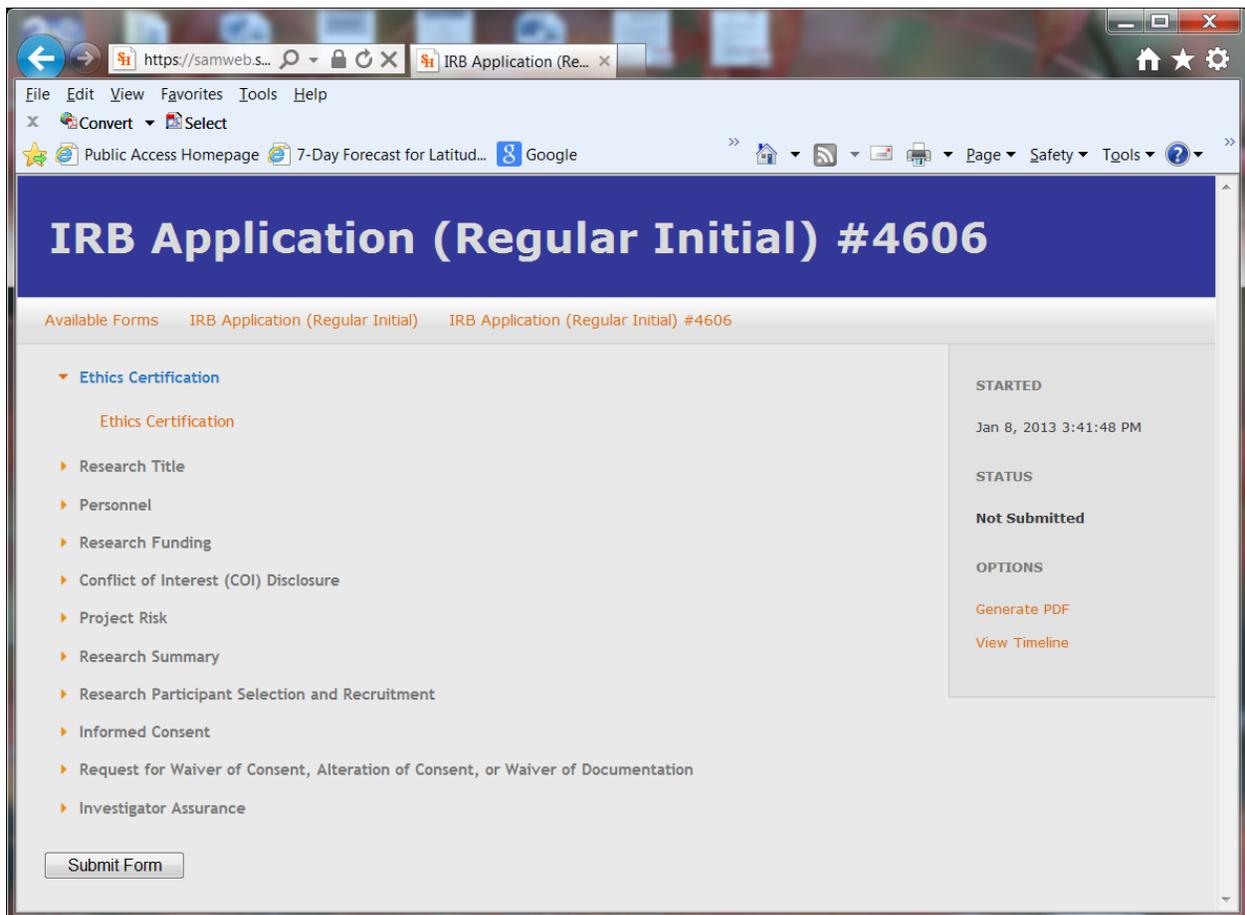


The New IRB Form System

Completing IRB Forms—the IRB Application (Regular Initial)

When you select to complete a new form the form will automatically be created and assigned an identification number. Below you will see that I've chosen to start a new **IRB Application (Regular Initial)** form. It has been assigned the **#4606** by the form system.



