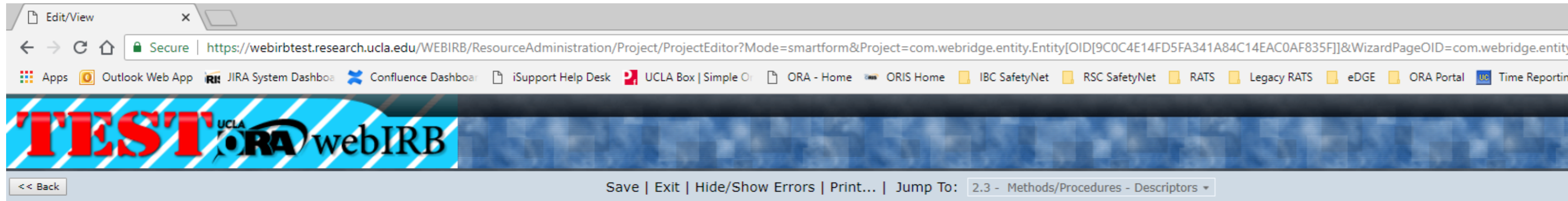




Creating a New Application in



Initiating Radiation Review in webIRB



Methods/Procedures - Descriptors

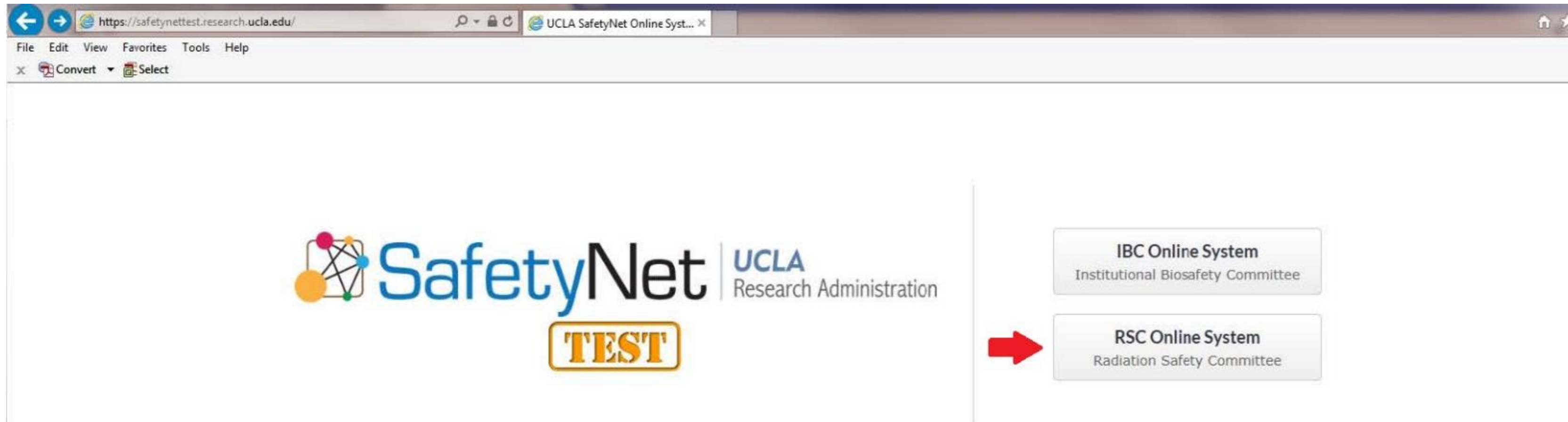
Note: The items listed below are not an inclusive list of methods and procedures that may be used in research studies. The list only includes items that will trigger additional questions related to the research or are needed for the review process

1.0 ***Indicate all that apply to this study.**

- Audio, Visual or Digital Recordings
- Behavioral Observations (only applicable if you selected Exempt Category 2 in section 5.3)
- Certificate of Confidentiality for research not supported by NIH
- Clinical Trial of a Drug, Biologic, Device or a Behavioral Intervention
- Community Based Research
- Controlled Substances (Schedule I or II)
- Deception or Partial Disclosure
- Devices/Diagnostics (including Humanitarian Devices - HUD)
- Drugs/Biologics/Dietary Supplements
- Expanded Access to Drug, Device or Biologic for Treatment Purposes (aka Compassionate Use, Treatment Use)
- Genetic Analyses/Genotyping
- Human Embryonic Stem Cells and/or Induced Pluripotent Stem Cells
- Human Gene Transfer/ Recombinant DNA
- Infectious Agents
- Non-FDA approved medical equipment used with UCLA hospital patients or research participants that operate under the UCLA Hospital License.
- Radiation (Standard of Care or Investigational use of radioactive materials or ionizing radiation)
- Substance Abuse Research (with Medication)
- Treatment in an Emergency Setting (with request to waive consent)
- None of the above

1. A webIRB application must be submitted first. If radiation is identified in section 2.3 of the webIRB application, a radiation review will be required.
2. When the webIRB application is completed, the user will be prompted to go to SafetyNet to submit an MRSC/RDRC application.

