

How to Use the Comprehensive Ancillary Forms Engine (CAFÉ) for DSMB/ISPRC Initial Submission

The Comprehensive Ancillary Forms Engine (CAFÉ) allows Study Teams to submit DSMB and ISPRC submissions to the Jonsson Comprehensive Cancer Center – Office of Regulatory Compliance (JCCC-ORC).

Please contact the JCCC-ORC team with any questions regarding the DSMB/ISPRC application at jcccorc@mednet.ucla.edu.

How to Access the System

Steps:

1. Open a **web browser** on your workstation
2. Click the following **URL**: <http://10.2.18.155:8080/cafe.html> or Copy/Paste it in your launched browser



Bookmark the URL to easily and quickly access the software in the future.



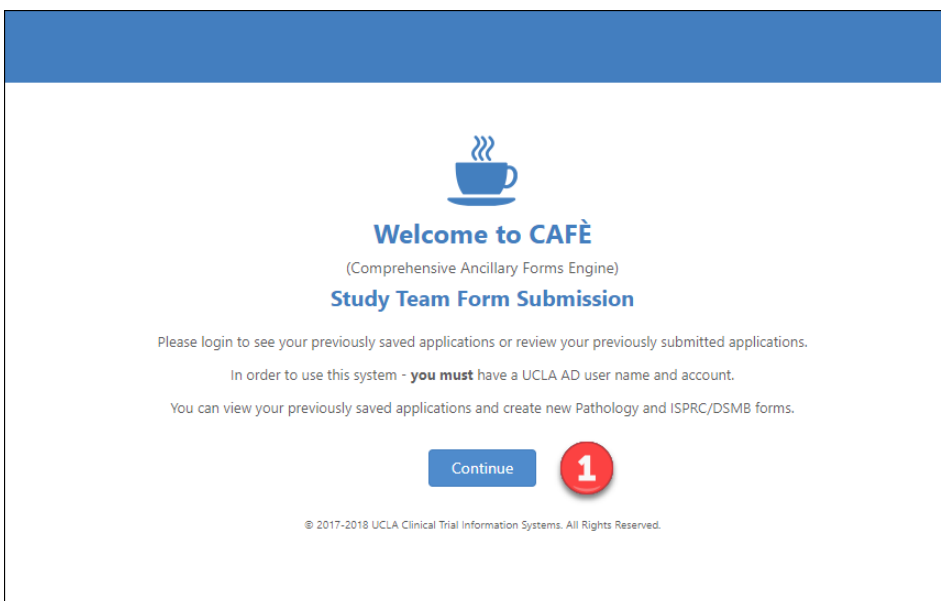
To utilize all functionalities of the Comprehensive Ancillary Forms Engine, pop-ups must be enabled within the web browser being used.

Submitter View

The Submitter View is the view that Users will see when they come to submit an application. Users are required to have a UCLA AD Login and be listed as Study Staff in OnCore in order to access the system.

Steps:

1. Click **Continue**



2. Enter your **AD User Account** and **AD Password**
3. Click **Login**

Welcome to CAFE
Study Team Form Submission

In order to use this system - **you must** have a UCLA AD account.
If you don't have one - please see your supervisor for direction.

User Name **2**

Password **2**

3 Login Using Your UCLA AD Account Cancel

Understanding the Components of the “Submit an Application” Page

How to Start a New Application

When Users click within the “Start A New Application” drop-down field, they will be able to select a form type that they wish to initiate. Multiple options may display if the Ancillary has more than one form type.

Steps:

