system configuration.

Some of the roles available in this section include the following:

Principal Investigator – All studies in iRIS™ must be assigned a Principal Investigator (PI). Without a PI, the third section of the Study Shell cannot be completed, and the study will remain in Draft mode. Note that there may only be one PI per study. If additional PIs exist, add them to the “Additional Investigators” section.


Additional Investigators – Any non-PI investigators. There is no limit to the number of Additional Investigators that can be added to a study. Each user in this section is given a specific study role.

Research Support Staff – Any non-investigator study personnel. There is no limit to the number of Research Support Staff that can be added to a study. Each user in this section is given a specific study role.

Contact – User(s) on the study who will receive study related notifications from the system, such as Continuing Review notifications, Submission Correction notifications, Review Response notifications, etc. The Principal Investigator defaults as the study contact, but this is editable. Any number of contacts be defined for a given study.

Department Administrator – If a study requires department approval before being submitted to a review board, a Department Administrator (DA) may be added. This administrator will appear in the form’s submission routing configuration, giving users the ability to send the application to the DA before being approved by a review board. More details on this process are given later in this document. Any number of DAs may be defined for a given study. Users added as DAs will populate in the “Designated Department Approval(s)” section of the Study Shell section 3.0.

Administrative Assistants – If you would like to give an administrative assistant access to the study for data entry purposes, you can assign them this role. Any number of Administrative Assistants may be added. These users typically have limited access to the study, will not be considered KSP in the education check, and will not be included in the submission signoff process. As this role is not considered KSP, you may add users to this role without review board approval.

You may remove a user from the study by clicking the  delete icon next to their name. If removing the Principal Investigator, you must also select a replacement, as no study record in iRIS™ can be missing a PI. Note that if the study’s status is such that personnel modifications are locked, a KSP change form must be sent to the review board for approval.

To complete the changes to the “Define Study Access” screen, click the **Save Access to the Study** button and then click **Back** to return to the main Study Management screen.

My Workspaces IRB Number: **IRB-21-476** PI: Investigator, John Study Assistant **Define Study Access** Back

Study Status: **Active** IRB Number: IRB-21-476 Study Title: Malaria in Juveniles
IRB Expiration Date: 06/24/2022

[Save Access to the Study](#)

3.0 Assign key study personnel (KSP) access to the study Click Here to Setup Study Personnel

3.1 * Please add a Principal Investigator for the study:

| Name | Role | Responsibility | Training Record |
|-------------------|------------------------|--------------------------------------|--------------------------------------|
| John Investigator | Principal Investigator | <None added> Add/Modify | View Training Record |

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

| Name | Role | Responsibility | Training Record |
|-------------------|--|---|--------------------------------------|
| Coordinator, Sean | <input type="text" value="Additional Principal Investigator"/> | Administrative Reviewer , Student training delivery Add/Modify | View Training Record |
| Jefferson, Tom | <input type="text" value="Co-Investigator"/> | <None added> Add/Modify | View Training Record |

B) Research Support Staff

| Name | Role | Responsibility | Training Record |
|-------------------|------------------------------------|--------------------------------------|--------------------------------------|
| Jefferson, George | <input type="text" value="Nurse"/> | <None added> Add/Modify | View Training Record |
| Mossman, Nathan | <input type="text" value="Nurse"/> | <None added> Add/Modify | View Training Record |

Non-Investigators

| Name | Role | Responsibility | Training Record |
|------|------|----------------|-----------------|
|------|------|----------------|-----------------|

Department Access

The Department Access link opens the “Study Department Access” page, which displays all departments that have been associated to the study. This information is pulled from section 2.0 of the Study Shell in the study application form.

My Workspaces IRB Number: **IRB-21-476** PI: Investigator, John Study Assistant **Study Department Access** Back

Study Status: **Active** IRB Number: IRB-21-476 Study Title: Malaria in Juveniles
IRB Expiration Date: 06/24/2022

| <input type="checkbox"/> | Department Name | Institution | Contact | Phone | Address | Primary |
|--------------------------|------------------|----------------------------|---------|-------|---------|----------------------------------|
| <input type="checkbox"/> | General Hospital | General Hospital Woodstock | | | | <input checked="" type="radio"/> |

The **Primary** column in the department display table shown above enables you to designate a department as “Primary”. As this is a radio button field, only one department may be elected the primary department. If any changes are made to this designation, a **Save Access** button will appear on the screen. Click this to save your changes to the study department access and click **Back** to return to the main Study Management screen.