Logon to SafetyNet



1. Once you arrive at the SafetyNet site (<https://safetynet.research.ucla.edu>), select RSC Online System.
2. Once you are in the site, click “Login”, and complete your multi-factor authentication with your UCLA Logon account.

Human Use Study w/ Radiation
[Create MRSC/RDRC Application](#)

Radiation Use Authorization
[Create RUA Application](#)

My Applications | Technical Review | Member Review | Committee Review | Post Review

My Inbox

ID	Name	Date Created	Date Modified	State	Coordinator	PI
MRSC-2018-017	FIRST RAD Study	7/20/2018 8:50 PM	7/20/2018 8:52 PM	Admin Review		USER (PI) 1
MRSC-2018-015	ASF to Improve Diet Quality and Growth and Cognitive Development in East African Children	4/19/2018 10:23 AM	4/19/2018 10:36 AM	Admin Review		RSCTEST PI 2
MRSC-2018-002	Cross-sectional study (J.Trevillyan)	2/26/2018 8:56 AM	4/10/2018 12:13 PM	Admin Review		RSCTEST PI 1
MRSC-2017-031	Cross-sectional study (J.Trevillyan)	12/17/2017 6:30 PM	3/29/2018 10:25 PM	Member Review		RSCTEST PI 1
MRSC-2018-006	ASF to Improve Diet Quality and Growth and Cognitive Development in East African Children	3/15/2018 11:49 AM	3/27/2018 2:58 PM	Modifications Review	DINA BOKTOR	RSCTEST PI 2
MRSC-2017-026	Cross-sectional study (J.Trevillyan)	10/20/2017 3:39 PM	2/26/2018 10:13 AM	Member Review	JOSEPH CALLAHAN	RSCTEST PI 1
MRSC-2017-027	ASF to Improve Diet Quality and Growth and Cognitive Development in East African Children	11/1/2017 11:30 AM	11/7/2017 1:58 PM	Pre-Submission		RSCTEST PI 2
MRSC-2017-008	ASF to Improve Diet Quality and Growth and Cognitive Development in East African Children	10/6/2017 1:51 PM	10/6/2017 2:09 PM	Pre-Submission		RSCTEST PI 2

8 items | page 1 of 1 | 25 / page

1. Select *Create MRSC/RDRC Application*.

The screenshot shows the SafetyNet RSC Online System interface. The main page is titled "1.0 Basic Information" and contains a form with several fields: "1. * IRB #:", "2. Title of Protocol:", "3. Short Title:", "4. Lay Summary of Research:", "5. Principal Investigator:", "6. Faculty Sponsor:", "7. The maximum number of study participants you hope to enroll:", and "8. How many participants do you expect you will need to recruit, consent at". A red arrow points to the "Select..." button next to the "1. * IRB #:" field. A dialog box titled "Select IRB Stub" is open in the foreground, displaying a table of IRB stubs. The table has two columns: "ID" and "Study Name". The first row is selected, showing "IRB#18-000020" and "MY webIRB RSC Integration Demo 1". The dialog box also includes a "Filter by" dropdown menu set to "ID", a "Go" button, a "Clear" button, and an "Advanced" link. The "Total Selected" is 1. The dialog box has "OK" and "Cancel" buttons at the bottom.

