IITB Committee chair:
Dr. PL Beck
Dept. of Medicine
Division of Gastroenterology
Ph. 403-220-4500
Protocol # REB14-2429/#18142

Intestinal Inflammation Tissue Bank & Database

Access Proposal

The Intestinal Inflammation Tissue Bank (IITB) is a repository of human samples used in biomedical research. The bank stores and has the ability to collect intestinal biopsies, blood, gingival swabs, and stool from patients with inflammatory conditions as well as healthy ones.

The Gastrointestinal Database (Committee Chair: Dr. Gil Kaplan) is an electronic repository of patients' phenotypic data (and control subject) as well as genetic and environmental data for the Alberta Inflammatory Bowel Disease Consortium (the Consortium), and related gastrointestinal and liver research projects/initiatives.

To access the bank and /or data from the database, a completed access proposal must be submitted to the IITB Research Liaison who will then send it for review to the Tissue Bank Committee (TBC) and the Database Committee. Following approval by committee and the Conjoint Health Research Ethics Board (CHREB), collection and distribution of samples for the project can commence.

The samples are provided in an anonymous fashion where only information on the age, gender, diagnosis and current medications of patients are revealed. The CHREB guidelines require that any specimens provided to projects are to be used only for the specific protocol approved by CHREB, TBC and Database committees.

Upon project completion of the project, any remaining material from the specimens provided (unused biopsies, RNA, cDNA, histology slides, etc…) must be returned to the IITB.

Price List (subject to change on annual basis):

$400.00 fee for access to the tissue bank, per project
$200.00 fee /every six months (**admin/task fee that covers fee for inventory, admin tasks, data request etc.**))
$25.00 per two biopsy samples
$25.00 per blood sample, in addition to any costs of collection

Additional services such as special chart review and questionnaires are available. Prices for additional services will be set on a project to project basis.

For questions or clarifications of any services provided by the bank or regarding completion of this form, please contact:

Translational Research coordinator:
Gurmeet Bindra, MSc.
Department of Medicine
University of Calgary
E-mail: gkbindra@ucalgary.ca
Office: (403)-210-7013

General Information

Date:

Project title:

Short title:

This request is:

☐ New project request. ☐ Re-opening of a previous project. ☐ Other: _____

☐ Extension of a current project. ☐ Alteration of an existing project

Principal Investigator(s):	**Department:**	**Phone #:**	**Email:**
Principal Clinical Investigator(s):	**Department:**	**Phone #:**	**Email:**

**** NOTE:** Clinical Investigators <u>should</u> be included as Authors on any publications arising from this project .In addition the IITB Research group should be acknowledged** *(refer to acknowledgment policy on page 12 and find link))*

Research Coordinators, Employees and trainees:

Sponsors (If this is a grant funded project, please provide the grant summary and budget pages)

☐ Please check here if **t**his project is receiving funds from the Alberta IBD Consortium.

Timeline	**Date of submission:** (dd/mm/yyyy)	**Date of Approval:** (dd/mm/yyyy)	**Comments:**
IITB Access Proposal:			
Ethics submission to CHREB:			
Project debut (expected):			
Addendum # 1			
Addendum # 2			
Addendum # 3			

If approved by the CHREB, please indicate Ethics ID # _____

*** NOTE:* ***It is the responsibility of the Principal Investigator to inform the IITB of any changes to this proposal.***

Background & Hypothesis

***Provide a brief scientific description of the project and use of the material requested that will allow the committee to judge the scientific value of this project and give it a priority rating amongst other applications*:**

Preliminary results / Previous IITB projects / Reason for Addendum

Include a brief summary of any preliminary results or previous IITB project related to the current request as well as a brief explanation regarding the changes you would like to make to an existing proposal.

Protocol

1) Number and type of samples

1.1) Total number of participants: Please indicate the total number of participants you will request for this project; as well as your timeline to receive the samples.

If your project is on-going and/or a request with a high number of participants, please specify how many participants you would need per "phase" of your project.

We will aim to complete a full "phase" of collection for your project, and then we will re-assess the priority of projects in queue for collection.

	Total	**Phase 1**	**Phase 2**	**Phase 3**	**Phase 4**
Expected date of completion (yyyy/mm/dd)					
Total # of CD participants					
Total # of UC participants					
Total # of IBS participants					
Total # of Celiac participants					
Total # of Healthy participants					
Total # of Other participants					

1.2) Tissue samples

Group/Type of patients	Number of patients / per group	Number of biopsies / per patient	Special request for patient / sample (e.g. specific intestinal section)
☐ Ileal CD Active			
☐ Ileal CD Inactive			
☐ Colonic CD Active			
☐ Colonic CD Inactive			
☐ UC Active			
☐ UC Inactive			
☐ IBS Active			
☐ IBS Inactive			
☐ Celiac Disease Inactive			
☐ Celiac Disease Inactive			
☐ Healthy Control			

☐ Other: _____			

1.3) Blood samples			
Group/Type of patients	Number of patients / per group	Number of samples / per patient	Special request for patient / sample (e.g. patient on immunomodulator)
☐ Ileal CD Active			
☐ Ileal CD Inactive			
☐ Colonic CD Active			
☐ Colonic CD Inactive			
☐ UC Active			
☐ UC Inactive			
☐ IBS Active			
☐ IBS Inactive			
☐ Celiac Disease Inactive			
☐ Celiac Disease Inactive			
☐ Healthy Control			
☐ Other: _____			