Changes to the departments themselves must be performed either in the study application or by submitting a change form to the review board, depending on the current status of the study.

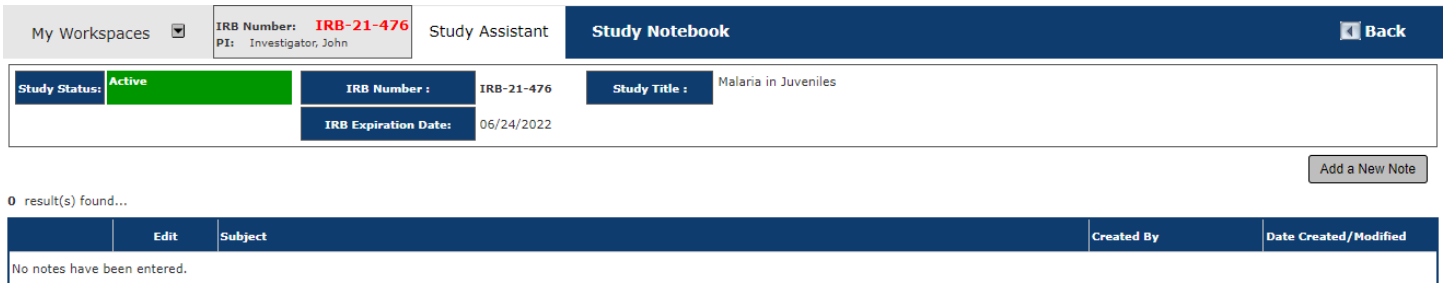
Study Tasks



Study Notebook

The Study Notebook is used to collect and maintain study documentation. This documentation may include internal notes between study personnel or generated correspondence.

The Study Notebook for a new study will by default be empty, as shown below.



Click **Add a New Note** to create a new note for this study. This will open the following page.

My Workspaces

IRB Number: **IRB-21-476**
 PI: Investigator, John

Study Assistant

Study Notebook

 Back

Study Status: Active

IRB Number : IRB-21-476

Study Title : Malaria in Juveniles

IRB Expiration Date: 06/24/2022

Save Note

***Subject**

***Occurrence Date**

Upload Document(s)

Drag your file here or click in this area.

| Delete | Name | Date | View the Document |
|-----------------------|------|------|-------------------|
| No Attachments added. | | | |

***Use Correspondence with this Note?**

Yes No

Content

B *I* U ~~S~~ x₂ x² Font Family 12

Enter a **Subject** (required), **Occurrence Date** (required), and **Content** for the note. Note that the **Content** field is not required in order to create the note.

A document may be attached to the note by clicking the **Upload Document(s)** dashed box or directly dragging in a file.

If you choose not to select **Use Correspondence with this Note**, you may save and add this new note to the Study Notebook ledger by clicking the **Save Note** button. This note will be visible to any user with access to the Study Notebook.

If you instead choose to send correspondence with this note, select “Yes” for the **Use Correspondence with this Note** field.

***Use Correspondence with this Note?**

Yes No

- **Send Email with Correspondence**
 - Yes No
- **Start Date for Correspondence**
 - (MM/DD/YYYY)
 - or
 - days from occurrence date
- **Send Correspondence**
 - Once on start date
 - or
 - Every day(s) from start date
- **Complete**
 - Yes No
- **Recipient(s):**
- **Additional recipient(s):**

Doing so will present a list of options allowing you to customize the correspondence. Each field is discussed below:

- **Send Email with Correspondence** – Choosing “Yes” means that an email will be generated with this note and sent to the selected recipients. Indicating “No” means that the Correspondence will be sent through iRIS™ only.
- **Start Date for Correspondence** – The date that the correspondence will generate. This can either be a calendar date or a number of days after the occurrence date.
- **Send Correspondence** – The frequency that the Correspondence will be sent.
- **Complete** – Choosing “Yes” marks the Correspondence configuration as completes and generates the message according to the options defined above. The default selection is “No”, meaning that the Correspondence is considered incomplete and will not generate upon saving the note.
- **Recipients** – This is a clickable link that will open a page listing all current Study Personnel, as seen in the image below. If the Study Application has been submitted, members of the review board overseeing your study will be listed as well. After selecting who will receive the correspondence, click the **Save Changes** button.