1. Click on the drop down arrow within the “**Start A New Application field**”
2. Click on the **Form Type**

Submit An Application

Logged in as [username] | Log Out


5 Saved Applications **1**

View Previously Submitted Application... **1**

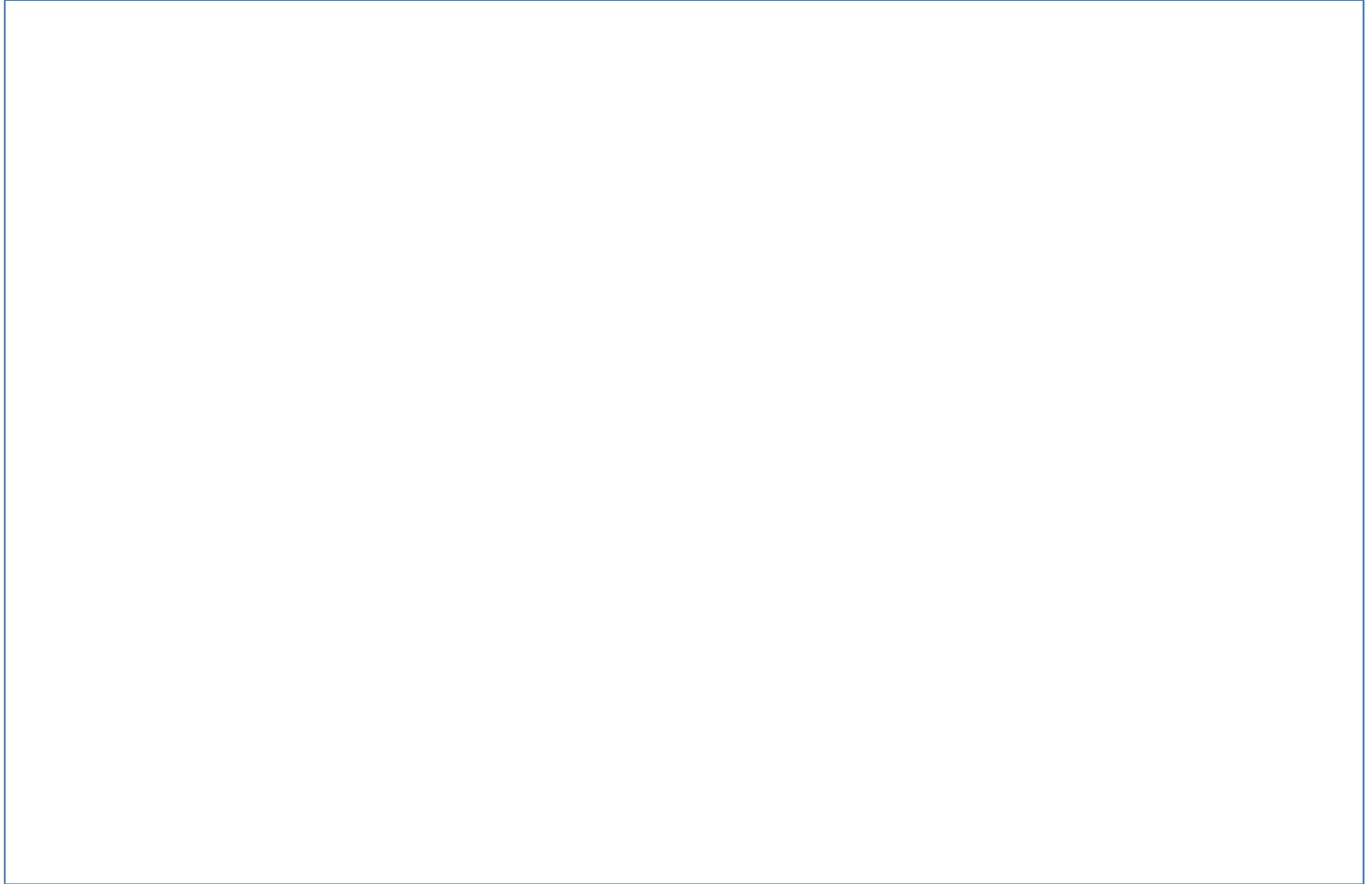
Start A New Application **1**


DSMB/ISPRC Initial Submission **2**

Pathology/Lab Application Form

 A new window will populate to display the new application.


