James Hogg iCAPTURE Centre for Cardiovascular and Pulmonary Research

STANDARD OPERATING PROCEDURE

Title:	**Obtaining Informed Consent**		
Procedure:	BB.009.01	**Supercedes:**	none
Originator and Date:	Lise Matzke 22OCT2008	**Effective Date:**	22OCT2008
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Revision History		
Date	**Reviewer**	**Summary of revision**
20Apr2009	Crystal Leung	Reformatted to iCAPTURE format

Purpose

This document outlines the manner in which informed consent for the purpose of research may be obtained.

Responsibilities

This procedure is applicable to:

- Biobank personnel
- Those conducting informed consent for the Biobank

Safety

There are no inherent safety risks in conducting informed consent.

Definitions

Informed Consent	A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial/research project, after having been informed of all aspects of the trial/project that are relevant to the subject's decision to

	participate. Informed consent is documented by means of a written, signed and dated informed consent form.
Research Coordinator	Person in charge of coordinating aspects of a clinical trial or research project
ID (Identification) Form	Unique form that identifies a patient as being consented and enrolled into a specific project
REB	Research Ethics Board

Materials and Equipment

REB approved, study specific consent form

Procedure

1. Consent from patient/ research subjects will be sought in the several different areas of St. Paul's Hospital. This must be approved by the REB. In any case, a nurse will ask patients if they wish to speak to a research coordinator regarding an ethically approved research project(s). If they do not with to speak to a coordinator, the patient will not be contacted by any research coordinator. If the patient agrees, patients will be approached by the research coordinator and a full and informed consent process will commence.

   A sample consenting script is included below:

   Hello Mr./Ms/Mrs. _____. My name is Jane Smith and I work for the iCAPTURE Centre. We're a University of British Columbia centre here at St. Paul's Hospital and we do heart and lung research. iCAPTURE is looking for solutions to heart and lung related diseases.

   I understand you have recently had heart surgery. I would like to know if you would be willing to let us use tissue that was removed as a normal course of your surgical procedure. After your surgery, this tissue is usually discarded, but I would like to know if you would be willing to let us use it for heart research. Your participation is completely voluntary. This is the only time we will need to visit you; you do not need to come back for subsequent visits.

Does this sound like something that is of interest to you? (Most people say yes) if yes:

I have some more information here that I would like to give you. This form (consent form) gives more information as to what we do and why I have come to see you today. When you read through this consent form, you will see that we are asking you for your consent to use the tissue from your surgery. Again, this tissue has already been removed: we do not need to collect any tissue from you as it has already been removed. If you decide that would like to participate in this study and in the future you decide that you've changed your mind and you don't want your tissue used for research purposes, you can always contact us and we can remove it from our holdings and will not use it further for research.

The last page of the consent form is for signatures. If you feel that you would like to participate in this study, then we will have you, a witness and myself sign this form. I will make a photocopy of this form and give a copy to you for your records.

I would like to leave you with this form so you have time to read through it and digest its contents. I will come back at the end of the day (or a specified time if they like) and answer any questions or concerns you might have. Do you have any questions now that I can answer?

When I come back I ask if they have any questions. I then review some of the points in the consent form and make sure they understand that the tissue, already removed, is what we are asking for permission to use and ask if they understand we may use their medical chart history, as indicated on the consent form. I remind them that it's voluntary participation. After answering questions and concerns:

Do you feel that you would like to participate in this research study? (if yes, we sign the consent form, if they say no, I thank them for their time)

Ok Mr/Ms/Mrs ____ thank you. I'm going to make a photocopy of this form so you have a copy for your records. This form has our contact information on it, so if you have any concerns or questions, please feel free to contact me. Again, if you decide in the future that you would like to have your tissue removed from the research; you can always contact us and withdraw from the research project.

2. Once signed, the research coordinator will make 2 photocopies of the signed consent for research form and give a copy to the patient/ research subject and included one copy in the patient chart. Further, an ID form will be placed in the

patient/ research subject's patient chart. This form is known by OR staff and denotes that a patient has consented to the use of their tissue for research. The research coordinator must also include the details of the consent encounter in the "Progress Notes" portion of the file; detailing to what the patient has consented, the date, and that a copy has been given to the patient.

3. Once a patient has their surgery, and the OR staff have seen the pink sheet in the patient file, they will contact the Biobank by pager for tissue collection.