| Contacts | Role | <input type="checkbox"/> | |
|------------------------|-----------------------------------|--------------------------|--------------------|
| Study Personnel | | | |
| | Principal Investigator | <input type="checkbox"/> | Investigator, John |
| | Additional Principal Investigator | <input type="checkbox"/> | Coordinator, Sean |
| | Co-Investigator | <input type="checkbox"/> | Jefferson, Tom |
| | Nurse | <input type="checkbox"/> | Jefferson, George |
| | | <input type="checkbox"/> | Mossman, Nathan |
| | Study Author | <input type="checkbox"/> | Investigator, John |
| | Contact | <input type="checkbox"/> | Smith, Betty |
| | Department Administrator | <input type="checkbox"/> | Sykes, Jeff |

- **Additional Recipients** – This is a clickable link that will open the “Correspondence Additional Contacts” page. Here you may add a contact to the Correspondence that does not have an account in iRIS™. To do this, click on the **Add a New Contact** button.

| <input type="checkbox"/> | Name | E-mail Address |
|---|------|----------------|
| No Additional Recipients have been added. | | |

Doing so will open the following page.

| <input type="checkbox"/> | Name | E-mail Address |
|--------------------------|----------------------|----------------------|
| <input type="checkbox"/> | <input type="text"/> | <input type="text"/> |

Here you may assign the new contact a name and email address. Using the **Add a New Contact** and **Remove Selected Contacts** buttons you may add or remove additional recipients to your liking. Once finished, click the **Save and Return** button to add the new contacts to the Correspondence.

Once all note fields have completed you may save the note record by clicking **Save Note**.

The screenshot shows the 'Study Assistant' interface. At the top, there is a navigation bar with 'My Workspaces', 'Study Assistant', and 'Study Notebook' (with a 'Back' button). Below this, a summary bar displays 'Study Status: Active', 'IRB Number: IRB-21-476', 'Study Title: Malaria in Juveniles', and 'IRB Expiration Date: 06/24/2022'. A 'Save Note' button is highlighted with a red box in the top right corner. The main form is divided into two sections: 'Subject' and 'Content'. The 'Subject' section includes fields for 'Subject' (Study Notes - 7/1), 'Occurrence Date' (07/01/2021), an 'Upload Document(s)' area with a dashed border and the text 'Drag your file here or click in this area.', a table with columns 'Delete', 'Name', 'Date', and 'View the Document', and radio buttons for 'Use Correspondence with this Note?' (Yes/No). The 'Content' section features a rich text editor with a toolbar containing various formatting options like bold, italic, underline, and font size.

The new note will now populate in the Study Notebook. At any time, you can view this note or generate additional notes for the study. Click the **Back** button to return to the main Study Management screen.

Sponsors & Subrecipients

The screenshot shows a dark blue header with the text 'Sponsors & Subrecipients'. Below the header, there are two menu items, each with a circular icon and a text label: 'Sponsor' and 'Subrecipients'.

Sponsor

Clicking the Sponsor link shown above opens the “Study Sponsor” page.

My Workspaces ▾ IRB Number: **IRB-21-476** Study Assistant **Study Sponsor** ⏪ Back
 PI: Investigator, John

Study Status: **Active** IRB Number: IRB-21-476 Study Title: Malaria in Juveniles
 IRB Expiration Date: 06/24/2022

Approved Sponsor

1 result(s) found...

| Open | Sponsor |
|--|--|
| <input type="checkbox"/>  | Sponsor Name: 3-M Pharmaceuticals Sponsor Type: Pharmaceutical |

Pending Approval

0 result(s) found...

| Open | Sponsor |
|---|---------|
| No sponsors are pending for approval for this study | |

All sponsors that were added to this study through data values in the Study Application Form will display here. The sponsors are divided into two groups: approved sponsors and sponsors that are pending approval. Modifications to this sponsor configuration require submitting an Amendment form to the review board.