3. Enter the **IRB Number** and then click **Search**




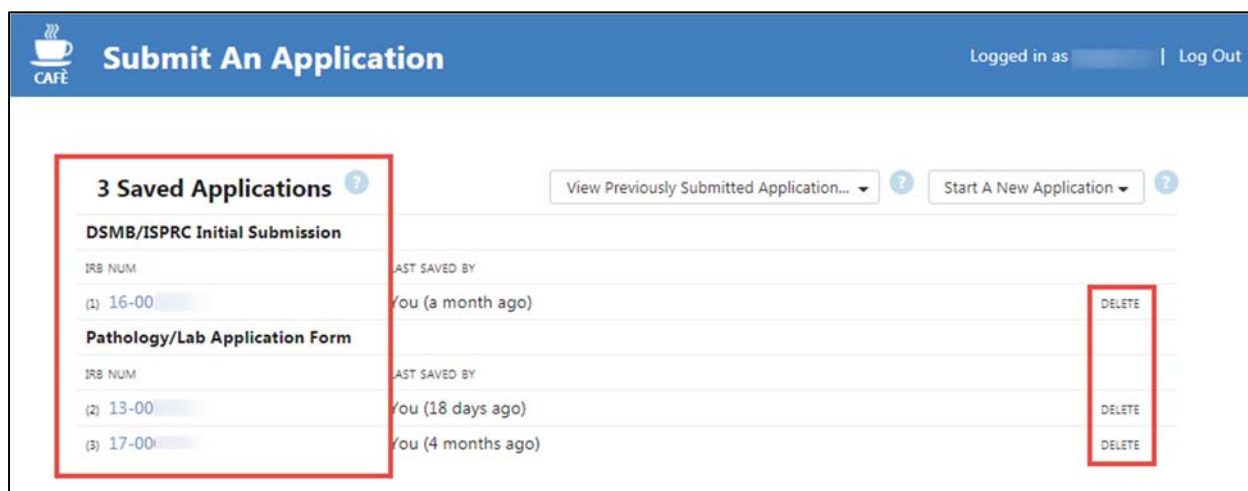
 *Once the valid IRB number has been entered, the application will automatically be saved if the User closes the window or gets far enough to click the “Save” button. The saved application will then appear in the “Saved Applications” section when the User logs back in.*

How to View/Access Previously Saved Applications

If a User has started an application and has either closed the window during submitting the application or, explicitly clicked the “Save” button prior to exiting, the previously saved application(s) will show up on this list. This list will show saved application(s) for **all the studies where the User is a member of the Study Team**, whether or not that particular user was the one to originally start or save the application.

 **The scientific review committee is unable to access Saved (Not yet submitted) Applications. All Study team members can access the application and update the save information on the application.**

 **Users can click on the IRB number to open the Saved/In-process application. Any saved information previously entered on an application will be restored.**



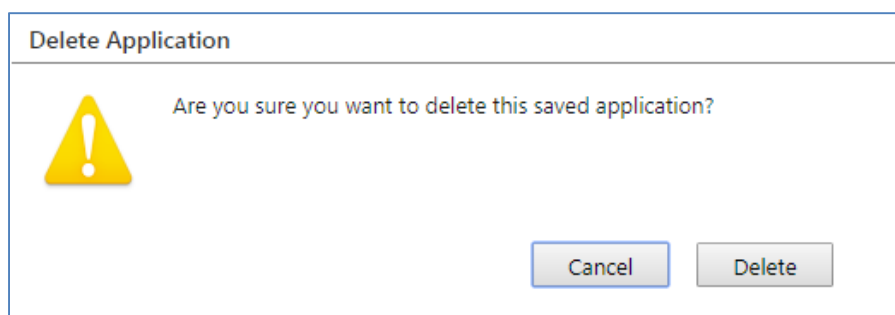
The screenshot shows the 'Submit An Application' interface. At the top, it says 'Submit An Application' and 'Logged in as [user] | Log Out'. Below this, there are two buttons: 'View Previously Submitted Application...' and 'Start A New Application...'. A red box highlights the '3 Saved Applications' section, which contains a table of saved applications. The table has columns for application title, IRB number, and 'LAST SAVED BY'. The first application is 'DSMB/ISPRC Initial Submission' with IRB number '(1) 16-00' and saved by 'You (a month ago)'. The second is 'Pathology/Lab Application Form' with IRB number '(2) 13-00' and saved by 'You (18 days ago)'. The third is 'Pathology/Lab Application Form' with IRB number '(3) 17-00' and saved by 'You (4 months ago)'. A red box also highlights the 'DELETE' buttons for each application.

