Research Ethics Board
OPG Building, 700 University Ave.
Suite 8-600, Toronto, Ontario, M5G 1Z5
t:: (416) 586-4875 f: (416) 586-4715
www.mt.sinai.on.ca/EthicsBoard

Application for the Use of Human Tissue/Blood/Body Fluid for Research Purposes

Submit typed, hard copy of this form with 'Original Signatures' for review. **Keep a copy for your files**		
SECTION 1a	**Study Title**	
Study Title:		
SECTION 1b	**Principal Investigator** *(Must be a MSH Staff Member)*	
Name:	Division/Department:	Program:
Address (Room Number):	Telephone:	Fax/Email:
SECTION 1c	**Co-Investigators(s)**	
Name:	Division/Department:	Program:
Address (Room Number):	Telephone:	Fax/Email:
SECTION 1d	**Person(s) who will perform the experiment** *(include as many persons as necessary)*	
Name:	Division/Department:	Program:
Address(Room Number):	Telephone:	Fax/Email:
SECTION 1e	**Person (s) who will access retrospective patient data if applicable** *(include as many persons as necessary)*	
Name:	Division/Department:	Program:
Address (Room Number):	Telephone:	Fax/Email:

SECTION 1f	Agreements

Confidentiality Agreement
I, the undersigned, agree to adhere to the **MSH Policy on Information and Data Security (Policy #I-H-5)** and understand that a breach of this policy will be just cause for termination of my employment and/or affiliation with the hospital. I agree that all health information, which I may have access to, is to be dealt with in keeping with the policies and procedures of Mount Sinai Hospital with respect to confidentiality. If identifying information is collected, the information will be kept secure and identifiers removed at the completion of collection. I also accept full responsibility for protection of information that has been collected by a delegate on my behalf.

Principal Investigator Signature:	Print Name:	Date (dd/mmm/yyyy):
Signature of Individual(s) Accessing Retrospective Data if applicable (if not PI):	Print Name:	Date (dd/mmm/yyyy):

Division/Department Approval
I have reviewed this proposal and agree that the proposed use of human tissue materials in the project represents appropriate use of the human tissues available for research.

Division/Dept. Head Signature:	Print Name:	Date (dd/mmm/yyyy):

Pathology & Lab Medicine Departmental/Division Representative *(please complete if this study will have an impact on Pathology & Lab Medicine)*
Pathology & Lab Medicine Contact: Maria Mendes, ext. 7551
I have reviewed the proposal and agree that appropriate human tissue materials are available for this study.

Pathology & Lab Medicine Representative Signature:	Print Name:	Date (dd/mmm/yyyy):

SECTION 2	Study Details	
Time Frame:	Proposed Start Date (dd/mmm/yyyy):	Termination Date (dd/mmm/yyyy):

How will the study be funded?
☐ Grant – Specify funding source:
☐ Industry – Sponsor:Provide Name & full billing address including a contact's name & email address:
☐ Internal – Specify funding source:
☐ No Funding Required

Tissue Source	☐ Archived Fixed Tissue
	☐ Frozen Tumour Bank

	Specify Bank:
	☐ Autopsy
	☐ Fetal
	☐ Fresh Tissue Obtained from: ☐ Surgical Specimen ☐ Excess Blood Sample ☐ Excess Body Fluid
	☐ Other Please specify:
Consent Attached? (Include consent to be used with application, if applicable).	☐ Yes ☐ No
Does the study involve genetic research?	☐ Yes ☐ No If yes, please provide details:

SECTION 3	**Research Proposal for the Study of Human Tissue**
1. Primary objective and hypothesis of the study:	
2. How will the tissue be collected? *(For prospective studies only)*	
3. Indicate the approximate number of tissue samples that will be required for this study.	
4. How will the tissue be identified? *(For prospective studies only)*	
5. Will any identifying information be recorded?	☐ Yes ☐ No If yes, please specify the identifying information and justify the necessity for its collection:
6. Will the individual identifiers be removed once the relevant data is collected? *(For prospectively collected tissue only)*	☐ Yes ☐ No If no, please justify:
7. How will security and confidentiality of the data	

be ensured?	
8. Is there any anticipated linkage of the data to be collected with a clinical database?	
9. Will the data be available or distributed to others?	☐ Yes ☐ No If yes, specify how confidentiality will be protected:
10. Will the data being collected be used now or in the future for commercial purposes?	☐ Yes ☐ No ☐ N/A If yes, please provide details:
11. Will the tissue be sent to another facility for study?	☐ Yes ☐ No If yes, please name the location and provide the REB approval letter of the institution: If yes, is there a Material Transfer Agreement: ☐ Yes ☐ No ☐ Pending
12. **Attached summary:	** Attach a brief summary of the research project (1 page maximum) or the summary page of the grant proposal.

SECTION 4	**Request to Access Retrospective Data for Research Purposes** ☐ *Please indicate if this section is not applicable (N/A) to your study*	
1. Data source: Identify all sources of data ☐ In Patient ☐ Day Surgery ☐ Emergency ☐ Database (Specify:)		
2. Specify the data to be collected or attach data collection form.		
3. Proposed number of research subjects/charts:		
4. Time period of requested data:	From (dd/mmm/yyyy):	To (dd/mmm/yyyy):
5. If personal health information is collected, used or disclosed, without consent from individuals to whom the information relates, explain		

why obtaining explicit consent would be impractical.		
6. How will relevant patient charts be identified?		
7. Have you already developed a list of specific patients?	☐ Yes ☐ No If Yes, please indicate how patients were identified:	
8. Will any identifying information be recorded?	☐ Yes ☐ No	
	If yes: i) Specify the identifying information and justify the necessity for its collection.	ii) Will individual identifiers be removed once the relevant data is collected? If not, please justify.
9. Will this data be transferred externally to MSH?	☐ Yes ☐ No If yes, where: Is there a Data Sharing Agreement: ☐ Yes ☐ No ☐ Pending How will the confidentiality be protected?	
10. Is this a multi-centre study?	☐ Yes ☐ No If yes, please identify the other sites and indicate the REB approval status:	
11. Is there any anticipated linkage of the data to be collected with other data?	☐ Yes ☐ No If yes, how will the linkage information be treated?	
12. Will this data be reported publicly? (e.g. publication)	☐ Yes ☐ No	
13. Will this data being collected be used now or in the future for commercial purposes?	☐ Yes ☐ No If yes, please provide details:	
14. How will security and confidentiality of the data be protected, maintained and retained?		