Sponsors that populate in the **Approved Sponsor** section are associated to a submission that has been approved by a review board. Changes to these sponsors must be submitted to board for approval.

Sponsors populate in the **Pending Approval** section whenever a sponsor modification request is in the process of being approved by the review board.

View the details of a sponsor by clicking on the icon in the **Open** column. This will open a page displaying a read-only printout of the sponsor information, as shown below.

My Workspaces ▾ IRB Number: **IRB-21-479** Study Assistant **Study Sponsor** ⏪ Back
 PI: Investigator, John

Study Status: **Open** IRB Number: IRB-21-479 Study Title: Malaria in Juveniles
 IRB Expiration Date: 06/29/2022

Info Sponsor Name: 3-M Pharmaceuticals
Contacts Sponsor Type: Pharmaceutical

Funding

ALL STUDIES IF SPONSOR(s)
 Add funding source(s) below:
 Federal, Sponsor, or Other, Select "Original Development by Applicant(s)" above if there is no funding for the study.

Please provide contact information below for the IRB Fee billing purposes.
 NOTE: * Denotes mandatory field.

Contact Name: *
 Sean McMurray

Contact Title: *
 Director

Mailing Address: *

Click the **Contacts** link on the left side of the screen to view or add sponsor contacts.

My Workspaces IRB Number: **IRB-21-479** Study Assistant **Study Sponsor** Back
 PI: Investigator, John

Study Status: **Open** IRB Number: IRB-21-479 Study Title: Malaria in Juveniles
 IRB Expiration Date: 06/29/2022

Go Back Add Contact Delete Contact

Info

Contacts

| | Name | Title | Division | Primary Phone | Primary Address |
|--------------------------|-------------------|-------|----------|---------------|-----------------|
| <input type="checkbox"/> | Bladivic, Krastan | | Finance | 8004578898 | |

Click **Add Contact** to open a list of contacts associated with the sponsor.

My Workspaces IRB Number: **IRB-21-479** Study Assistant **Study Contacts** Back
 PI: Investigator, John

Study Status: **Open** IRB Number: IRB-21-479 Study Title: Malaria in Juveniles
 IRB Expiration Date: 06/29/2022

Add a new Contact Add selected Contacts

| | Name | Title | Division | Primary Phone | Primary Address |
|--------------------------|--|-------|----------|---------------|-----------------|
| <input type="checkbox"/> | Alvarenga, Jorge | | iMedRIS | 9097989100 | |
| <input type="checkbox"/> | Bladivic, Krastan <i>already added</i> | | Finance | 8004578898 | |
| <input type="checkbox"/> | Test, Joe | | | | |

Check the box next to one or more contacts and click **Add selected Contacts** to add the sponsor contact to the study or click **Add a new Contact** to create a new contact for the sponsor.

My Workspaces IRB Number: **IRB-21-479** Study Assistant **Study Contacts** Back
 PI: Investigator, John

Study Status: **Open** IRB Number: IRB-21-479 Study Title: Malaria in Juveniles
 IRB Expiration Date: 06/29/2022

Save Changes

*Last Name:
 Title:

First Name: Middle Initial:
 Division:

Primary Address:
 Secondary Address:

Primary Phone:
 Secondary Phone:
 E-mail:

Comments:

Enter the contact's information and click **Save Changes** to add them to the study. This will also add the new contact to the master contact list associated with the sponsor.

My Workspaces IRB Number: **IRB-21-479** Study Assistant **Study Contacts** [Back](#)
 PI: Investigator, John

Study Status: **Open** IRB Number : IRB-21-479 Study Title : Malaria in Juveniles
 IRB Expiration Date: 06/29/2022

[Add a new Contact](#) [Add selected Contacts](#)

| | Name | Title | Division | Primary Phone | Primary Address |
|--------------------------|--|----------------------|----------|---------------|-----------------|
| <input type="checkbox"/> | Alvarenga, Jorge | | iMedRIS | 9097989100 | |
| | Bladivic, Krastan <i>already added</i> | | Finance | 8004578898 | |
| | Sykes, Jeff <i>already added</i> | Director of Research | Research | | |
| <input type="checkbox"/> | Test, Joe | | | | |

Click **Back** to return to the list of sponsor contacts on the study. If you added a contact in error, click the checkbox next to the contact name and click **Delete Contact**. Click **Go Back** to return to the main Study Sponsor screen.