Steps:

1. Click the **Study (IRB) Number hyperlink**


 **Users will always be taken to the beginning (first section) of the saved Application in a new pop-up window.**

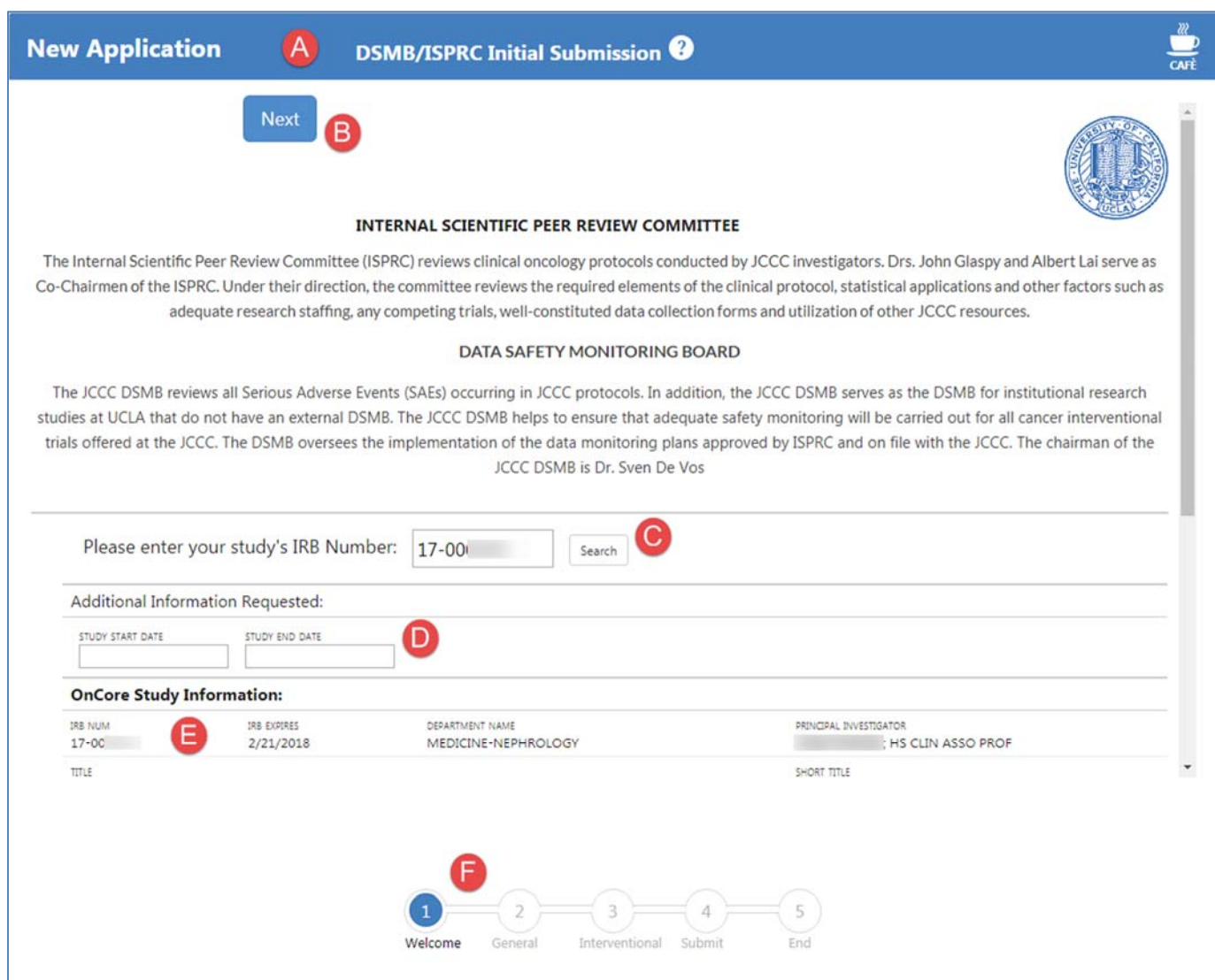
 **Click the Delete hyperlink and then the “Delete” button to permanently delete a saved application.**





The screenshot shows a 'Delete Application' dialog box. It features a yellow warning triangle icon with an exclamation mark. The text inside the dialog asks, 'Are you sure you want to delete this saved application?'. At the bottom of the dialog, there are two buttons: 'Cancel' and 'Delete'.

