

Coming soon to an IRB Panel near you...

INSPIR II

- Mary A. Banks
- Director, BUMC IRB
- March, 2011
- Training for IRB Board Members
 - Session 1

Upcoming System Changes

- **As of March 15th 2011 all IRB meetings will be run using INSPIR II**
- INSPIR II training for Board Members is in 2 parts
 - View video of INSPIR II basics and the “investigator” role
 - Look Power-point slides (these have been combined – they were previously in 2 parts)

Part I :The Basics

Understanding the “basics” of INSPIR including the investigator role

- Go to IRB website www.bumc.bu.edu/irb and click on the “INSPIR II image” to get to the INSPIR II page
- Click on the link under “Overview and Announcements” to find the “INSPIR II Introductory Training video”

INSPIR II

INSPIR II went LIVE! Click here (or on the image) to login.

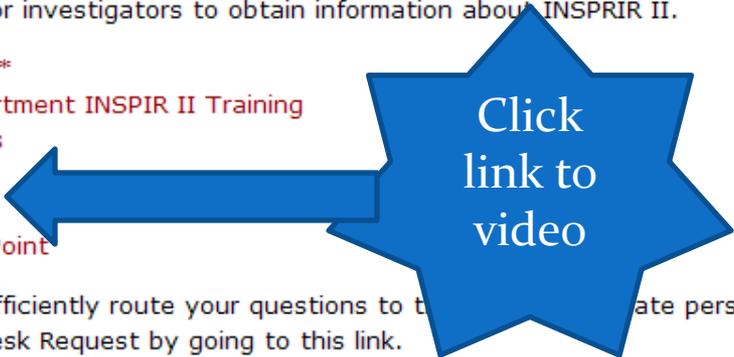
A Farewell Song to INSPIR I

INSPIR II Overview and Announcements

On March 15, 2011, the BUMC IRB switched to a new IRB software system called INSPIR II (replacing INSPIR). All protocols from INSPIR I were migrated over to the new system. Below are various resources for investigators to obtain information about INSPIR II.



- [Submit a INSPIR II Help Desk Request*](#)
- [Registration Form for Scheduling Department INSPIR II Training](#)
- [INSPIR II Instructions for Investigators](#)
- [February 2011 CR Times Article](#)
- [INSPIR II Introductory Training Video](#)
- [INSPIR II Introductory Training PowerPoint](#)



*INSPIR II Helpdesk Request - In order to efficiently route your questions to the appropriate person in the IRB office, please submit an INSPIR II Helpdesk Request by going to this link.

INSPIR II FAQs

- [User name/log-in/Personal Profile issues](#)
- [Migration Issues](#)
- [IRB Application Issues](#)
- [Consent/ Assent form issues](#)
- [Attachment Issues](#)

[Institutional Review Board](#)

[BUMC IRB Info](#)

[IRB Guidance](#)

[WIRB](#)

[UPSER & AEs](#)

INSPIR II

[Board Reviewers](#)

[Interpreter Services](#)

[Links](#)

[Research with Other Institutions](#)

[CRC IRB](#)

[News »](#)

The February edition of the Clinical Research Times is on the newsstands!

[Also See](#)

[Boston Population and Demographics](#)

[HIPAA Privacy Info](#)

Part II: Board Member “role”

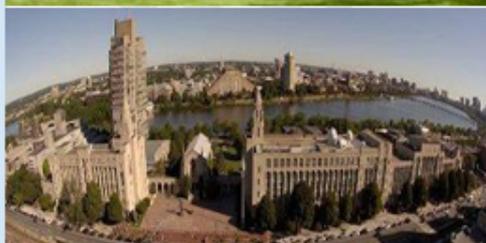
- The rest of this slide-set contains Power-Point slides specific to the Board Member role
- (The link to this slide-set is posted at the bottom of the IRB INSPIR II homepage)

How To Log In to INSPIR II



Go to <https://inspir.bu.edu> to get to the INSPIR II log-in page

Log In



INSPIR II

Integrated Network

for Subject Protection in Research

User ID:

Password:

