

THE UNIVERSITY OF TEXAS

MD Anderson  
~~Cancer~~ Center

Making Cancer History<sup>®</sup>

BIMS Protocol Registration

Training Guide for New Users

# Institutional Tissue Bank (ITB)

Important steps in Process of Biological Specimens Collections from Patients



**Protocol Registration Form**

**Instructions:** Please review and complete this form to initiate protocol registration in TissueStation. The requested information is necessary to correctly document your request for registration of an MDACC approved - IRB protocol for the collection of biospecimens for research purposes, and to ensure that the Tissue Biospecimen and Pathology Resource (TBPR) operates within the guidelines of MDACC and regulatory entities.

Principal Investigator	<input type="text"/>	<b>Workflow Preference</b>
Protocol Number	<input type="text"/>	<input type="checkbox"/> IR/Clinic Collection
Protocol Title	<input type="text"/>	<input type="checkbox"/> OR Collection
Pathologist	<input type="text"/>	<input type="checkbox"/> Vaccine Study
		<input type="checkbox"/> Clinical Trial
		<input type="checkbox"/> Data Only

Waiver granted per IRB? (If "Yes", please identify the circumstance(s) under which the waiver was granted.)  Yes  No

De-identified List Associated Consenting Protocol(s) below:

Retrospective

Deceased

Associated Consenting Protocol(s):

Diagnoses (list all):  Include metastasis with same diagnoses

Organs/Sites/Specimens for collection (list all):

Please select an official satellite bank as the operating bank for this protocol. This bank may or may not provide services to the protocol. If no selection is made, the Institutional Tissue Bank will be assigned by default.

Operating Bank:

Please identify who will be responsible for administering this protocol in TissueStation. Protocol Administrator(s) (up to four)

Please complete the following Billing Authorization form to initiate the protocol registration process. Protocol registration will not be initiated without a signed Billing Authorization Form.

**Billing Authorization Form**

Principal Investigator:

Protocol Number:

I understand that billing will occur on a monthly basis, and I agree to keep the ITB or the designated operational bank (if applicable) informed of account expiration dates and changes as they occur. I also acknowledge that fees are subject to change with advanced notice. Invoices for the assessment of charges should be forwarded to the Principal Investigator as well as the following billing contacts:

By selecting All for Charge Type, I hereby authorize assessment of the one-time \$25 registration fee and charges associated with services provided by the Institutional Tissue Bank, any satellite bank, and/or HistoCore Laboratory (if applicable) to the following chartfield string: (\*\*Different chartfield strings may be used for services provided, please select other and specify charges associated with each chartfield string provided.)

Charge Type:  All  \*\*Other (Specify)

BU	*Department	Fund Group	Fund	Account	*Fund Type	PC Business Unit	Project	Activity
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Typed Name:  Authorized Signature on Account:  Date of Signature:

Please provide a non-grant backup chartfield string account for restricted grant chartfield string(s):

BU	*Department	Fund Group	Fund	Account	*Fund Type	PC Business Unit	Project	Activity
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Typed Name:  Authorized Signature on Account:  Date of Signature:

\*\*Charge Type (Specify):

BU	*Department	Fund Group	Fund	Account	*Fund Type	PC Business Unit	Project	Activity
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Typed Name:  Authorized Signature on Account:  Date of Signature:

Upon completion of this form, please print out a copy and obtain an ink signature from the designated user of each chartfield string.

**I. Agreement to use of tissues and other biospecimens provided by MDACC Tissue Biospecimen and Pathology Resource (TBPR) via the Institutional Tissue Bank (ITB) or any of its satellite banks.**

- The recipient agrees that biospecimens and associated data will be used solely for purposes specifically approved by the IRB.
- The recipient agrees that they shall not transfer biospecimens, or any portion thereof, supplied by TBPR to third parties without the prior written permission of TBPR.
- The recipient agrees that it shall not sell any portion of the tissues provided by TBPR, or products directly extracted from these tissues (e.g., protein, mRNA or DNA).
- Patient privacy and confidentiality will be respected at all times and patient information will not be accessed protected health information linked to specimens except as specifically approved by the IRB

**II. Agreement to use appropriate safety measures.**

- The recipient understands that all biospecimens should be handled as if potentially infectious.
- The recipient agrees to follow appropriate safety measures, including OSHA guidelines, as well as MDACC Biosafety Regulations for handling human biospecimens (Refer to MDACC Biological Safety Manual).
- The recipient further agrees to assume all responsibility for informing and training personnel regarding the potential dangers of and appropriate procedures for handling of human tissues.

**III. Acknowledgement Agreement**

- I hereby agree to make the study results available to the scientific community and to acknowledge the contributions of the MDACC Tissue Biospecimen and Pathology Resource via the Institutional Tissue bank or any of its satellite banks in all publications resulting from the use of these tissues.
- The support of the TBPR must be acknowledged in all research that results in publication. A suggested acknowledgement statement is "This study was supported by the Tissue Biospecimen and Pathology Resource (TBPR) at the University of Texas M. D. Anderson Cancer Center in part by the National Institutes of Health Cancer Center Support Grant (CA016672)."