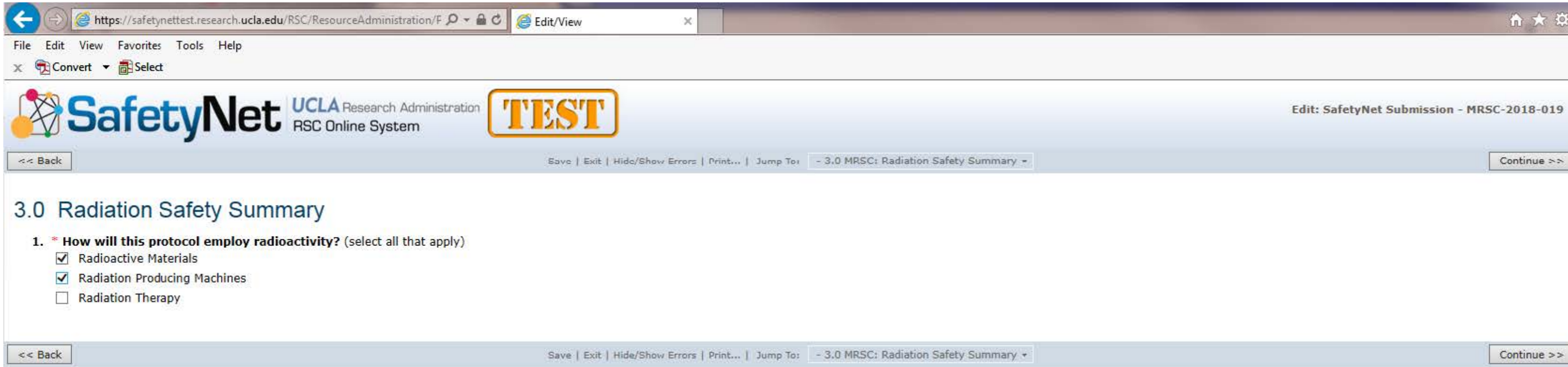
2. Click on the *Select* button. This will open a window listing all studies involving radiation that have been submitted through webIRB by your PI or PI Proxy accounts. Select the study that you wish to create an MRSC application for, and then click *OK*. Then, click on *Continue*.

The screenshot shows the SafetyNet web application interface. At the top, there is a navigation bar with the SafetyNet logo, 'UCLA Research Administration RSC Online System', and a 'TEST' badge. Below this is a breadcrumb trail: '<< Back' | 'Save | Exit | Hide/Show Errors | Print...' | 'Jump To: - 2.0 MRSC: Team Members -' | 'Continue >>'. The main content area is titled '2.0 Team Members' and contains a list of team members with columns for Name, Roles, Involved with Procedures, Completed Training, E-mail, and Phone. The 'Update' button for the first team member, JOEL HECHT, is circled in red. An 'Edit Study Team Member' dialog box is open in the foreground, showing the following steps:

- Select the team member:
JOEL HECHT
- Roles:
There are no items to display
- Is this team member involved with radiological procedures?
 Yes No [Clear](#)
 - Has this individual completed the UCLA Health Radiation Awareness Training?
 Yes No [Clear](#)

At the bottom of the dialog box, there is a '* Required' label and 'OK' and 'Cancel' buttons.

3. The list of Team Members will be automatically generated based on the webIRB application. Select *Update* for each team member and identify if each one will be involved in the radiological procedures. If they are, you will also need to indicate if the required training has been completed. Once this is done, click *Continue*.



4. Select which types of radiation procedures will be used for the study. Once this is done click *Continue*.

The screenshot shows the SafetyNet RSC Online System interface. The main page is titled "5.0 Radiation Producing Machines (RPM)" and contains two main sections:

- 1. * Identify each type of procedure that involves radiation producing machines.** This section has an "Add" button and a table with columns for "Procedures Type", "Scan Type", and "Mode". Below the table, it says "There are no items to display".
- 2. * Are any of the procedures listed above optional for study participants depending on specific criteria?** This section has radio buttons for "Yes" and "No", and a "Clear" button.

An "Add PR_Procedures Using Radiation Producing Machines" dialog box is open, showing the following fields:

- 1.0 *Type of Procedure:** A dropdown menu with "Computed Tomography" selected.
- 2.0 *Standard of Care - Identify the maximum number of procedures that are considered standard of care or routine within one year?** A text input field containing "5".
- 3.0 *Beyond Standard of Care - Identify the maximum number of procedures that are considered beyond standard of care or non-routine within one year?** A text input field containing "2".
- 4.0 *Specify the type of CT scan that will be performed:** A dropdown menu with "Chest/Abdomen/Pelvis" selected.
 - a. Mode:** Radio buttons for "Helical" (selected) and "Axial", with a "Clear" button below.
- 5.0 *Contrast:** Checkboxes for "With contrast" (checked) and "Without contrast".
- 6.0 *Physical location where the procedure will be performed:** A note states "Note: the UCLA MRSC/RDRC cannot review procedures being performed at non-UCLA facilities as these locations are outside of the committee's purview:". Below this is a text input field, an "Add" button, and a table with a "Name" column containing "200 Medical Plaza" and a "Remove" button.