The screenshot shows a web browser window with the URL <https://samweb.s...> and a tab titled "IRB Application (Re...". The browser's address bar shows the URL, and the page title is "IRB Application (Regular Initial) #4606". The browser's menu bar includes "File", "Edit", "View", "Favorites", "Tools", and "Help". The browser's toolbar includes "Convert", "Select", "Public Access Homepage", "7-Day Forecast for Latitud...", "Google", and various utility icons. The main content area has a blue header with the text "IRB Application (Regular Initial) #4606". Below the header, there are three tabs: "Available Forms", "IRB Application (Regular Initial)", and "IRB Application (Regular Initial) #4606". The main content area is divided into two columns. The left column has a "Submit Form" button at the bottom. The right column has a sidebar with the following information: "STARTED" (Jan 8, 2013 3:41:48 PM), "STATUS" (Not Submitted), and "OPTIONS" (Generate PDF, View Timeline).

The sidebar on the right side of the window displays information about the current form should it be available. Here it also provides us with the option to generate a PDF file of the form in its present state or to view the approval timeline. Because this form has not yet been submitted the timeline will be empty.

To the left we see a list of form categories and sections. The Ethics Certification category has one section. Clicking on a category name will display the sections that exist for it.

Disapproval of the Research

ALL PIs MUST COMPLETE

To your knowledge, has this protocol been reviewed and subsequently disapproved by any Protection of Human Subjects Committee (PHSC)? *

Yes

No

If you answered yes to the above question please provide details of the disapproval including the reviewing committee name, institutional affiliation, the date of review, the issues resulting in disapproval, and how these issues have been resolved.

Disapproval Documentation

Attach any Request for Modifications letters and any Response letters to these modifications here.

2012-11-3121_consent and survey.pdf
uploaded Jan 18, 2013 10:47:32 AM

Remove File

Browse... Upload File

Save Save & Continue Skip & Continue

This is the **Disapproval of the Research** section of the form. As you can see, I've already attached a PDF document to the **Disapproval Documentation** item. You can click the filename to view the file and use the visible buttons to remove it or add additional files.

The three buttons at the bottom of a section are:

1. **Save** – save the data entered and display the form categories as seen in the previous screenshot
2. **Save & Continue** – save the data entered and display the next section of the form
3. **Skip & Continue** – discard any unsaved data that's been entered and display the next section of the form

When you click **Save & Continue** or **Skip & Continue** on the last section of a form, it will display the form categories as seen previously and allow you to submit the full form.

Submitting a form can take several seconds as the data must be validated. If any errors are found they will be displayed.

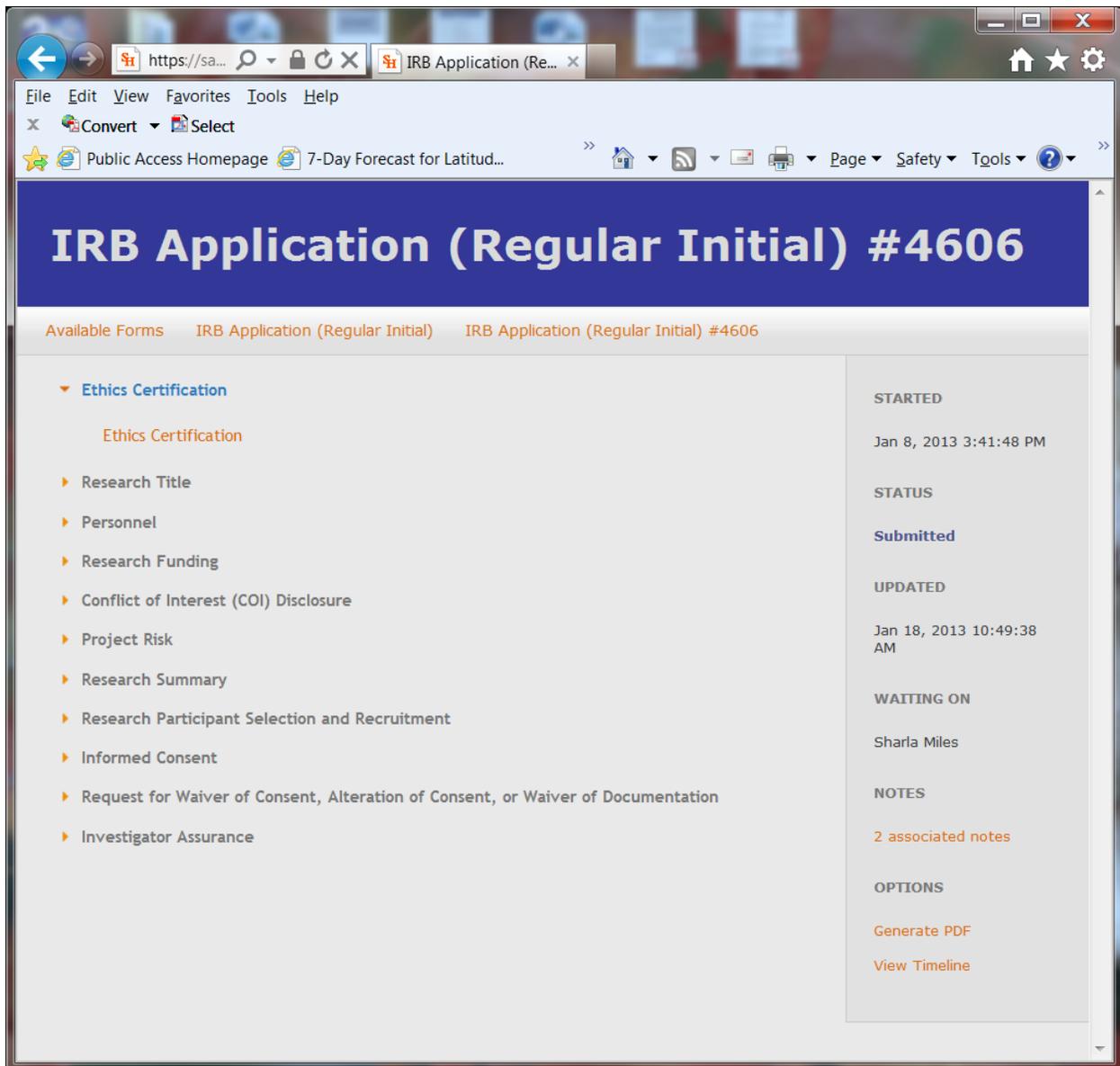
Below is my list of forms after I've submitted **IRB Application (Classroom Activity) #4606**:

The screenshot shows a web browser window with the URL <https://sa...> and a tab titled "IRB Application (Re...". The browser's address bar shows "Public Access Homepage" and "7-Day Forecast for Latitud...". The page content includes a blue header with the text "IRB Application (Regular Initial)". Below the header, there are two tabs: "Available Forms" and "IRB Application (Regular Initial)". The main content area is divided into sections: "Contact Information" for Sam Houston State University, "Please Note:" with instructions on form completion and PDF generation, and "Your Forms" with a sub-tab "Forms Pending Your Approval". A table lists the submitted forms:

Instance	Started	Status	Updated	Waiting On
IRB Application (Regular Initial) #4606	Submitted	Jan 18, 2013 10:41:22 AM	Jan 8, 2013 3:41:48 PM	Sharla Miles

It's listed at the very bottom. If a form in this list is **Waiting On** someone you can hover over that text to see the names of the people that it's waiting on – in this case, Sharla Miles.

At this point we wait for the form to make its way through the approval chain. An approver may attach a note to the submitted form for you to read. If this occurs you will receive an email notification and a link to the notes will be displayed in the sidebar:

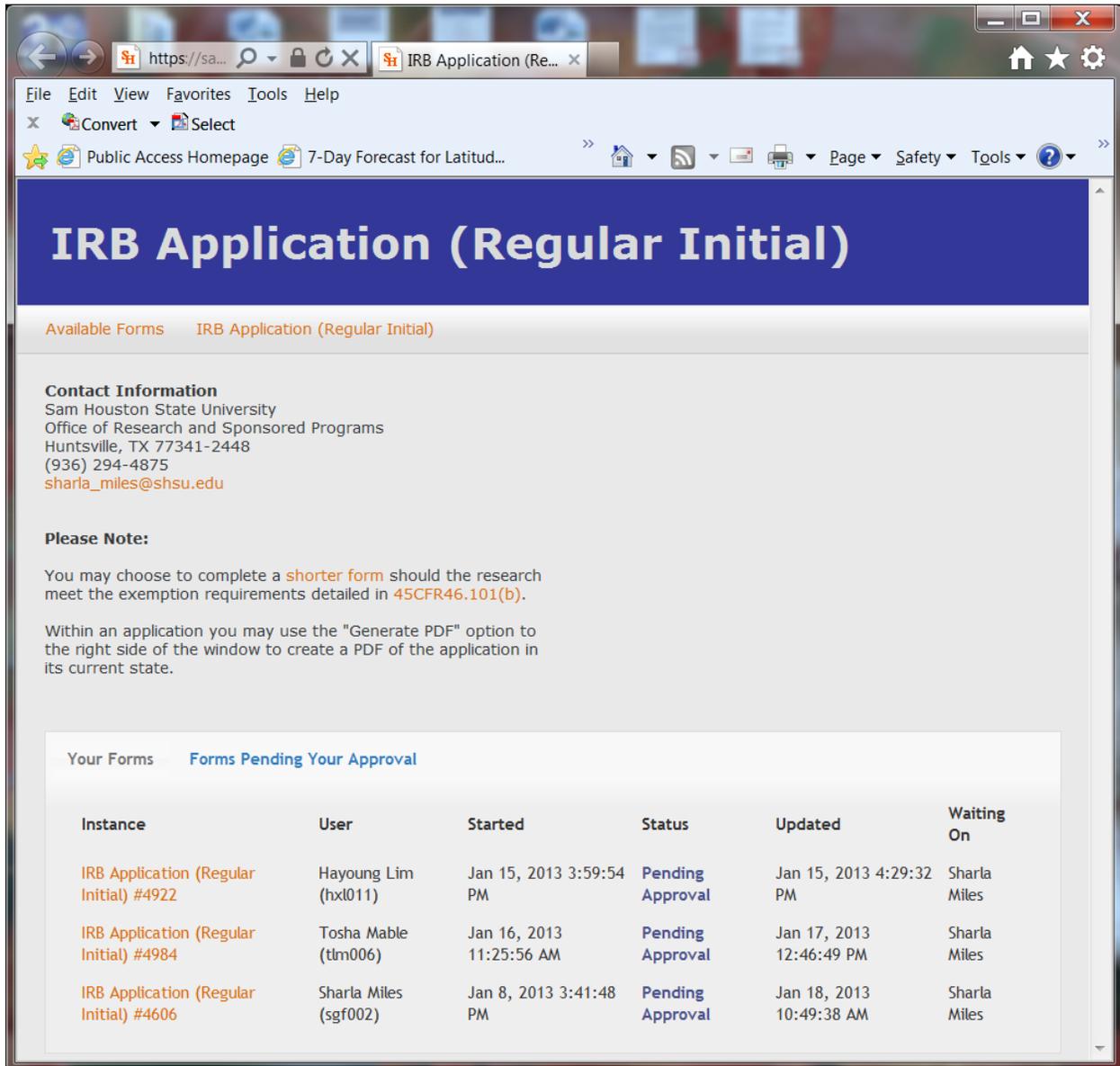


Clicking on this link (**2 associated notes**) will allow you to view existing notes and add notes of your own.

If an approver returns your form to you for corrections you will be able to edit the previously submitted information and resubmit it. The form will need to pass through the approval chain again.