Log In

Log-in using your BU user name (user ID) and Kerberos password

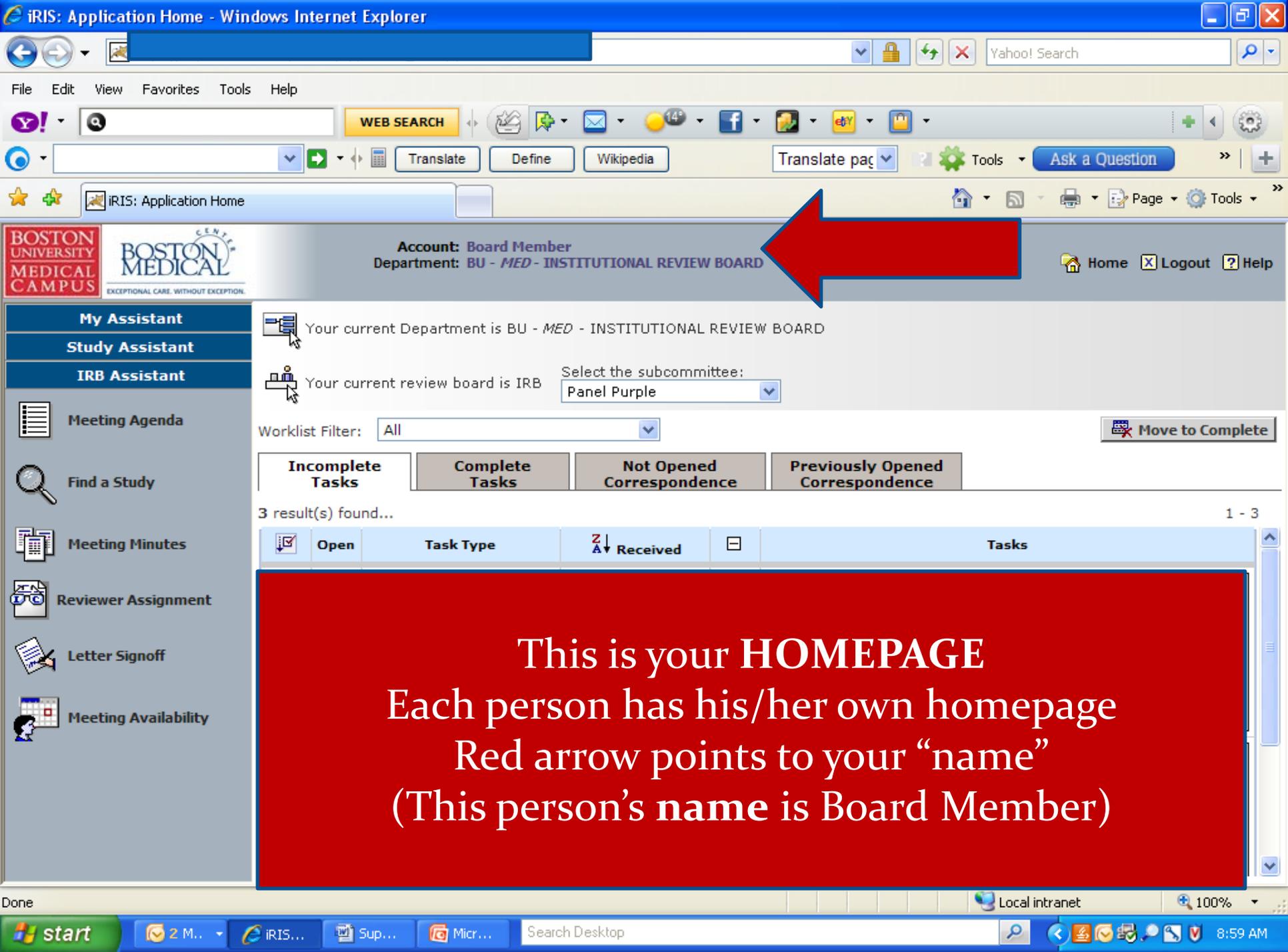
You must use your BU user name and password to log-in

[System/Browser Requirements](#)

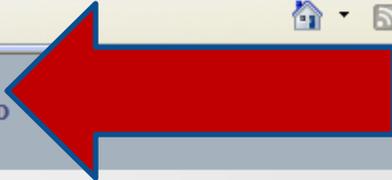
For help click [here](#).

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Version 8.02 Dev Build 1557 Updated 12/20/2010



Account: Board Member
Department: BU - MED - INSTITUTIONAL REVIEW BOARD



Your current Department is BU - MED - INSTITUTIONAL REVIEW BOARD

Your current review board is IRB
Select the subcommittee:
Panel Purple

Worklist Filter: All

Move to Complete

Incomplete Tasks Complete Tasks Not Opened Correspondence Previously Opened Correspondence

3 result(s) found...