How to Navigate the Application

- A. **Form Name** – Shows the type and the version of the form.
- B. **Navigation button** – Navigates to the next or previous question by clicking “Next” or “Back”.
- C. **IRB Number** – Searches for the study associated with the application.
-  *Users are only be able to continue if they are listed as Study Staff in OnCore for the particular Study.*
- D. **Additional Information Requested** – Records information that is outside of the OnCore data that is entered by the Study Team. Once this information is entered, any other ancillary’s application (or any other application type) for the same study will have this information automatically filled out in the future.
- E. **OnCore Study Information** – Shows study information that is coming directly out of OnCore.
- F. **Progress Bar** – Displays a “map” showing the number of different sections within the form.



New Application A **DSMB/ISPRC Initial Submission** ? 

Next B 

INTERNAL SCIENTIFIC PEER REVIEW COMMITTEE

The Internal Scientific Peer Review Committee (ISPRC) reviews clinical oncology protocols conducted by JCCC investigators. Drs. John Glaspy and Albert Lai serve as Co-Chairmen of the ISPRC. Under their direction, the committee reviews the required elements of the clinical protocol, statistical applications and other factors such as adequate research staffing, any competing trials, well-constituted data collection forms and utilization of other JCCC resources.

DATA SAFETY MONITORING BOARD

The JCCC DSMB reviews all Serious Adverse Events (SAEs) occurring in JCCC protocols. In addition, the JCCC DSMB serves as the DSMB for institutional research studies at UCLA that do not have an external DSMB. The JCCC DSMB helps to ensure that adequate safety monitoring will be carried out for all cancer interventional trials offered at the JCCC. The DSMB oversees the implementation of the data monitoring plans approved by ISPRC and on file with the JCCC. The chairman of the JCCC DSMB is Dr. Sven De Vos

Please enter your study's IRB Number: C

Additional Information Requested:

STUDY START DATE STUDY END DATE D

OnCore Study Information:

IRB NUM 17-00	IRB EXPIRES 2/21/2018	DEPARTMENT NAME MEDICINE-NEPHROLOGY	PRINCIPAL INVESTIGATOR ; HS CLIN ASSO PROF
TITLE			SHORT TITLE

1 Welcome —
 F 2 General —
 3 Interventional —
 4 Submit —
 5 End

How to Answer Questions on the Application

- A. **Navigation Button** – Click “Back” to go to previous questions or “Next” to go to the next question.
- B. **Application Question** – Click on one of the boxes to select an answer to the question or enter the information in a free text field.
- C. **Save Button** – Click this button at any point to save the information that has been entered.
- D. **Save and Close Button** – Click this button to save the information entered and close out of the Application Form.



The application will automatically be saved if Users close the window.



Questions that display a red asterisk [*] are required and must be answered. Users are unable to skip required questions.



Questions are designed to populate on the form based on the answers selected by the User. If an answer is changed, a new sequence of questions may populate based on the application’s logic and the progress bar will also be updated accordingly.



Once the application has been submitted, it will drop off the saved applications list.