Approving Forms

Form approvers will receive an email notification when a new form has been submitted for their approval. The link provided in the email will bring you to a page listing all submissions of this form that are awaiting your approval.



The screenshot shows a web browser window with the URL <https://sa...> and the page title "IRB Application (Regular Initial)". The browser's address bar shows "Public Access Homepage" and "7-Day Forecast for Latitud...". The page content includes:

- Available Forms**: IRB Application (Regular Initial)
- Contact Information**: Sam Houston State University, Office of Research and Sponsored Programs, Huntsville, TX 77341-2448, (936) 294-4875, sharla_miles@shsu.edu
- Please Note:** You may choose to complete a [shorter form](#) should the research meet the exemption requirements detailed in [45CFR46.101\(b\)](#). Within an application you may use the "Generate PDF" option to the right side of the window to create a PDF of the application in its current state.
- Your Forms**: Forms Pending Your Approval

Instance	User	Started	Status	Updated	Waiting On
IRB Application (Regular Initial) #4922	Hayoung Lim (hx1011)	Jan 15, 2013 3:59:54 PM	Pending Approval	Jan 15, 2013 4:29:32 PM	Sharla Miles
IRB Application (Regular Initial) #4984	Tosha Mable (tm006)	Jan 16, 2013 11:25:56 AM	Pending Approval	Jan 17, 2013 12:46:49 PM	Sharla Miles
IRB Application (Regular Initial) #4606	Sharla Miles (sgf002)	Jan 8, 2013 3:41:48 PM	Pending Approval	Jan 18, 2013 10:49:38 AM	Sharla Miles

Simply click on one to review the submitted data.

