



GIVING LIFE TO POSSIBLE

BSLMC Application for Administrative Review of Research

Department Reviewer/Approver Instructions

Version 1.0

Office of Clinical Research

Table of Contents

Definitions	3
Email to Department Reviewer/Approver	4
Logging into BSLMC Administrative Application	5
Basic Layout and Navigation	5
Department Review and Approval/Deferral	7
Institutional Approval or Deferral	8

Definitions

Enterprise Computing Account (ECA) – Access to the application requires a BCM ECA. This is also known as your Baylor email username. If you do not have an ECA, please contact the IT Service Center at 713-798-8737 or <https://sso.bcm.edu>.

Reviewer/Approver – There could be one more persons assigned as reviewer and/or approver for each hospital clinical area that plans to be used for the research study. This person(s) would receive the emails that there is an application that needs to be reviewed for their department for approval.

Principal Investigator (PI) – The person(s) in charge of a clinical trial or a scientific research grant. The principal investigator prepares and carries out the clinical trial protocol (plan for the study) or research paid for by the grant. The principal investigator also analyzes the data and reports the results of the trial or grant research.

Review Team – Review team or Administrative Review Team is the staff in the Office of Clinical Research that will review application for completeness and seek all necessary approvals from Baylor St. Luke's Medical Center. Review team will be the primary contacts for any questions during the review.

Study Team – This consists of the PI and any of his staff working on the study.

Defer - Deferral of a study does not disapprove it, unless you enter a comment that you wish to disapprove it and reason. When a deferral is sent, the review team will let the study team know what questions or concerns the department or area may have to try to resolve them. If the issue is resolved, the department/area will be sent another email to re-review the study to either Approve or Defer again.

Approve – There are no concerns that need to be addressed and the department/area approves the study to be done.

Institutional Approval – BSLMC administrative approval from institutional official over research. Final approval before study can start at BSLMC.

Email to Department Reviewer/Approver

All department reviewers and/or approvers will be sent an email for hospital areas/departments identified on the application for administrative review as needed for the study. The review team will enter a comment relevant to each department on what will be done in that area/department. The department reviewer/approver will click on the link to the BSLMC Administrative Application System and login with their assigned ECA.

AUTOMATED EMAIL FROM APPLICATION SYSTEM TO ALL DEPARTMENTS IDENTIFIED
(Highlighted areas will be filled in from application information.)

From: bslmc_research@bcm.edu
To: [Department Reviewer/Approver Name]
Cc: [BSLMC Research](mailto:BSLMC_Research@bcm.edu)
Subject: BSLMC Administrative Application – Review/Approval needed by [Department Reviewer/Approver Name] on behalf of [Department Name]–IRB # [IRB#], [Study Name], [PI Name]
Date: Wednesday, July 10, 2019 7:42:04 AM

Dear [Department Reviewer/Approver Name],

The attached research protocol [IRB#] for [PI Name] has been submitted for administrative review. Prior to administrative approval, departments to be impacted by the research study must review how their department will be utilized. Please review the specific study information below along with the attachments. If the tests/procedures are standard of care (SOC), department approval is not required.

Please log in to [BSLMC Administrative Application System](#) to review the application on behalf of [Department Name].

Please let us know if there are any questions or concerns that need to be addressed.

Thank you,

BCM Office of Research
Baylor St. Luke's Medical Center
BSLMC_Research@bcm.edu
713-798-6024

Administrative Review Team Comments: [Device will be provided at no cost and will be implanted during SOC right heart cath.]

Administrative Review Team Comment above is specific for each department.

Logging into BSLMC Administrative Application

Log in using your username and password. If you do not have a Baylor ECA, you can submit a request from BCM IT service portal (<https://sso.bcm.edu>) by entering a ticket.

The screenshot shows the login page for the Baylor St. Luke's Medical Center BSLMC Application for Administrative Review of Research. The page has a dark blue header with the text "Baylor St. Luke's Medical Center" and "BSLMC Application for Administrative Review of Research". There are links for "Home", "Help", and "Logout". The main content area contains a login form with fields for "User name:" and "Password:", a "Log in" button, and a "Forgot Password?" link. A note at the bottom suggests using the latest version of Mozilla Firefox for optimum system performance.

Basic Layout and Navigation

Home – takes you to the Welcome Screen.



Help – pop-up screen with contact information.



Logout – logs out of system, user name and password are required to re-enter system.



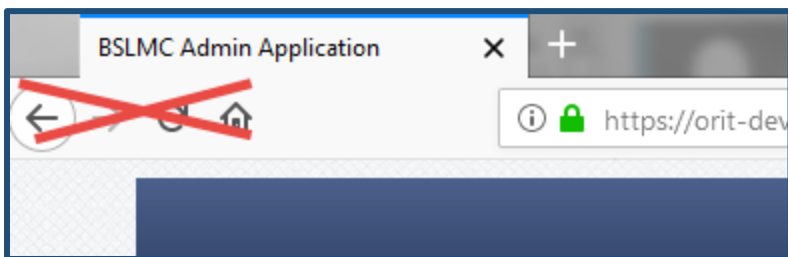
Menu – allows reviewer/approver to see any other applications pending approval and applications that have been completed.