1 - 3

<input checked="" type="checkbox"/>	Open	Task Type	Z A ↓ Received		Tasks
-------------------------------------	------	-----------	-------------------------	--	-------

This is your **HOMEPAGE**
Each person has his/her own homepage
Red arrow points to your "name"
(This person's name is Board Member)

From Your HOMEPAGE

From your homepage you will have 3 major options

- **My Assistant** – this is where you update your personal profile & contact information about **YOU** (all about YOU!)
- **Study Assistant** –this is where you find and update all **YOUR STUDIES** (if you have any)- including studies where you are a PI or co-investigator or study staff. Here is where you would also create a new protocol.
- **IRB Assistant**- this is where you find materials assigned to you for your IRB review as a **Board Member**



Most of the time you will see the IRB Assistant Role at the bottom of the screen on the left hand side. Click on the "IRB Assistant" and IRB Assistant will move to the top of the column.



Account: Board Member
 Department: BU - MED - INSTITUTIONAL REVIEW BOARD

Home Logout Help

My Assistant

Study Assistant

Add a new Study

My Studies

My Appointments

IRB Assistant

Your current Department is BU - MED - INSTITUTIONAL REVIEW BOARD

Your current review board is IRB
 Select the subcommittee:
 Panel Purple

Worklist Filter: All

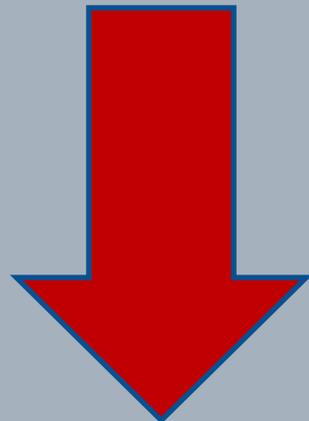
Move to Complete

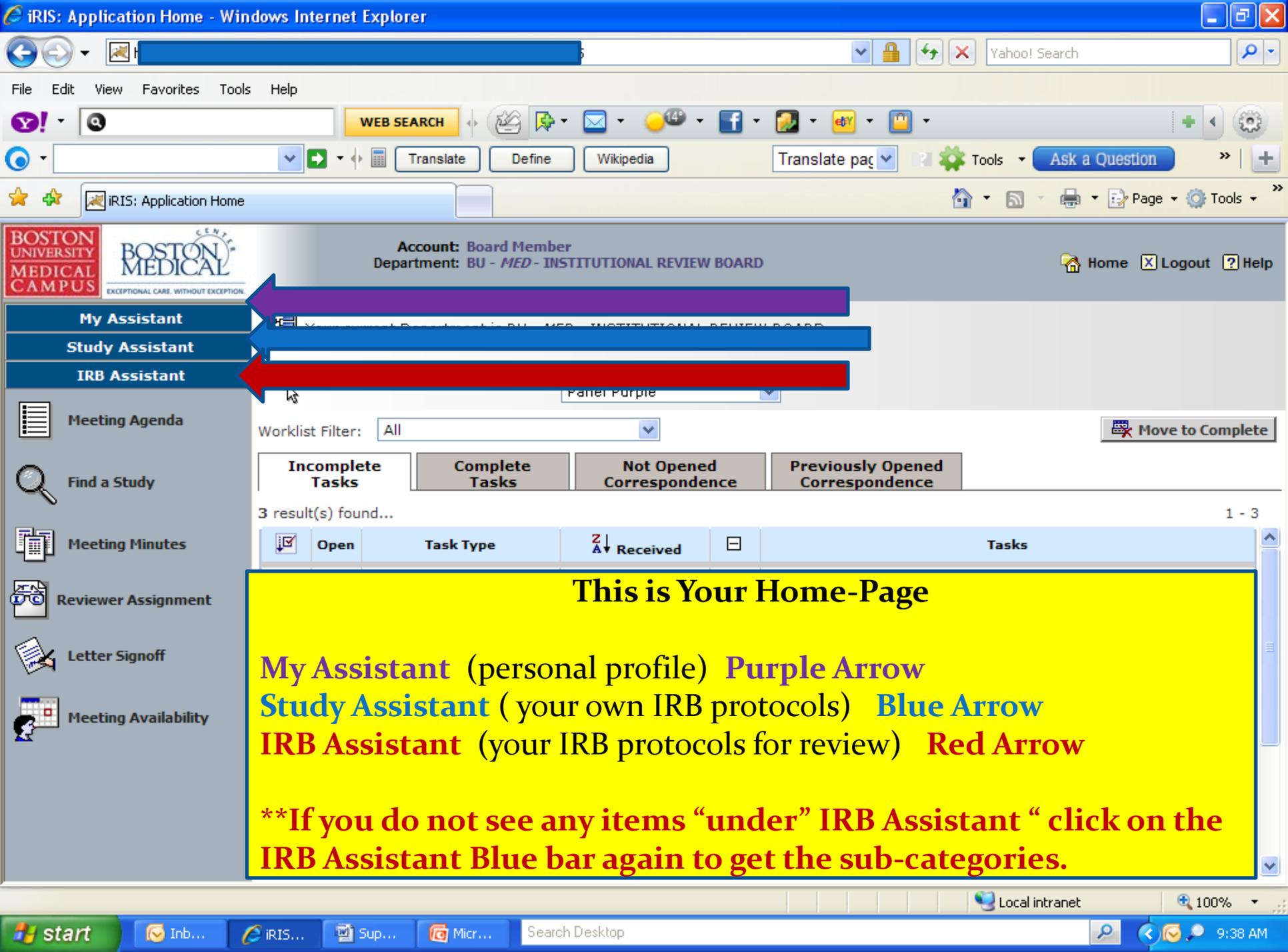
Incomplete Tasks Complete Tasks Not Opened Correspondence Previously Opened Correspondence