OR

"This research was supported in part by the National Institutes of Health through M. D. Anderson's Cancer Center Support Grant (CA016672) for Tissue, Biospecimens and/or Data obtained through services provided by the Tissue Biospecimen and Pathology Resource (TBPR)."

**BY MY SIGNATURE I AGREE TO THE TERMS SET FORTH IN AGREEMENTS I, II & III Above**

Principal Investigator:  Protocol Number:

Signature of Principal Investigator

Date of Signature

Please return the completed form to the Institutional Tissue Bank at [tissuebank@mdanderson.org](mailto:tissuebank@mdanderson.org).

# BIMS: Protocol Registration

- Protocol Registration begins by filling out the required registration form.
- The form can be requested by the ITB at any time a new protocol is to be created.
- Once filled, it should be emailed to [ITBTeam@mdanderson.org](mailto:ITBTeam@mdanderson.org) so that it can be registered in BIMS.
- The Registration process comes with a Study Registration Fee of \$25.
- If unsure about which Operating Bank your protocol should be under, the recommended default is ITB.

# Protocol Activation in BIMS

The screenshot displays the MD Anderson BIMS Administration interface. The top navigation bar includes 'MD Anderson BIMS', 'Administration', and 'MONTEMAYOR JR, Francisco'. A search bar is present with a dropdown menu set to 'Protocol / Bank' and a search input field. Below the search bar are buttons for 'Search', 'Reset', 'Run Report', and 'Register New Bank'. A table lists protocols with columns for Protocol / Bank, Principal Investigator, Operating Bank, and Registration Status. Below the table, detailed information for a specific protocol is shown, including the protocol number, title, principal investigator, IRB approval and activation dates, review expiration date, IRB termination date, operating bank administrator(s), and protocol administrator(s).

Protocol / Bank	Principal Investigator	Operating Bank	Registration Status
2016-0142	Hoffman, Karen	Breast	Approved
2016-0164	Bedrosian, Isabelle	Breast	Approved
2016-0251	Kaseb, Ahmed	Lower GI	Approved
2016-0260 - Inactive	Layman, Rachel M.	Breast	Initiated
2016-0269	Badgwell, Brian D.	Lower GI	Approved
2016-0338	Parseghian, Christine	Lower GI	Approved
2016-0412 - Inactive	Raghav, Kanval P.	Lower GI	Inactive
2016-0418 - Inactive	Karuturi, Meghan S.	Breast	Inactive
2016-0419	Layman, Rachel M.	Breast	Approved
2016-0538	Karuturi, Meghan S.	Breast	Approved

**Protocol Number:** 2004-0453      **Registration Date:** 08/31/2012  
**Title:** A Phase III Trial Evaluating the Role of Ovarian Function Suppression and the Role of Exemestane as Adjuvant Therapies for Premenopausal Women with Endocrine Responsive Breast Cancer  
**Principal Investigator:** Koenig, Kimberly B.      **# of Patients:** 27  
**IRB Approval Date:** 07/21/2004      **# of Samples:**  
**IRB Activation Date:** 01/20/2005      **# of Samples per Patient:**  
**Review Expiration Date:** 11/12/2022      **Protocol Type:** Unknown  
**IRB Termination Date:**      **Waiver Status:** Protocol Specific Consent Required  
**Operating Bank Administrator(s):** Elena Bogatenkova, Mallory P. Psenda  
**Protocol Administrator(s):** Wanda J. Williams, Aurora G. Guerrero  
**Exempt:**

- Once the Registration form has been submitted to ITB, all the information will be entered in BIMS and the protocol will become "Initiated."
- When this change is made in BIMS, an automated email will be sent out to the Protocol's Principal Investigator (PI) and the listed administrators.
- Once initiated in BIMS, to activate the protocol, the entered information must be reviewed by the Protocol's Administrators and approved upon inspection.
- This can be done using the "Administration" module under the "Resource Administration" tab.

Tasks Pending Review

Search By: Protocol / Bank

Protocol / Bank:

[View All](#) [View By Page](#)

Protocol / Bank	Principal Investigator	Operating Bank	Registration Status
ITB		ITB	Approved

**Bank Name:** Institutional Tissue Bank  
**Shorthand Name:** ITB  
**Operating Bank Administrator(s):** Sharon P. Miller, Elena Bogatenkova, Mallory P. Psenda  
**Bank Administrator(s):** Sharon P. Miller, Elena Bogatenkova, Mallory P. Psenda

**Bank Director(s):** Elena Bogatenkova  
**Date Created:** 10/24/2005

# Protocol Activation in BIMS (cont.)

- To view entered information and confirm accuracy of information, choose/enter your protocol in the “Protocol/Bank” box.
- Click on the protocol from the list below to open the Management screen allowing you to view the whole protocol.
- Press the “Edit” button at the bottom of the screen to review all entered information.