My Workspaces IRB Number: **IRB-21-479** Study Assistant **Study Sponsor** [Back](#)
 PI: Investigator, John

Study Status: **Open** IRB Number : IRB-21-479 Study Title : Malaria in Juveniles
 IRB Expiration Date: 06/29/2022

[Go Back](#) [Add Contact](#) [Delete Contact](#)

| | Name | Title | Division | Primary Phone | Primary Address |
|--------------------------|-------------------|----------------------|----------|---------------|-----------------|
| <input type="checkbox"/> | Bladivic, Krastan | | Finance | 8004578898 | |
| <input type="checkbox"/> | Sykes, Jeff | Director of Research | Research | | |

Drugs and Devices

Drugs, Devices and Agents

- Drug/Biologic/Chemical agents**
- Agents**
- Devices**

Drug/Biologic/Chemical Agents

Clicking this link opens a page listing all drugs that were added to the study through the Study Application data value. These are broken up into two parts, Approved Drugs and Pending Drugs, as seen in the image below.

My Workspaces

IRB Number: **IRB-21-478**
 PI: Investigator, John

Study Assistant

Study Drug/Biologic/Chemical agent

 Back

Study Status: **Open**

IRB Number : IRB-21-478

Study Title : Malaria in Juveniles

IRB Expiration Date: 06/28/2022

Approved Drugs

1 result(s) found...

| Open | Drug Name | IND Number |
|------|--|------------|
| | Trade Drug Name Amoxicillin Generic Drug Name Amoxicillin A1 Investigational Drug Name | |

Pending Drugs

0 result(s) found...

| Open | Form Name | Drug Name | IND Number |
|---|-----------|-----------|------------|
| No drugs are pending for approval in this Study | | | |

Drugs populate in the **Approved Drugs** section when the review board approves a submission to which the drug is associated. Once a drug becomes approved, any modifications to that drug must be submitted to the review board for approval.

Drugs populate in the **Pending Drugs** section whenever a modification to an existing drug is requested, or a new drug is in the process of being approved by the review board.

You can view this page in a print friendly format by clicking the **Print Friendly** button on the top right of the page.

View a drug’s details by clicking on the icon in the **Open** column.

My Workspaces

IRB Number: **IRB-21-478**
 PI: Investigator, John

Study Assistant

Study Drug/Biologic/Chemical agent

 Back

Study Status: **Open**

IRB Number : IRB-21-478

Study Title : Malaria in Juveniles

IRB Expiration Date: 06/28/2022

Approved Drugs

1 result(s) found...

| Open | Drug Name | IND Number |
|------|--|------------|
| | Trade Drug Name Amoxicillin Generic Drug Name Amoxicillin A1 Investigational Drug Name | |

Pending Drugs

0 result(s) found...

| Open | Form Name | Drug Name | IND Number |
|---|-----------|-----------|------------|
| No drugs are pending for approval in this Study | | | |

This will open a read-only printout of the drug information.

| | | | | |
|--|---|---------------------------------|---|------|
| My Workspaces | IRB Number: IRB-21-478 PI: Investigator, John | Study Assistant | Study Drug/Biologic/Chemical agent | Back |
| Study Status: Open | | IRB Number : IRB-21-478 | Study Title : Malaria in Juveniles | |
| | | IRB Expiration Date: 06/28/2022 | | |

| | |
|-----------------|----------------------|
| Trade Drug Name | Amoxicillin |
| Dose Range | <input type="text"/> |