3 result(s) found...

1 - 3

Open	Task Type	Received	Tasks
	Reviewer Assignment	03/16/2011 08:36 AM EDT	<p>Board Member has been assigned as the Chair for an Expedited Review on the Initial Review Submission Form</p> <p>Study Title: Roth expedited Principal: Timothy Roth Investigator: Timothy Roth Submission Type: Initial Review Submission Form Reference Number: 311321 IRB Number: H-30020</p>
	Reviewer Assignment	02/16/2011 11:06 AM EST	<p>Board Member has been assigned as the Primary Reviewer for a Board Review on 02/17/2011 on the Continuing Review Submission Form</p> <p>Study Title: Testing 2/3/2011 - Amend 2 Principal: Principal Investigator Investigator: Principal Investigator Submission Type: Continuing Review Submission Form Reference Number: 311297 IRB Number: H-30016 IRB Expiration: 02/09/2012</p>





Browser navigation bar including back, forward, address bar, search engines (Yahoo!, Google), and utility buttons like Translate, Define, and Wikipedia.

Header section with Boston University Medical Campus logo, user account information (Board Member, BU - MED - INSTITUTIONAL REVIEW BOARD), and navigation links (Home, Logout, Help).

Navigation menu with 'My Assistant', 'Study Assistant', and 'IRB Assistant' highlighted. Three colored arrows (purple, blue, red) point to these items.

Main content area showing a 'Worklist Filter' set to 'All', tabs for 'Incomplete Tasks', 'Complete Tasks', 'Not Opened Correspondence', and 'Previously Opened Correspondence', and a table of 3 results found.

This is Your Home-Page
My Assistant (personal profile) **Purple Arrow**
Study Assistant (your own IRB protocols) **Blue Arrow**
IRB Assistant (your IRB protocols for review) **Red Arrow**
****If you do not see any items “under” IRB Assistant “ click on the IRB Assistant Blue bar again to get the sub-categories.**

Training about the “Roles”

- On the investigator training video and Power-point slides you will find instructions about the first two roles
 - My Assistant
 - Study Assistant
- **IRB Assistant**
 - The rest of these slides relate specifically to the **IRB Assistant** role
 - It is here that you will find all the materials you need for your IRB reviews of protocols as Board Members

Navigation bar with back, forward, and search buttons. Search bar contains "Yahoo! Search".

Menu bar: File, Edit, View, Favorites, Tools, Help

Toolbar: Translate, Define, Wikipedia, Translate page, Tools, Ask a Question

Additional icons: Home, RSS, Print, Page, Tools

Back on your Home-Page

BOSTON UNIVERSITY MEDICAL CAMPUS **BOSTON MEDICAL CENTER** EXCEPTIONAL CARE. WITHOUT EXCEPTION.

