



GIVING LIFE TO POSSIBLE

BSLMC Application for Administrative Review of Research

Institutional Reviewer/Approver Instructions

Version 1.0

Office of Clinical Research

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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>.

Submitter – Person that completes the investigational device assessment form and/or application for BSLMC administrative approval for submission to the PI. This can be a regulatory person, administrative person, coordinator, or anyone working on the study with knowledge about the research study.

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.

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.

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 the submitter and PI for any questions during the review.

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

Email to Institutional Reviewer/Approver

Institutional reviewer/approver will be sent an email indicating that a study is ready for review and approval.

From: bslmc_research@bcm.edu
To: [BSLMC \[Administrative Reviewer/Approver\]](#)
Cc: [BSLMC Research](#)
Subject: BSLMC Administrative Application submitted for BSLMC institutional review– IRB # [IRB#], [Study Name], [PI Name]
Date: Tuesday, August 06, 2019 4:35:44 PM

The above-named clinical study is ready for your review and approval on behalf of BSLMC. The application has been reviewed and approved by the BSLMC Research Office and all BSLMC areas that will be impacted by the study. Please see bottom of this email for the study summary. The following supporting documents may be accessed in the online [BSLMC Administrative Application System](#):

- Draft Approval Letter: Provided
- Financial Agreement, approved by BSLMC Finance on : Provided
- Research Pharmacy Services Agreement: N/A
- Research Contract: N/A
- IRB Approval Letter: Provided
- Administrative Approval checklist/tracking sheet: Provided
- Compliance review checklist: Provided
- Executed device agreement & FDA approval of IDE: Provided

Please log on to [BSLMC Administrative Application System](#) to review and approve the application.

Please contact the BSLMC Research Office at 713-798-6024 or BSLMC_Research@bcm.edu if you have any questions or concerns.
Thank you.

Study Summary: Testing adding documents after submission to update PDF

Administrative Review Team Comments: Study is only doing SOC MRI's.

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 BSLMC Application for Administrative Review of Research. The page has a dark blue header with the Baylor St. Luke's Medical Center logo and navigation links for Home, Help, and Logout. The main content area is white and contains a login form with fields for User name and Password, a Log in button, and a link for Forgot Password. A note at the bottom recommends using the latest version of Mozilla Firefox.

Institutional Approver Review, Approval or Deferral

The screenshot shows the Institutional Approver Review, Approval or Deferral page. The page has a dark blue sidebar with navigation links for Application, PI, Application Institutional Review, and Documents. The main content area is white and contains an Application Summary table with fields for IRB of record, H number, Project start date, PI first name, PI institution, PI department, PI e-mail, IRB of record number, Short title, Project end date, PI last name, Section, and PI phone. There are three red circles with numbers 1, 2, and 3. Circle 1 is around the View Application button. Circle 2 is around the Documents link in the sidebar, with a red arrow pointing to it. Circle 3 is around the Approve and Defer buttons.

1. Review application
2. Review additional documents.
 - a. Print administrative approval letter for signature
 - b. Scan and save signed approval letter in Additional Documents
3. Click Approve
If not approved, click Defer and do not sign letter.

Additional Documents	
1. BSLMC Approval letter	<input type="text"/> <input type="button" value="Browse..."/>
2. BSLMC financial agreement	<input type="text"/> <input type="button" value="Browse..."/>
Financial agreement approved by BSLMC Finance on	<input type="text"/> 
3. Research pharmacy services agreement	<input type="text"/> <input type="button" value="Browse..."/>
4. Research contract	<input type="text"/> <input type="button" value="Browse..."/>
5. IRB approval letter	<input type="text"/> <input type="button" value="Browse..."/>
6. Administrative approval checklist/tracking sheet	<input type="text"/> <input type="button" value="Browse..."/>
7. Compliance review checklist	<input type="text"/> <input type="button" value="Browse..."/>
8. Executed device agreement & FDA approval of IDE	<input type="text"/> <input type="button" value="Browse..."/>
9. Operations Summary	<input type="text"/> <input type="button" value="Browse..."/>
<input type="button" value="Save"/> <input type="button" value="Cancel"/>	

If the study is approved, an email with copy of signed letter and if applicable, financial agreement is sent to the PI and submitter informing them their study was approved. An email is also sent to the administrative review team and department/area reviewer/approver informing them of the approval.

From: bslmc_research@bcm.edu
To: [\[PI name\]](#)
Cc: [BSLMC Research](#)
Subject: BSLMC Administrative Application approved for – IRB # [IRB#], [Study Name], [PI]
Date: Tuesday, August 06, 2019 4:38:11 PM
Attachments: [\[Admin Approval Letter.pdf\]](#)
[\[Financial Agreement.pdf\]](#)

Dear [PI Name],

IRB of Record #: [IRB#]

Study Title: [Study Name]
Principal Investigator: [PI Name]

Thank you for submitting a [BSLMC Administrative Application System](#) for the above-named study. We are pleased to inform you that your application has been approved. Please review the attached approval letter, which includes important information on BSLMC study conduct requirements. If applicable, your financial agreement with research pricing is also attached again here for your convenience.

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

From: bslmc_research@bcm.edu
To: [BSLMC Research](#)
Subject: BSLMC Admin Review – Institutional Approval Submitted for – IRB # [IRB#], [Study name], [PI]
Date: Tuesday, August 06, 2019 4:38:11 PM

Dear BSLMC Research Office,

BSLMC Institutional Approval has been submitted by Approver, Institutional for the following study:

IRB of Record #: [IRB#]

Study Title: [Study Title]

Principal Investigator: [PI Name]

Please log in to [BSLMC Administrative Application System](#) to review the application.

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 emails are sent to the PI, the department/area reviewer/approver and the administrative review team informing them of the deferral.

From: bslmc_research@bcm.edu
To: [PI Name](#)
Cc: [BSLMC Research](#)
Subject: BSLMC Administrative Application deferred for – IRB # [IRB#], [Study Name], [PI]
Date: Monday, September 16, 2019 1:54:42 PM

Dear [PI Name],

IRB of Record #: [IRB#]

Study Title: [Study Title]

Principal Investigator: [PI Name]

The above-named clinical study been deferred for implementation at BSLMC, for the reasons described to you in previous communications from the BSLMC Research Office.

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

From: [BSLMC Research](#)
To: [Ashibuogwu, Obiajulum](#); [Esquivel, Angelita R.](#)
Subject: FW: BSLMC Admin Review – Institutional Deferral Submitted for – IRB # [IRB#], [Study name], [PI]
Date: Monday, September 16, 2019 1:54:43 PM

Dear BSLMC Research Office,

BSLMC Institutional Deferral has been submitted by Approver, Institutional for the following study:

IRB of Record #: [IRB#]

Study Title: [Study Name]

Principal Investigator: [PI Name]

Please log in to [BSLMC Administrative Application System](#) to review the application.

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.