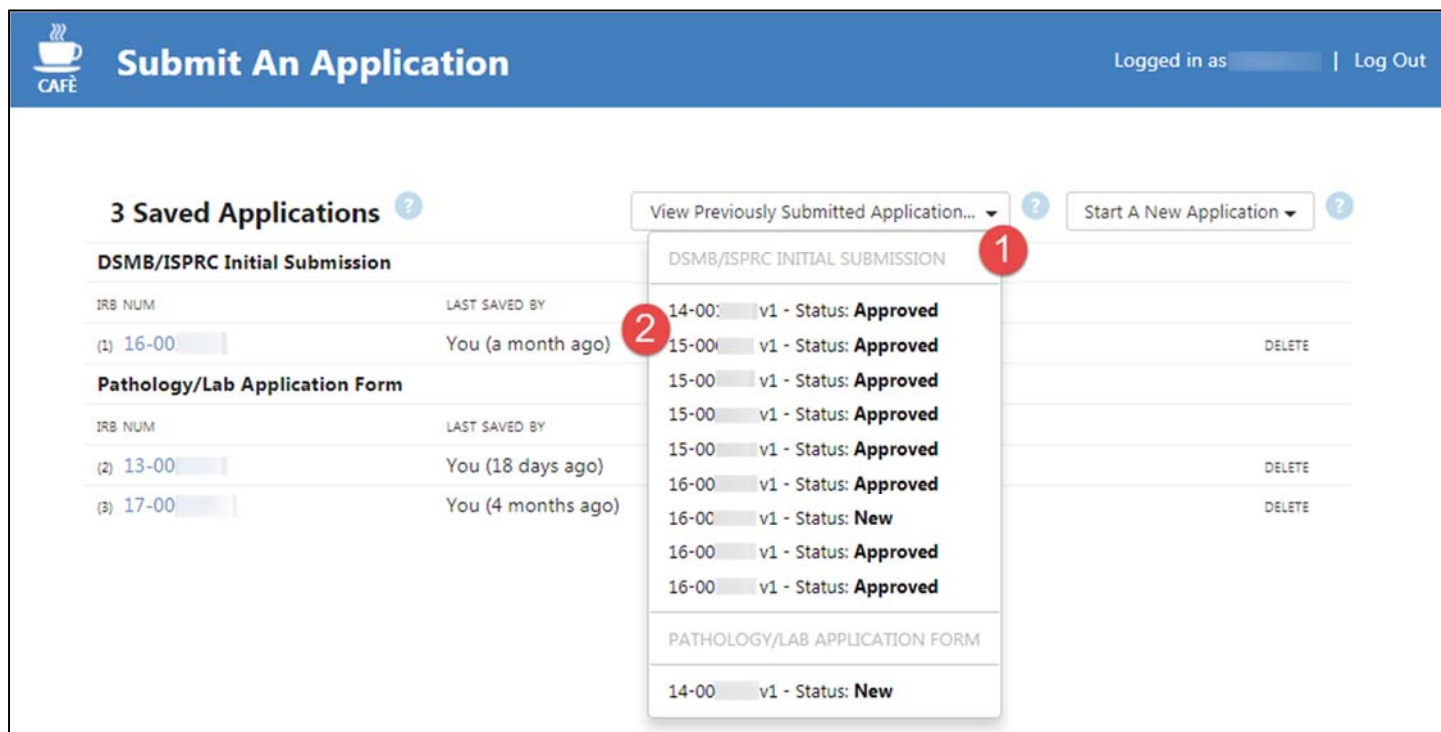
How to View Previously Submitted Applications

When the User clicks within the “View Previously Submitted Application” drop-down field, they will see a list of all their previous submissions. The list includes the IRB number, the Status of the application (as determined by the ancillary in their own management console), and the name of the application (in case the ancillary has more than one application).


Steps:

1. Click on the **drop down arrow** within the View Previously Submitted Applications field
2. Click on the **IRB Number**

 A new window will populate to display the previously submitted application.



The screenshot shows the 'Submit An Application' page. At the top, there is a blue header with the 'CAFÉ' logo and the text 'Submit An Application'. On the right side of the header, it says 'Logged in as [redacted] | Log Out'. Below the header, there are three sections: '3 Saved Applications', 'View Previously Submitted Application...', and 'Start A New Application'. The '3 Saved Applications' section has a question mark icon. The 'View Previously Submitted Application...' section has a dropdown arrow and a question mark icon. The 'Start A New Application' section has a dropdown arrow and a question mark icon. The dropdown menu for 'View Previously Submitted Application...' is open, showing a list of applications. The first two sections of the list are 'DSMB/ISPRC INITIAL SUBMISSION' and 'PATHOLOGY/LAB APPLICATION FORM'. The 'DSMB/ISPRC INITIAL SUBMISSION' section has a red circle '1' next to it. The 'PATHOLOGY/LAB APPLICATION FORM' section has a red circle '2' next to it. The list of applications includes IRB numbers, versions, and statuses: 14-00 v1 - Status: Approved, 15-00 v1 - Status: Approved, 15-00 v1 - Status: Approved, 15-00 v1 - Status: Approved, 16-00 v1 - Status: Approved, 16-00 v1 - Status: New, 16-00 v1 - Status: Approved, 16-00 v1 - Status: Approved, and 14-00 v1 - Status: New. There are also 'DELETE' buttons next to some of the applications.