Account: Board Member
Department: BU - MED - INSTITUTIONAL REVIEW BOARD

Home Logout Help

- My Assistant
- Study Assistant
- IRB Assistant
- Meeting Agenda
- Find a Study
- Meeting Minutes
- Reviewer Assignment
- Letter Signoff
- Meeting Availability

Under "IRB Assistant" Role

Your current Department is BU - MED - INSTITUTIONAL REVIEW BOARD

Worklist Filter: All

Move to Complete

Incomplete Tasks Complete Tasks Not Opened Correspondence Previously Opened Correspondence

3 result(s) found... 1 - 3

Open	Task Type	Received	Tasks
<input checked="" type="checkbox"/>	Reviewer Assignment	02/16/2011	

Reference Number: 311324
IRB Number: H-30023

You will see multiple options :
Meeting agenda- to view upcoming agenda
"Find a study" to locate a specific study"
(other options will be discussed later)

- My Assistant
- Study Assistant
- IRB Assistant
- Meeting Agenda
- Find a Study
- Meeting Minutes
- Reviewer Assignment
- Letter Signoff
- Meeting Availability

Your current Department is BU - MED - INSTITUTIONAL REVIEW BOARD

Your current review board is IRB

Select the subcommittee:
Panel Purple



Worklist Filter: All

Move to Complete

Incomplete Tasks Complete Tasks Not Opened Correspondence Previously Opened Correspondence

3 result(s) found... 1 - 3

Open	Task Type	Received	Tasks
Make sure that you verify that you have selected the correct IRB Panel from the drop-down menu (see red arrow)			

Navigation bar of Windows Internet Explorer showing back, forward, and search buttons. The address bar contains "iRIS: Application Home". The search bar has "WEB SEARCH" and "Translate" buttons. The toolbar includes icons for home, RSS, print, and page settings.

Header section with logos for Boston University Medical Campus and Boston Medical Center. Text indicates the user's account is "Board Member" and their department is "BU - MED - INSTITUTIONAL REVIEW BOARD". Navigation links for "Home" and "Logout" are present.

Left sidebar navigation menu with the following items: My Assistant, Study Assistant, IRB Assistant, Meeting Agenda, Find, Meeting, Review, Letter, Meeting availability. A large red arrow points upwards from the bottom towards the "Meeting Agenda" item.

Your current Department is BU - MED - INSTITUTIONAL REVIEW BOARD
Your current review board is IRB
Select the subcommittee:
Panel Green
Worklist Filter: All



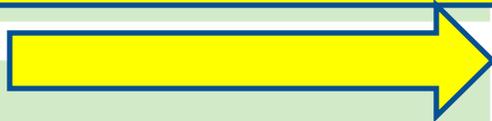
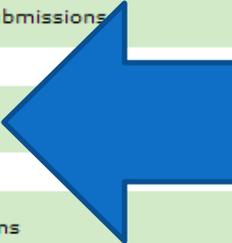
Task filters: Incomplete Tasks, Complete Tasks, Not Opened Correspondence, Previously Opened Correspondence

3 result(s) found...

Open	Task Type	Received	Tasks
<p>Once you have verified that you have the correct IRB Panel Click on "Meeting Agenda" (under the IRB Assistant Role) (red arrow)</p>			

This will bring you to the Meeting Agenda Page

Use right hand scroll bar to scroll down (yellow arrow)



On this page you will see

Panel Name- **Green Arrow**

Meeting Date: -**Red Arrow**

Items for review by category- **Blue arrow**

Meeting Chair - **Purple arrow**

IRB - Review Board Meeting Agenda

Items to be Reviewed at Panel Green Meeting :

◀ 03/03/2011 ▶

Meeting Start Time:

Meeting End Time:

Meeting Chair: --none--

Initial Review(s) - 0 Submissions

0 Items for review in this category.

Continuing Review(s) - Full Board - 0 Submissions

0 Items for review in this category.

Amendment(s) - 0 Submissions

0 Items for review in this category.

Report of Adverse Event(s) - 0 Submissions

0 Items for review in this category.

Expedited Initial Review(s), Continuing Review(s), Amendment(s) - 0 Submissions

0 Items for review in this category.

Others - 2 Submissions

IRB - Review Board Meeting Agenda Back

Items to be Reviewed at Panel Green Meeting : ◀ 03/03/2011 ▶ Submission Review validation

