

Hematology Cell Bank of BC

Guidelines for Researchers Re: Ethics Submissions

This is a guideline for the *Ethics* submission of individual projects accessing samples from the Hematology Cell Bank of BC.

Principal Research Investigators of individual projects should also be familiar with:
“*General Guidelines for Researchers*”

(1) A project summary must be reviewed by a hematology working group prior to commencing the Ethics application for a project linked to the Hematology Cell Bank. The purpose of this review is to determine if the research described falls within the scope of research governed by the Hematology Cell Bank of BC and to determine if it will be possible to meet the needs of the researcher's sample requirements.

(2) Project must fall within the following scope of research:

- a. Normal blood cell production
- b. Development of methods for ex vivo blood cell production (for use in transplant and/or transfusion)
- c. Methods of increasing blood production in the body
- d. Genetic modification of blood cells and leukemic blood cells
- e. Differences between normal blood cells and leukemic blood cells
- f. Genetic and cellular events which lead to disease in normal cells
- g. Which treatments/agents are superior with respect to efficacy & preservation of normal cells
- h. Hematopoietic Stem Cell Transplant
- i. Methods of improving transfusion support

(3) Specimens collected:

- 5 – 10 mls of bone marrow material
- 5 - 50mls of blood
- 5mls of cells (stem, lymphocytes)
- excess WBC product from leukapheresis

(3.1) Requests for specimens outside the routine clinical procedures must be made in writing to the Project Coordinator (See General Guidelines for Researchers)

(4) Project must be submitted for Ethical Review (and approved by the Ethics Board) prior to commencing the project. In order to submit a project for Ethical Review:

- Projects will be submitted electronically to the BCCA Research Ethics Review Board. (Do not submit projects linked to the Hematology Cell Bank to the UBC CREB located at VGH.) As of April 3, 2006 all submissions and department approval of applications submitted to the BCCA REB must use the new **Researcher Information Services (RISe)** system.
- See website: <https://rise.ubc.ca/rise> . You will need a CWL login name and password to login
 - Chose to create a new application for Human Ethics

(5) Filling out the Ethics Board application:

- **Part 1. Principal Investigator & Study Team**
 - **Section 1.1.** Principal Investigator: add your name
 - **Section 1.3.** Co-Investigators: Add any other co-investigators.

- **Section 1.4.** Additional Study Team Members: add Study Team Members: *Anna Koochin*, (BCCA/Hematology and Stem Cell Trans (BCCA) and any other study team members (i.e. anyone you would like to have rise access to your study - Amanda Kotzer, Post Doc Fellows)
 - **Section 1.5.** Additional Study Team Members – No Online Access: Add to this section all collaborating researchers who will not have on line access (this may include researchers from centers outside BC or Canada and/or private industry collaboration – please list the research center and contact person.)
 - **Section 1.7.** Project Title: this will be the name of your project (which will be different than the name of the project on the consent form)
- **Part 4. Study Review Type**
 - **Section 4.2** Institutions and Sites for Study A. Enter all sites including VGH - follow the instructions to insert the letter “V” to add VCHRI/VCHA. (VGH hospital approval is necessary. Adding VCHRI ensures access by the hospital research institute to your ethics approval.)
 - **Section 4.3. Pt. A.** Proposal is linked to any other proposal: your proposal will be linked to the Hematology Cell Bank of BC. Here is where you enter the Research Ethics Board number and the following statement: **H04-61292 is the Hematology Cell Bank Project (approved by the UBC-BCCA REB) which maintains oversight of specimens and related clinical data that will be requested for use in this research project. H04-61292** will be the number that you reference throughout the rest of this application) **Pt. B.** Describe the relationship: enter “This will make use of specimens collected under project H04-61292”
 - **Section 4.5.** Minimal Risk: project H04-61292 is considered “minimal risk” therefore answer yes
- **Part 5. Summary of Study and Recruitment**
 - **Section 5.2.** Inclusion Criteria: patients consenting to have specimens collected under project H04-61292
 - **Section 5.3.** Exclusion Criteria: patients not consenting to have specimens collected under project H04-61292
 - **Section 5.4.** Method of Recruitment: patients will be recruited in the Leukemia/BMT inpatient and outpatient units as indicated in project H04-61292 and the procedures will be the same
 - **Section 5.6.** Summary of Procedures: This project makes use of specimens collected under project H04-61292 and the procedures will be the same.
- **Part 6. Subject Information and Consent Process**
 - **Section 6.1.** How much time will a subject be asked to dedicate to the project beyond that needed for normal care?: enter “N/A This study makes use of specimens collected under project H04-61292 and the procedures will be the same”.
 - **Section 6.2.** N/A This study makes use of specimens collected under project H04-61292 and the procedures will be the same.
 - **Section 6.3.** This study makes use of specimens collected under project H04-61292 and the risks are the same.
 - **Section 6.6.** Who will explain the consent: Physicians in the Leukemia/BMT Program or their delegates will consent patients as described in project H04-61292 and the procedures will be the same
- **Part 8. Data Monitoring**
 - **Section 8.4.** Please enter the following statement: Every effort will be made to safe guard the identity of subjects. A unique code is assigned to each specimen collected. Access to related clinical data that may or may not identify an individual will be closely protected under the oversight of the Hematology Cell Bank. Only a researcher who has IRB approval for their project linked to the Hematology Cell Bank (H04-61292) will have

access to identifiable subject data. All clinical data that has identifiable subject information will be de-identified by the researchers conducting this study when removed from a health records department or data base system. Only a subject study code will be used to reference this data. The researcher will not in any way share information that will identify a subject, nor will any information that will identify a subject be published or entered into a researcher's data base system. All data accumulated by a researcher will be stored in a de-identified form. A researcher will maintain this de-identified data until its destruction.