Protocol Information: Drugs and Biological Products

| | |
|--|---|
| Does your study involve INVESTIGATIONAL drugs, reagents, or chemicals? | Has this study been submitted to the Institutional Biosafety Committee (IBC) review? The IRB requires documentation of IBC approval before final approval of the study can be granted. <input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> N/A |
| | Investigational New Drug Application (IND)# <input type="text" value="554689"/> |
| | Is the drug provided free of charge? <input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> N/A |
| | What is the cost of the investigational drug to your institution? <input type="text" value="\$17"/> |
| | Manufacturer: <input type="text"/> |
| | Form of Administration: <input type="text"/> |
| | Procedure for Minimizing Adverse Events: <input type="text"/> |
| | Is IND held by the sponsor? If Yes, provide a copy of the investigator's brochure and the sponsor's protocol in the Attachments section. <input type="text"/> |
| | Is IND held by the Investigator(s)? If Yes, provide a copy of the IND application letter submitted to the FDA in the Attachments section. <input type="text"/> |

Devices

Click this link to view all devices that have been added to the study via the Study Application Form data value. These devices are divided into two categories, Approved Devices and Pending Approval, as seen in the image below.

| | | | | |
|--|---|---------------------------------|------------------------------------|------|
| My Workspaces | IRB Number: IRB-21-476 PI: Investigator, John | Study Assistant | Study Device | Back |
| Study Status: Active | | IRB Number : IRB-21-476 | Study Title : Malaria in Juveniles | |
| | | IRB Expiration Date: 06/24/2022 | | |

[Print Friendly](#)

Approved Devices

1 result(s) found...

| Open | Device Name |
|------|---------------|
| | Cardiac Stent |

Pending Approval

0 result(s) found...

| Open | Form Name | Device Name |
|---|-----------|-------------|
| No devices are pending for approval in this Study | | |

Devices populate in the **Approved Devices** section when the review board approves a submission to which the device is associated. Once a device is approved, any modifications to that device must be submitted to the review board for approval.

Devices populate in the **Pending Approval** section whenever a modification to an existing device is requested, or a new device is in the process of being approved by the review board.

You can view this page in a print-friendly format by clicking the **Print Friendly** button on the upper right corner of the page.

You can view device details by clicking on the icon in the **Open** column.

My Workspaces IRB Number: **IRB-21-476** Study Assistant **Study Device** Back
 PI: Investigator, John

| | | | | | |
|---------------|--------|----------------------|------------|---------------|----------------------|
| Study Status: | Active | IRB Number : | IRB-21-476 | Study Title : | Malaria in Juveniles |
| | | IRB Expiration Date: | 06/24/2022 | | |

Approved Devices

1 result(s) found...

| Open | Device Name |
|------|---------------|
| | Cardiac Stent |

Pending Approval

0 result(s) found...

| Open | Form Name | Device Name |
|---|-----------|-------------|
| No devices are pending for approval in this Study | | |

This will open a read-only printout of the device information.

My Workspaces IRB Number: **IRB-21-476** Study Assistant **Study Device** Back
 PI: Investigator, John

| | | | | | |
|---------------|--------|----------------------|------------|---------------|----------------------|
| Study Status: | Active | IRB Number : | IRB-21-476 | Study Title : | Malaria in Juveniles |
| | | IRB Expiration Date: | 06/24/2022 | | |

| | | |
|--|-------------|---------------|
| | Device Name | Cardiac Stent |
|--|-------------|---------------|

Protocol Information: Medical Equipment, Study Devices

| | |
|--|---|
| <p>BIOMEDICAL FULL BOARD EXPEDITED STUDIES</p> <p>Study Devices</p> <p>General Hospital defines a "study device" as a medical device that is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device.</p> | <p>Manufacturer:</p> <p>Amgen</p> <p>Describe how dispensing of the study device(s) will be controlled; describe where the device(s) will be stored and how access to the device(s) will be limited to only the individuals listed as study personnel on the protocol.</p> <hr/> <p>Regulatory Status: The FDA is responsible for defining the development, testing, approval, and marketing of each medical device. Except for certain low-risk devices, each new medical device must be submitted to the FDA for review and assignment of its regulatory status. For more information, see FDA Information Sheet, titled "Medical Devices."</p> |
|--|---|

Pending request tables improvements

A modification has been made to the “Pending Request” tables that affects drugs, devices, species, analgesia, strain etc. In previous versions of iRIS™, the above items would populate in the “Pending” table as soon as they were added to the Study Application via the respective data values.