The screenshot shows a web browser window with the following content:

- Browser Address Bar:** <https://sa...> and [IRB Application \(Re...](#)
- Page Title:** IRB Application (Regular Initial) #4606
- Breadcrumbs:** Available Forms > IRB Application (Regular Initial) > IRB Application (Regular Initial) #4606
- Main Content Area:**
 - Principal Investigator (PI)**
 - ALL PIs MUST COMPLETE
 - Name: *** Sharla Miles
 - University Status/Title: *** Staff
 - Department: *** ORSP
 - College: *** AA
 - Phone Number: *** 4-4875
 - Email Address: *** sharla_miles@shsu.edu
- Right Sidebar:**
 - SUBMITTED BY:** Sharla Miles (sgf002)
 - STATUS:** Pending Your Approval
 - STARTED:** Jan 8, 2013 3:41:48 PM
 - UPDATED:** Jan 18, 2013 10:49:38 AM
 - WAITING ON:** Sharla Miles
 - NOTES:** 2 associated notes
 - OPTIONS:**
 - Generate PDF
 - View Timeline

The sidebar to the right will display current submission information. It also provides you with a link for adding notes to a submission. A submitter will be able to respond to notes that you've added and they will be visible to all form owners and future approvers in the approval chain.

You can also generate a PDF file from the current data as well as view the timeline for this submission. The timeline will show you each submission of this form as well as anyone who has approved, denied, or returned this form along the way.

The screenshot shows a web browser window with the following elements:

- Browser Tab:** IRB Application (Re... x
- Address Bar:** https://sa...
- Navigation:** Back, Forward, Home, Star, Settings icons.
- Menu Bar:** File, Edit, View, Favorites, Tools, Help.
- Toolbar:** Convert, Select, Public Access Homepage, 7-Day Forecast for Latitud..., Page, Safety, Tools, Help.
- Page Header:** IRB Application (Regular Initial) #4606
- Breadcrumbs:** Available Forms > IRB Application (Regular Initial) > IRB Application (Regular Initial) #4606
- Section Header:** Timeline
- Timeline Entries:**
 - Jan 18, 2013 10:41:22 AM: Form submitted
 - Jan 18, 2013 10:47:02 AM: **Sharla Miles (Sharla Miles)** updated status to **Returned for Corrections**. The form has been **Returned for Corrections**.
 - Jan 18, 2013 10:47:45 AM: Form resubmitted
 - Jan 18, 2013 10:48:24 AM: **Sharla Miles (Sharla Miles)** updated status to **Returned for Corrections**. The form has been **Returned for Corrections**.
 - Jan 18, 2013 10:49:38 AM: Form resubmitted. Waiting on **Sharla Miles**.
- Submission Details (Right Panel):**
 - SUBMITTED BY:** Sharla Miles (sgf002)
 - STATUS:** Pending Your Approval
 - STARTED:** Jan 8, 2013 3:41:48 PM
 - UPDATED:** Jan 18, 2013 10:49:38 AM
 - WAITING ON:** Sharla Miles
 - NOTES:** add note
 - OPTIONS:** Generate PDF, View Timeline

Approval options are displayed on the form category page:

The screenshot shows a web browser window displaying the IRB Application (Regular Initial) #4606 page. The browser's address bar shows the URL https://sa... and the page title is IRB Application (Regular Initial) #4606. The page content includes a navigation menu on the left with categories like Ethics Certification, Research Title, Personnel, Research Funding, Conflict of Interest (COI) Disclosure, Project Risk, Research Summary, Research Participant Selection and Recruitment, Informed Consent, Request for Waiver of Consent, Alteration of Consent, or Waiver of Documentation, and Investigator Assurance. The main content area displays the application details, including the submitter (Sharla Miles), status (Pending Your Approval), and submission date (Jan 8, 2013 3:41:48 PM). At the bottom, there are three buttons: Approve, Deny, and Return for Correction.

Returning this form for corrections would send it back to the original submitter. They would then make any necessary corrections and resubmit the form. If you choose to do this, you may want to add notes prior to returning the form so that the original submitter understands what changes need to be made.

Approving this form would send it to the next person in the approval chain. If there is no one else after you in the approval chain for this form then the form will be finalized as approved and the relevant parties will be notified.

NOTE: Only Sharla Miles and IRB members have the option to **Deny** an application; therefore, faculty sponsors, Department Chairs, or College Deans reviewing IRB applications will not see the Deny option.