- **Section 8.5.** Regarding data: Please add this statement: Only the researchers conducting the research described in this application will have access to identifiable data, which will be stored as de-identified data, using only a subject study code. No data will be stored by the researcher where a link to the identifiable data is possible. The researcher's study or laboratory personnel will have access to de-identified data only.

- **Section 8.6.** Regarding data: Please add this statement: The dataset will remain stored as de-identified data. When this project is completed the researcher will submit a completion notice to the REB describing the planned disposition of the data.

- **Part 9. Documentation**

- **Section 9.1.** Protocol: Individual projects are required to submit a protocol. The protocol must outline the following criteria:

- 1) **Objectives:** State the objectives of the study. Some examples are:
 - a. to characterize a patient population selected by disease, stage, clinical finding or other characteristic
 - b. to estimate the median, mean and standard deviation of a predictor or outcome measure
 - c. to estimate the median event-free, progression-free or overall survival in a patient group
 - d. to characterize the toxicity of an intervention, determining likelihood of occurrence, possible severity
 - e. to determine the convenience and time requirements of an intervention
- 2) **Eligibility:** Indicate the inclusion and exclusion criteria for subjects to be studied.
- 3) **Confidentiality:** Please refer to section 8.4 for guidelines outlining confidentiality. If you have additional guidelines or will not be using identifiable subject clinical data please specify this in your protocol. (It is suggested to leave the option for the use of identifiable clinical data open)
- 4) **Relevance:** Describe the relevance of the study. What will be learned from the study that will be of usefulness to patient management or a follow-up/main study?
- 5) **Sample size:** State the sample size of the study and explain how the sample size was determined.
- 6) **Data Collection:** Describe specifically what will be measured or what information will be collected in the study.
- 7) **Analysis:** Describe the statistical analysis to be used in the study indicating the specific statistical techniques that will be used. Be sure the following questions are answered.
 - a. How and why was the number of subjects (sample size) or the number of samples chosen?
 - b. Which specific criteria or observations will be used to do the core analysis?
 - c. With what specific endpoints or outcomes will these criteria or observations be correlated? Be sure these end-points will be available at the time of the planned analysis.
 - d. What statistical tests will be employed in the core analysis on which the success or failure of the project will rest? For simple retrospective

- e. How will the significance of correlations be decided? How will validity of the correlations be assessed? State specific p values or correlation statistics if applicable.
- f. What specific criteria will be used to determine if this is a successful research project? These criteria should be clearly identified.
- 8) Use of Information:** State how the information from the study will be used; for example, to determine whether to go ahead with a follow-up/main study and/or to assist with the design of the follow-up/main study.
 - **Section 9.2.** Consent forms: add project H04-61292 Hematology Cell Bank consents (see directions below on how to access these consents*).
- **Part 10. Fee for Service**
 - **Pt. A.** select Fee N/A as per above criteria.
- **Part 11. Hospital Information**
 - **Section 11.1** indicate “no” if you have not already received hospital approval; if “yes” please add the VCHRI/VCHA hospital approval number.
 - **Section 11.2 A. B.** complete these sections. **C** add Dr. Clayton Smith if you do not have a medical affiliation with VGH or add an alternate VGH affiliated co-investigator. Add ‘yes’ if you have a UBC appointment.
 - **Section 11.3** select Vancouver Acute

Note: If you require further assistance. Contact Anna Koochin at 604-875-4111 ext. 67409 (email: akoochin@bccancer.bc.ca)

(6) Once the application is complete click the submit button and select the correct Department Head to sign off on the RISE application. If you are a researcher with the TFL and are submitting to Dr. Connie Eaves you choose from the drop down departmental head menu “*BCCA/Terry Fox Lab (BCCA)*”. If you are a researcher affiliated with the Leukemia/BMT Program at VGH choose Dr. Clayton Smith or Dr. Peter Tsang if Dr. Clay Smith is listed as a co-investigator.

(7) * For current copies of the two consent forms: contact Anna Koochin (clinical research nurse) at 604-875-4111 ext. 67409 (email akoochin@bccancer.bc.ca)

(8) It is the responsibility of the investigator to submit approved projects for annual review and to submit amendments of projects to the BCCA REB. For assistance contact Anna Koochin at 604-875-4111, ext 67409 or email: akoochin@bccancer.bc.ca

If you need additional information go to the BCCA website for Research Ethics Board at <http://www.bccancer.bc.ca/RES/REB/default.htm> or feel free to contact Anna Koochin.

(9) VCHRI Approval is required for all research that involves subjects at VCHA.

- Complete the *Request for Approval to Conduct Research at VCHA*
- Complete the *Security and Confidentiality Review and Agreement for Access to Personal Information for Research Purposes*

The Project Coordinator (Anna Koochin) or the Research Assistant will complete these documents and forward them to you for signature.

(10) Annual Renewal: for all ethics documentation is the responsibility of the researcher. A copy of the certificate of approval must be kept on file by the researcher and a copy kept with the Project Coordinator. REB approval must be demonstrated before a researcher may have access to samples from the Hematology Cell Bank.

The following need annual renewal:

- BCCA REB certificate

- VCHRI approval certificate