This modification prevents these items from populating in the “Pending” table until the study no longer has a status of “Draft”. That is, the study must be submitted to a review board before the drugs, devices, etc. defined in the Study Application Form are displayed as “Pending”. This applies to any form that contains associated drugs, devices, and species, i.e. Amendment and Correction forms as well.

My Workspaces

IRB Number: **IRB-21-479**
 PI: Investigator, John

Study Assistant

Study Drug/Biologic/Chemical agent

 Back

Study Status: **Draft**

IRB Number : IRB-21-479

Study Title : Malaria in Juveniles

[Print Friendly](#)

Approved Drugs

0 result(s) found...

| Open | Drug Name | IND Number |
|--|-----------|------------|
| No drugs have been added to this Study | | |

Pending Drugs

0 result(s) found...

| Open | Form Name | Drug Name | IND Number |
|---|-----------|-----------|------------|
| No drugs are pending for approval in this Study | | | |

Once the submission has been sent to the review board and the “Draft” status is changed, the items will populate in their respective “Pending” tables.

My Workspaces

IRB Number: **IRB-21-479**
 PI: Investigator, John

Study Assistant

Study Drug/Biologic/Chemical agent

 Back

Study Status: **Pending - Submitted for Initial Review**

IRB Number : IRB-21-479

Study Title : Malaria in Juveniles

IRB Expiration Date: 06/29/2022

[Print Friendly](#)

Approved Drugs

0 result(s) found...

| Open | Drug Name | IND Number |
|--|-----------|------------|
| No drugs have been added to this Study | | |

Pending Drugs

1 result(s) found...

| Open | Form Name | Drug Name | IND Number |
|------|---------------------------------|--|------------|
| | IRB Application (Version 1.0) | Trade Drug Name Amoxicillin Generic Drug Name Amoxicillin A1 Investigational Drug Name | |

Once the submission is approved, the items will then move into the “Approved Drugs” table.

My Workspaces IRB Number: **IRB-21-479** Study Assistant **Study Drug/Biologic/Chemical agent** [Back](#)
 PI: Investigator, John

Study Status: **Open** IRB Number : IRB-21-479 Study Title : Malaria in Juveniles
 IRB Expiration Date: 06/29/2022

[Print Friendly](#)

Approved Drugs

1 result(s) found...

| Open | Drug Name | IND Number |
|------|--|------------|
| | Trade Drug Name Amoxicillin Generic Drug Name Amoxicillin A1 Investigational Drug Name | |

Pending Drugs

0 result(s) found...

| Open | Form Name | Drug Name | IND Number |
|---|-----------|-----------|------------|
| No drugs are pending for approval in this Study | | | |

If a study revision is created, the original data will not be saved and thus not populate in the “Pending” tables .

Enrollment Criteria

Enrollment Criteria

- Inclusion Criteria
- Exclusion Criteria

Inclusion Criteria and Exclusion Criteria

These two links provide access to the Inclusion and Exclusion Criteria entered in a study’s application form. The information below applies to both types of criteria, and Inclusion Criteria is used as an example.

Clicking the “Inclusion Criteria” link opens the following page.

My Workspaces IRB Number: **IRB-21-476** Study Assistant **Study Criteria** [Back](#)
 PI: Investigator, John

Study Status: **Active** IRB Number : IRB-21-476 Study Title : Malaria in Juveniles
 IRB Expiration Date: 06/24/2022

[Print Friendly](#)

Approved Criteria

0 result(s) found...

| Open | Definition | Order Number |
|--------------------------------|------------|--------------|
| No criteria have been defined. | | |

Pending Approval

0 result(s) found...

| Open | Definition | Order Number |
|---------------------------------------|------------|--------------|
| No criteria are pending for approval. | | |

This page is broken up into two sections, Approved Criteria and Pending Approval.

Criteria populate in the **Approved Criteria** section when the review board approves a submission to which the criteria is associated. Once approved, any modifications to these criteria must be submitted to the review board for approval.

Criteria will populate in the **Pending Approval** section whenever a modification to an existing criteria record is requested, or new criteria are in the process of being approved by the review board.

You can view this page in a print-friendly format by clicking the **Print Friendly** button on the upper right corner of the page.

You can view criteria details by clicking on the icon in the **Open** column, which will open a read-only printout of the criteria information.