Pending for Area Approval						
IRB Number	Principal Investigator	Status	Approval Group Name	Application PDF	Device Form PDF	
19-02-911-2019	[REDACTED]	Signed by PI	Endoscopy	View File		

Completed Area Approval						
IRB Number	Principal Investigator	Status	Approval Group Name	Application PDF	Device Form PDF	Approval Status
24152415	[REDACTED]	Send for Administrative Approval	Inpatient/Nursing	View File	View File	Approved
24152415	[REDACTED]	Send for Administrative Approval	Non-invasive Cardiology	View File	View File	Approved
24152415	[REDACTED]	Send for Administrative Approval	Pathology	View File	View File	Approved
24152415	[REDACTED]	Send for Administrative Approval	THI Clinic	View File	View File	Approved

Do not use the browser's back button. Use the menu in the system to navigate between pending and completed approvals.



Department Review and Approval/Deferral

Once the reviewer/approver logs into the system, the following screen will come up. Here you can use the menu to go to pending requests to see previously completed requests. You can also click on the Back to Pending Approval List to select the study you want to review if there are multiple. To see the full application for administrative review and study documents that are attached (i.e., protocol, consent, schedule of events, etc.), click on View Application. The comments box gives you information entered by the review team that may be specific to your department/area. To complete the process, you can enter a reply comment to the review team or comment to be shared with the study team and either click Approve or Defer.

Application Area Review

- Pending for Area Approval
- Completed Area Approval

Application Summary

[Back to Pending Approval List](#)
[View Application](#)

IRB of record	<input type="text" value="Other"/>	IRB of record number	<input type="text" value="19-02-911-2019"/>
H number	<input type="text"/>	Short title	<input type="text" value="TEST 9/11"/>
Project start date	<input type="text"/>	Project end date	<input type="text"/>
PI first name	<input type="text" value="Stephen"/>	PI last name	<input type="text" value="Williams"/>
PI institution	<input type="text" value="Baylor College of Medicin"/>		
PI department	<input type="text" value="Research"/>		
PI e-mail	<input type="text" value="aresquiv@bcm.edu"/>		
		Section	<input type="text"/>
		PI phone	<input type="text" value="(713) 798-6064"/>

Status history
No history found

Comments

Research colonoscopy at 6 & 12 months. SOC colonoscopy annually.

Approve
Defer

Application Area Review

- Pending for Area Approval
- Completed Area Approval

Pending for Area Approval

IRB Number	Principal Investigator	Status	Approval Group Name	Application PDF	Device Form PDF
19-02-911-2019	<input type="text"/>	Signed by PI	Endoscopy	View File	

Once you click on Approve or Defer, an email is sent back to the review team informing them of the department approval or deferral.

You may contact the Office of Clinical Research for any questions at BSLMC_research@bcm.edu or 713-798-6024.

Institutional Approval or Deferral

If the study is approved, an email is sent to the department/area reviewer/approver informing them of the approval.

From: bslmc_research@bcm.edu
To: [\[Department Reviewer/Approver Name\]; \[Department Reviewer/Approver Name\];](#)
Cc: [BSLMC Research](#)
Subject: BSLMC Administrative Application approved for – IRB # [IRB#], [Study Name, [PI] - Attn: [Department]
Date: Tuesday, August 06, 2019 4:38:11 PM

Dear [Department Reviewer/Approver Name],

IRB of Record #: [IRB#]

Study Title: [Study Title]

Principal Investigator: [PI Name]

The above-named clinical study has received institutional for implementation at BSLMC. The study had previously received your approval on behalf of **Radiology**. For your convenience, below is the brief description of the study purpose and study activities occurring in Radiology.

If you have any questions, please contact the BSLMC Research Office at 713-798-6024 or BSLMC_Research@bcm.edu.

Many thanks.

[BSLMC Administrative Application System](#)

Study overall purpose: Testing adding documents after submission to update PDF

Study activities occurring in Radiology:

If study is deferred or not approved, then an email is sent the department/area reviewer/approver informing them of the deferral.

From: [BSLMC Research](#)
To: [\[Department Reviewer/Approver\]](#)
Subject: FW: BSLMC Administrative Application approved for – IRB # [IRB#], [Study name], [PI] - Attn: [Dept./Area]
Date: Monday, September 16, 2019 1:54:44 PM

Dear [Department Reviewer/Approver],

IRB of Record #: [IRB#]
Study Title: [Study Name]
Principal Investigator: [PI Name]

The above-named clinical study has been deferred for implementation at BSLMC. The study had previously received your approval on behalf of Inpatient/Nursing. For your convenience, below is the brief description of the study purpose.

If you have any questions, please contact the BSLMC Research Office at 713-798-6024 or BSLMC_Research@bcm.edu.

Many thanks.

[BSLMC Administrative Application System](#)

Study overall purpose: Study will investigate the use of WISE CRT system.