At the bottom of the dialog box, there are buttons for "OK", "OK and Add Another", and "Cancel", along with a legend for "* Required".

5. For each type of radiation, click *Add* in order to specify each procedure being used. Complete the form for each procedure. Note that all fields marked with an asterisk must be completed before continuing.

7.0 Supporting Documents

- 1. Current Consent Forms:**

Name	Version
There are no items to display	
- 2. * Attach current schedule of procedures:**

Document Name	Date Modified
There are no items to display	
- 3. Any additional relevant materials:**

Document Name	Date Modified
There are no items to display	

6. The current Informed Consent Form submitted to the IRB will be automatically included in the Supporting Documents section. For question 2, a schedule of procedures must be uploaded. This is typically found in the study protocol, and is a table or list of all procedures a subject will undergo during the study. If it is not in the protocol, please create one.

The screenshot shows the SafetyNet webIRB RSC Integration 1 interface. A 'Submit' modal window is open, displaying the following content:

Submit

The PI is required to submit the application and complete the PI assurances.

PI Assurances

Refer to Chapter 1 of the UCLA EH&S Radiation Safety Manual for PI responsibilities and reporting requirements:

- I attest that the information contained in the attached application is accurate and complete to the best of my knowledge.
- I certify that I have communicated with the appropriate UCLA physician (e.g. supervisor/operator and/or authorized user) who provided guidance in determining the information provided for any radiological procedures in this application.
- I will abide by the reporting requirements and submit a report to EH&S Radiation Safety and the MRSC for the following:
 - All accidents that result in an unintended exposure from the radiological procedures described in this application.
 - Any illness that may have been caused by the radiation described in this application.
 - Theft or loss of the radioactive materials described in this application.
 - All spills outside of containment equipment.
 - Environmental contamination/release of the radioactive materials described in this application.
 - Improper disposal of the materials described in this application.
- I understand my responsibilities as PI and agree to comply with these responsibilities.
- I understand the application must be reviewed periodically and it is my responsibility to submit the application for continuing review and any amendments in accordance with deadlines communicated by the MRSC.

If you have finished filling out your application, click "OK". Afterwards you will no longer be able to edit the application. You will receive email when each approval is granted or refused, and again when all the required approvals are received.

If you are not ready to submit your application, click Cancel.

* I agree with the above statement:

1. Comments:

[Text area for comments]

2. Supporting documents:

Add

Document Name	Date Modified
There are no items to display	

OK Cancel

The background interface shows the 'MRSC-2018-019 : webIRB' application details, including the Principal Investigator (GARY SCHILLER), Faculty Sponsor, Owner, and Technical Reviewer. A workflow diagram shows the current state as 'Pre-Submission'. The 'Actions by Team Members' section has a 'Submit' button circled in red.

7. The application will now be in the “Pre-Submission” state. Click on *Submit* in order to finalize its submission to MRSC. A window will appear with PI Assurances. Note that **ONLY** the PI listed on the study will be able to complete the Assurances.

MRSC-2018-019 : webIRB RSC Integration 1

Principal Investigator: GARY SCHILLER
 Faculty Sponsor:
 Owner:
 Technical Reviewer:
 Primary Contact: VENU LAGISHETTY
 Admin office: UCLA
 PI proxies: VENU LAGISHETTY, DINA BOKTOR

Submission Type: Initial Protocol
 RDRC: No
 Review Type:
 Letter: None
 Approval Date:
 Expiration Date:
 webIRB Protocol Number: IRB#18-000021

webIRB Protocol Status: IRB Assignment

```

  graph LR
    A[Pre-Submission] --> B[Specialist Review]
    B --> C[Committee Review]
    C --> D[Post-Review]
    D --> E[Review Complete]
    B --> B1[Clarification Requested]
    C --> C1[Clarification Requested]
    D --> D1[Modifications Required]
    B1 --> B
    C1 --> C
    D1 --> D
  
```

Activity	Author	Activity Date
Submitted	BOKTOR, DINA WADIE	7/25/2018 12:16 PM
webIRB information refreshed	BOKTOR, DINA WADIE	7/24/2018 9:37 AM
No webIRB Information changed		
MRSC RDRC Created	BOKTOR, DINA WADIE	7/24/2018 9:37 AM

8. Once the status at the top of the left bar is in the “Admin Review” state, the application has been successfully submitted.