 Users can hover over the “?” icon to the right of the “Saved Applications,” View Previously Submitted Applications,” and “Start A New Application” sections to get a description of the content available/displayed in the section.

Fields within a Previously Submitted Application:

- A. **IRB Number** – The IRB number associated to the submitted application.
- B. **Form Name** – Identifies the form being used.
- C. **Submission Information** – Displays the form name, submitter name, and submission date.
- D. **Question/Section** – Displays the applicable questions and sections for the application.
- E. **Response** – Displays the recorded responses to the applicable questions for the application.


The screenshot shows the 'View Application' page with a blue header containing 'View Application' and 'Save / Print Application' buttons. The main content area is divided into sections: 'IRB Number: 14-00' (labeled A) and 'Application Version: 1' (labeled B); 'Submission Information' (labeled C) including 'Form Name: DSMB/ISPRC Initial Submission' and 'Submitted by: [redacted] on Monday, February 19, 2018 at 10:44:30 AM'; a table with columns 'Question/Section' (labeled D) and 'Response' (labeled E); and 'Total Study Recruitment Period Type: Weeks'.

Question/Section	Response
General	
Provide the name of the primary study contact for prospective subjects (for display on the JCCC web site and ClinicalTrials.gov): * Required if your study will be published to the JCCC web site and/or ClinicalTrials.gov. If the contact changes or you have any questions, please notify jcccrc@mednet.ucla.edu.	
Phone number for the JCCC web site/ClinicalTrials.gov contact: * Required if your study will be published to the JCCC web site and/or ClinicalTrials.gov. If the contact changes or you have any questions, please notify jcccrc@mednet.ucla.edu.	
Primary Completion Date (mm/dd/yyyy) The date on which the last participant in a clinical study is expected to be examined or receive an intervention and that data for the Primary Outcome Measure is collected.	12/01/2018
Total Study Recruitment Period Type:	Weeks

How to Save/Print a Previously Submitted Application

Steps:

1. Click on the **drop down arrow** within the View Previously Submitted Applications field
2. Click on the **IRB Number**
3. Click on **Save/Print Application**

 *By default, a saved .html version of the application will be downloaded to your computer when clicking on Save/Print Application.*

4. Click on the downloaded **.html** document


View Application New Version **3** Save / Print Application

IRB Number: **14-00** Application Version: **1**

Submission Information:
 Form Name: *DSMB/SPRC Initial Submission*
 Submitted by: [redacted] on Monday, February 19, 2018 at 10:44:30 AM

Question/Section	Response
General	
Provide the name of the primary study contact for prospective subjects (for display on the JCCC web site and ClinicalTrials.gov): * Required if your study will be published to the JCCC web site and/or ClinicalTrials.gov. If the contact changes or you have any questions, please notify jccorc@mednet.ucla.edu.	[redacted]
Phone number for the JCCC web site/ClinicalTrials.gov contact: * Required if your study will be published to the JCCC web site and/or ClinicalTrials.gov. If the contact changes or you have any questions, please notify jccorc@mednet.ucla.edu.	[redacted]
Primary Completion Date (mm/dd/yyyy) The date on which the last participant in a clinical study is expected to be examined or receive an intervention and that data for the Primary Outcome Measure is collected.	12/01/2018
Total Study Recruitment Period Type:	Weeks

irb_14-00_v1.html Show all X

 A printable copy will be opened in a new web browser tab. Here the User can directly print from the browser or save a copy in a pdf format.

Print

Total: 3 sheets of paper

Destination: HP LaserJet 600 M601 ...