- Amendment(s)** - 0 Submissions
0 Items for review in this category.
- Report of Adverse Event(s)** - 0 Submissions
0 Items for review in this category.
- Expert Review(s), Continuing Review(s), Amendment(s)** - 0 Submissions
0 Items for review in this category.
- Others** - 2 Submissions

Red Arrow points to how protocols will be listed

Click where it says "click to open" to OPEN the protocol

Order	Click to open	Ref Num	COI	Letters	Outcome	IRB Number	Type	Principal Investigator	Reviewer(s)	Date Board Received
		<i>Title</i>								
		311322	⊗		Approved	H-30025	Initial Review Submission Form	Cho, Heeyoun		02/15/2011
		<i>The Happy New Year Protocol- Emergency Use</i>								
1		311175	⊗	✓	Approved	H-30018	Initial Review Submission Form	Banks, Mary		02/11/2011

The screenshot shows the iRIS IRB Submission Form interface. A yellow arrow points from the top navigation bar to the 'IRB - Initial Review Submission Form' header. Another yellow arrow points from the 'General Information' section to the 'Study Nickname: 111' field. A red arrow points from the 'Submission Components' link in the left sidebar to the 'Submission Components' section in the main content area. A third yellow arrow points from the 'Study Personnel' table to the 'Principal Investigator: Heeyoun Cho' entry.

Account: Board Member
Navigation: Home > meeting agenda

IRB Number: H-30025 **Study Nickname:** 111
PI: Cho, Heeyoun

IRB - Initial Review Submission Form

Protocol Items | Miscellaneous | Submission Forms | Additional Attached F...

Study Status: **Approved / Open** **Study Title:** Title
Ref Number: 311322 **Expiration Date:** 02/02/2012

General Information

Submission Components
Correspondent
Workflow
Review Changes and Comments
Recommendations
Stipulations

General Information:

Study Nickname: 111
Study Classification:
[Edit the Master Lay Summary](#) This study is **very important** and thus it is very challenging to explain in 300 words.
[Click Here to edit the submission summary](#)
Enrollments: 0 **Accrual Target:** 0
Meeting Date: 03/03/2011

Department
BU - MED - INSTITUTIONAL REVIEW BOARD

Study Personnel [Update personnel training status to latest](#) - Click on the icon next to each name for the personal profile

Role	Name	Personnel Certification in Human Subject Training Training:
Principal Investigator:	Heeyoun Cho	
Study Contact:	Heeyoun Cho	

This opens the "cover" page for this study H-30025

You will see "general info" Study number , PI, study status, study (lay) summary (yellow arrows)

From here Click on **Study Components** (red arrow) to OPEN the protocol , consents and attachments

PI name

IRIS: IRB Submission item - Windows Internet Explorer

File Edit View Favorites Tools Help

WEB SEARCH Translate Define Wikipedia

IRIS: IRB Submission item

BOSTON UNIVERSITY MEDICAL CAMPUS BOSTON MEDICAL CENTER EXCEPTIONAL CARE. WITHOUT EXCEPTION.

Account: Board Member
Navigation: Home > meeting agenda

IRB Number: H-30025 Study Nickname: 111
PI: Cho, Heeyoun

IRB - Initial Review Submission Form

Protocol Items Miscellaneous Submission Forms Additional Attached F...

Study Status: **Approved / Open** Study Title: Title
Ref Number: 311322 Expiration Date: 02/02/2012

General Information
Submission Components
Correspondence
Workflow Tracking
Review Checklist and Comments
Recommendation
Stipulation

Submission Components:

Show History	Open	Type	Document Name	Version	Date Submitted into Workflow
		Submission Form	Initial Review Submission Form <i>* This form was part of this submission.</i>	Version 1.0	02/15/2011 02:24 PM EST
Submission Attachments below:					
		Application	Study Application <i>* This application was part of this submission.</i>	Version 1.0	02/15/2011 02:24 PM EST
		Sub Form	Sample Collection <i>This form has not been completed!</i>	Version 1.0	02/15/2011 02:24 PM EST
		Consent (English)	hnkjkk <i>* This consent was part of this submission.</i>	Version 1.0	02/15/2011 02:24 PM EST
		Document -	test <i>* This document was part of this submission.</i>	Version 1.0	02/15/2011 02:24 PM EST

From this “submission components” page you will see:

- The submission form
- The Application
- The consent forms
- Other study docs (= attachments)

Click on the “icon” next to each item to OPEN it



File Edit View Favorites Tools Help

Y! WEB SEARCH Translate Define Wik

iRIS: Study Application

BOSTON UNIVERSITY MEDICAL CENTER
EXCEPTIONAL CARE. WITHOUT EXCEPTION.