1.4) Urine samples			
Group/Type of patients	Number of patients / per group	Number of aliquots / per patient	Special request for patient / sample (e.g. patient on immunomodulator)
☐ Ileal CD Active			
☐ Ileal CD Inactive			
☐ Colonic CD Active			
☐ Colonic CD Inactive			
☐ UC Active			
☐ UC Inactive			
☐ IBS Active			
☐ IBS Inactive			
☐ Celiac Disease Inactive			
☐ Celiac Disease Inactive			
☐ Healthy Control			

☐ Other: _____			
1.5) Stool samples			
Group/Type of patients	Number of patients / per group	Number of samples/ per patient	Special request for patient / sample (e.g. patient on immunomodulator)
☐ Ileal CD Active			
☐ Ileal CD Inactive			
☐ Colonic CD Active			
☐ Colonic CD Inactive			
☐ UC Active			
☐ UC Inactive			
☐ IBS Active			
☐ IBS Inactive			
☐ Celiac Disease Inactive			
☐ Celiac Disease Inactive			
☐ Healthy Control			
☐ Other: _____			
1.6) Other type of sample			
Group/Type of patients	Number of patients / per group	Number of samples / per patient	Special request for patient / sample (e.g. patient on immunomodulator)
☐ _____			
☐ _____			

2) Inclusion and Exclusion Criteria		
Criteria	Inclusion	Exclusion
☐ Age		
☐ Gender		
☐ Medication		
☐ Active Disease		
☐ Inactive Disease		
☐ Comorbidities		
☐ Other:_____		

☐ Other:_____		

3) Media / Tubes to be collected in:		
Medias	Tubes (BD Vaccutainer)	Special request (e.g. storage instruction):
☐ RNA later*	☐ 10 ml Na/Heparin (green top)*	
☐ Zamboni's fixative	☐ 5 ml No anti-coagulant (red top)*	
☐ Gluteraldehyde fixative	☐ 6 ml K_2EDTA (lavender top)*	
☐ RPMI	☐ 10 ml K_2EDTA (lavender top)	
☐ Other:	☐ Other: _____	
The medias / tubes identified with an (*) are readily available. All other media or tubes must be provided to the Research Coordinator of the IITB.		

4) Patient information required		
☐ Age at sample collection*	☐ Disease extent / location	☐ Comorbidities
☐ Gender*	☐ Disease Index[1]: _____	☐ Surgical history
☐ Disease diagnosis*	☐ Medication at time of collection*	☐ Serological profile
☐ Date of diagnosis	☐ Medication history	☐ DNA profile
☐ Disease Activity / Severity	☐ Smoking status	☐ Other: _____
The variables identified with (*) are readily available. Other information might require in-depth chart review or analysis, which will affect 1) permissions 2) pricing and 3) time of release. Indexes[1]: SCCAI, HBI PUCAI, etc.		

5) Database request *(Indicate any data analysis to be performed with the data, as well as special requirements)*

6) Laboratory contact for pick-up *(please include name, laboratory location, phone # and email)*

7) Laboratory methods *(immunohistochemistry, RT-PRC, culture, etc.)*

8) Disposal / Storage of samples:
Upon completion of project, any remaining samples, processed or unprocessed should be returned to the IITB for storage and future use. *Please note that any use of processed samples (i.e.: extracted DNA, RNA, etc.) that have not been mentioned and approved in this proposal have to be disclosed to the IITB and additional fees might be charged.* *The IITB will inquire at time of billing about any remaining samples.*

IITB is set up on the principle that bio specimens will be openly shared, so applicants must be willing to deposit results and data in the IITB repository at the end of the study

Agreement

Project specific special request/condition:

Please specify any special request or condition for this project:

By signing this Access Proposal I agree to the condition and terms outlined in this agreement.

Principal Investigator: _____ (please print)

_____ (signature) _____ Date (dd/mm/yyyy)

Tissue Bank Committee Approval:

TBC Delegate: _____ (please print)

_____ (signature) _____ Date (dd/mm/yyyy))

If required: Database Committee Approval:

DC Delegate: _____ (please print)

_____ (signature) _____ Date (dd/mm/yyyy)

***** NOTE: It is mandatory that the clinical investigator and Intestinal Inflammation Tissue Bank research group be acknowledged in any publications or patents arising from the use of tissues/samples from the tissue bank, as per the IITB Acknowledgment guidelines. A copy of the any publications must be submitted to the Tissue Bank concurrently with submission to the journal.***

The following are IITB acknowledgement guidelines for 1) direct and 2) indirect (in-kind) support by way of funding and data/infrastructure:

1Clinical investigator should be included as author on any publication arising from the use of tissues/samples /data from the tissue bank. .

2) IITB Research group be acknowledged in any publications arising from tissue/samples/data from tissue bank.

Author need to include the IITB research group link under the URLs sections at the end of publication.

IITB research group- link

3) We ask that you acknowledge that "this research has been conducted using the Biobank Resource."