# Approving Entered Information

General Organ/Site Diagnosis

\* Operating Bank: Institutional Tissue Bank

\* Pickup Password: .....

\* Confirm Pickup Password: .....

Unlimited Collection # of Patients: 98999 # of Samples: # of Samples per Patient:

Outpatient Clinic Collection:  Clinical Trial:

Prospective OR Collection:  Data Only:

Vaccine Study:  De-Identify:

Comments:  
03/06/2017 09:16:51 Approved  
01/12/2018 11:28:22 Approved  
09/06/2018 10:16:36 Approved

Waiver Status: Protocol Specific Consent Required

De-Identified:  Retrospective:  Deceased:  Associated Consenting Protocol:

Save & Return Submit for Approval Cancel

- Please go through each tab (General, Organ/Site, Diagnosis) and confirm the accuracy of all entered information.
- Should any errors exist please correct the information or alert the ITB team and we will correct the information.
- Once all information has been confirmed, please press the “Submit for Approval.”
- This will change the status of the protocol to “Pending Bank Review” and an email will be sent to all involved.

# Modifying Protocol Further

- The protocol can be modified further by anyone with Administrator access.
- Adding personnel to the protocol can be done in the “Personnel” tab using the “Add New” button.
- There are different roles that can be granted depending on the level of access needed by the employee.
  - Administrator
  - Pickup
  - Reader
  - Requestor
  - Technician

Protocol Management Search By

Protocol Number: 2014-0938 Registration Status: Approved

Protocol

General | Workflow | Organ/Site | Diagnosis | Attributes | Project | Personnel | Summary | Comments

Personnel

View All << Prev 1 2 3 4 5 6 7 8 9 10 Next >>  
Showing 1 to 15 out of 287

Name	Roles	ADM	CON	DIS	HIS	INV	REQ	S&R	SMP	BIL
① Ahmed, Shahab U.	PICKUP									
	REQUESTOR		RW				RW			
① Al Rawi, Ahmed N.	READER	RO	RO			RO	RO	RO	RO	RO
	REQUESTOR		RW				RW			
① Albert, Aisha C.	REQUESTOR		RW				RW			
① Ali, Azad H.	PICKUP									
	REQUESTOR		RW				RW			
	TECHNICIAN	RO	RW	RW		RW	RW	RW	RW	RW
① Allen, Daniel J.	READER	RO	RO			RO	RO	RO	RO	RO
	REQUESTOR		RW				RW			
① Alvarez, Brittany T.	PICKUP									
	REQUESTOR		RW				RW			
	TECHNICIAN	RO	RW	RW		RW	RW	RW	RW	RW
① Anjier, Ariana R.	PICKUP									
① Araujo, Dejka M.	COLLABORATOR		RW				RW			

Add New Edit Delete Update Collaborators



**Protocol Management** Search By

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Protocol Number: 2014-0938 Registration Status: Approved

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**Protocol**

General | Workflow | Organ/Site | Diagnosis | Attributes | Project | Personnel | Summary | Comments

**Summary**

<p><b>Principal Investigator:</b> Wistuba, Ignacio I.  <b>Title:</b> APOLLO  <b>IRB Approval Date:</b> 08/19/2015  <b>IRB Activation Date:</b> 01/06/2016  <b>Review Expiration Date:</b> 08/25/2023  <b>Registration Date:</b> 03/06/2017  <b>OR Collection:</b> Yes  <b>Outpatient Clinic Collection:</b> Yes  <b>Clinical Trial:</b> No  <b>Data Only:</b> No  <b>Vaccine Study:</b> No  <b>De-Identify:</b> No  <b>Consent req. for sample entry:</b> Yes</p>	<p><b>Protocol Type:</b> Unknown  <b>IRB Termination Date:</b>  <b>COA:</b>  <b>Operating Bank:</b> Institutional Tissue Bank  <b>Protocol Administrator(s):</b>  <b>Pickup Password:</b> Yes  <b># of Patients:</b> 98999  <b># of Samples:</b>  <b># of Samples per Patient:</b>  <b>Waiver Status:</b> Protocol Specific Consent Required  <b>Exempt:</b></p>
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<p><b>Select All Diagnosis:</b> Yes  <b>Include Mets with same Diagnosis:</b> Yes</p>	<p><b>Select All Organ Sites:</b> Yes</p>
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Diagnosis	Organ/Site
No data to display	No data to display

# Finished Protocol Registration

- Remember that future changes to operating bank, organ/sites, and diagnosis will require confirmation/approval from the operating bank and/or ITB. Attribute values are editable by the PI or Administrators without outside approval and immediately available for use in the application once updated.



Address additional questions  
and training requests to:  
[ITBteam@mdanderson.org](mailto:ITBteam@mdanderson.org)  
and  
Sharon P. Miller  
([spmiller@mdanderson.org](mailto:spmiller@mdanderson.org))  
Principal Business Systems  
Analyst



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