Department: Board Member
Department: BU - MED - INSTITUT
Name: Home > meeting ag

IRB Number: H-30025 Study Nickname: 111
PI: Chou

Section view of Application Entire view of the Application

- 1.0 General Information
- 2.0 Setup Department(s) Access
- 3.0 Grant key study personnel(KSP) access to the study
- 4.0 External non-BU/BMC Investigators
- 5.0 Investigator Information from INSPIR I
- 6.0 COI
- 7.0 Funding Source
- 8.0 Study Summary
- 9.0 Study Site Information
- 10.0 Navigation Menu
- 11.0 Purpose
- 12.0 Subjects
- 13.0 Design/Procedure
- 14.0 Sample Size/Specimens/Data

This will open up the "IRB Application" for H-30025

You can view it Section by Section (red arrow) or Look at it in its entirety (Blue Arrow)

1.0 General Information

1.1 *Please enter the full title of your study (Spell out acronyms):

Title		
-------	--	--

1.2 *Please enter the Study Nickname you would like to use to reference the study:

111		
-----	--	--

1.3 Please identify the Study Phase?

--none--		
----------	--	--

1.4 Please identify the Research Type?

--none--		
----------	--	--

After you have reviewed the IRB application – go back to the “submission” to review the other components of the submission (the consent forms and attachments). Do this by clicking on “submission item” on the navigation bar (red arrow) or by using the “back” arrow (blue arrow)

BOSTON UNIVERSITY MEDICAL CAMPUS | **BOSTON MEDICAL** | EXCEPTIONAL CARE. WITHOUT EXCEPTION.

Account: Board Member
Department: BU - MED - INSTITUTIONAL REVIEW BOARD
Navigation: Home > meeting agenda > submission item

Home | Logout | Help

IRB Number: H-30025 | Study Nickname: 111 | PI: Cho, Heeyoun

Study Application

Back | Print | Find

Section view of Application | Entire view of the Application | Review | Sections

1.0 General Information

1.1 *Please enter the full title of your study (Spell out acronyms):

Title		
-------	--	--

1.2 *Please enter the Study Nickname you would like to use to reference the study:

111		
-----	--	--

1.3 Please identify the Study Phase?

--none--		
----------	--	--

1.4 Please identify the Research Type?

--none--		
----------	--	--

Done | Local intranet | 100% | start | 3 M... | iRIS... | Sup... | Micr... | Search Desktop | 11:19 AM

Now that you are back on the “submission components” page – from here you can open the consent form (blue arrow) or other study documents (yellow arrow).

Click on the “open icon” next to each item to OPEN it

MEDICAL CAMPUS MEDICAL EXCEPTIONAL CARE. WITHOUT EXCEPTION.

Navigation: Home > meeting agenda Home Logout Help

IRB Number: H-30025 Study Nickname: 111 IRB - Initial Review Submission Form Back

PI: Cho, Heeyoun

Protocol Items Miscellaneous Submission Forms Additional Attached F...

Study Status: **Approved / Open** Study Title: Title

Ref Number: 311322 Expiration Date: 02/02/2012

Printer Friendly

General Information

Submission Components

Correspondence

Workflow Tracking

Review Checklist and Comments

Recommendation

Stipulation

Submission Components:

Show History	Open	Type	Document Name	Version	Date Submitted into Workflow
		Submission Form	Initial Review Submission Form * This form was part of this submission.	Version 1.0	02/15/2011 02:24 PM EST
Submission Attachments below:					
		Application	Study Application * This application was part of this submission.	Version 1.0	02/15/2011 02:24 PM EST
		Sub Form	Sample Collection This form has not been completed!	Version 1.0	02/15/2011 02:24 PM EST
		Consent (English)	hnkjkk * This consent was part of this submission.	Version 1.0	02/15/2011 02:24 PM EST
		Document -	test * This document was part of this submission.	Version 1.0	02/15/2011 02:24 PM EST