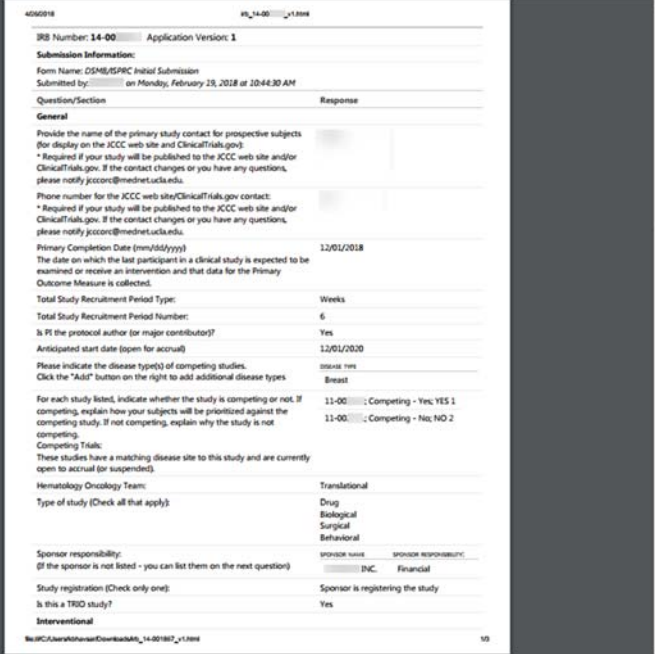
Pages: All
 e.g. 1-5, 8, 11-13

Copies:

Layout: ▾

[+ More settings](#)

[Print using system dialog... \(Ctrl+Shift+P\)](#)



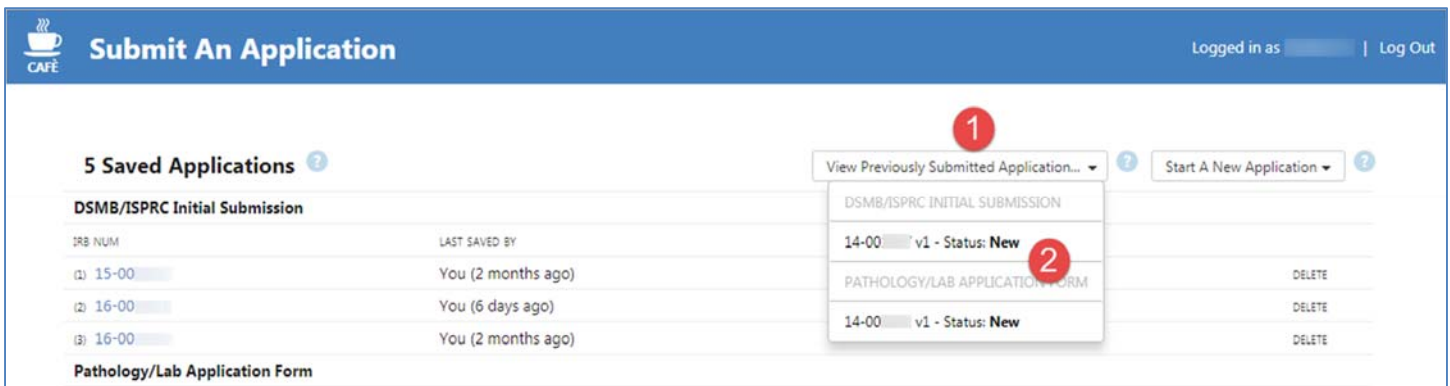


How to Create a New Version Based on a Previously Submitted Application

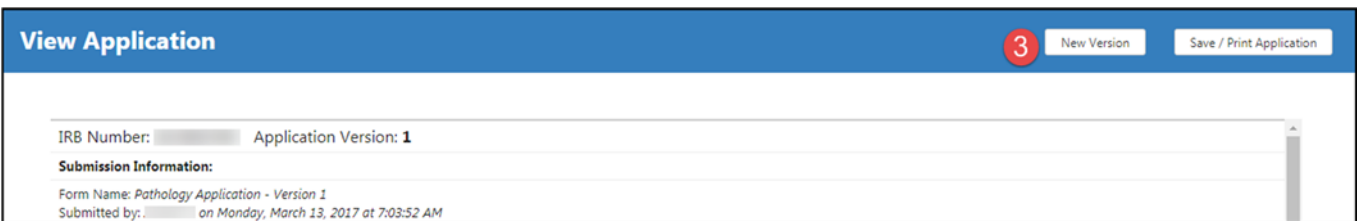
Users can utilize previously submitted applications to create new applications for the same Study by utilizing the New Version option. This option is only available for applications that have already been Submitted and is in an **Approved** state. The New Version option can be utilized by Study Teams in cases where a new Amendment requires minor changes to the Ancillary services.

Steps:

1. Click on the **drop down arrow** within the View Previously Submitted Applications field
2. Click on the **IRB Number**



3. Click on the **New Version** button



4. Click **OK** on the New Version popup message

