Master IRB File for FHCRC Cryobiology Repository of Bone Marrow and Peripheral Blood Stem Cells for Research Studies

PROTOCOL 1362.00

Fred Hutchinson Cancer Research Center
University of Washington School of Medicine
Seattle Veterans Administration
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1. Master IRB File for FHCRC Cryobiology Repository of Bone Marrow and Peripheral Blood Stem Cells for Research Studies

Principal Investigator: Derek Stirewalt, MD, Member, FHCRC (206 667 5386)

Investigators: Michael Linenberger, MD, Member, FHCRC, Professor, UW; Lynn Bonham, PhD, Associate Director, Cellular Therapeutics, SCCA (606-2022); David Yadock, Repository Manager, FHCRC (667-4609).

2. INTRODUCTION

Per Fred Hutch/ SCCA policy, all transplant patients and/or their representatives are requested, at the time of component collection, to sign a contractual agreement for marrow or peripheral blood stem cell storage. This contract details the agreement surrounding storage of cells not used clinically, which includes an option to turn these unused cells over to FHCRC to be made available for research purposes.

3. BACKGROUND

The SCCA processes and stores bone marrow or other peripheral blood stem cells collected from patients or donors for potential clinical transplant use by the patient. Cells left unused after clinical treatment are stored for an initial period of 24 months. At the end of this period, or if the patient dies while the cells are stored at the SCCA, the contract will terminate. A 60-day period is then allowed for the patient or their authorized representative to notify the SCCA with one of the following options: continued cell storage by the SCCA for a fee; shipment of cells to another location at patient's expense; destruction of cells; or transfer of the cells to the SCCA, FHCRC, or Seattle Children's to be made available for research.

When determining whether to continue storing cell products, patients are encouraged to discuss with their physician to confirm they are confident they have all the information needed to make this decision. The SCCA Cellular Therapy Lab Medical Director is also available for questions and discussion if needed. If a decision is made to dispose or turn the cells over to research s, the patient's physician must also be consulted before the cells will actually be removed from SCCA storage.

4. OBJECTIVES

a. Establishment of a repository of cryopreserved bone marrow and peripheral blood stem cell specimens for research. This repository will primarily contain components from deceased patients or their donors. Additional products will include samples where patients have chosen to discontinue storage and have given specific permission to transfer the cells to FHCRC to be used for research purposes.

b. Establishment of an IRB approved master protocol that can be used as a reference file by investigators who wish to use components of the repository for research studies. This master file will address issues regarding the patient confidentiality, risk, and consent. Individual investigators will submit a separate minimal risk application to the IRB for approval to access the Repository components.

5. PROCEDURES

When the required signed and verified documentation has been obtained designating specific transfer of cells to the FHCRC to be used for research purposes, the Cellular Therapeutics Laboratory (CTL) will contact the CCEH Core B lab to arrange for transfer of the components to the Protocol 1362 Repository freezers. Information on these designated components will be entered into a separate Protocol 1362 Repository database. Restricted reports from this database, containing non-confidential data such as cell numbers and disease type, will be made available to investigators for evaluation and determination of research need. If the investigators determine that certain stored products are potentially useful for their research studies, a minimal risk IRB application that details the proposed research studies, and cross-references the Protocol 1362 Repository master file, will be submitted.

Upon IRB approval the investigator can request those specific components. The Repository manager will first re-verify that the requested component does indeed have the appropriate documentation, then inform a laboratory technician of the storage location of that product and generate a unique coded identifier label. The technician will recover the component from the freezer, verify with a second technician in the lab that the correct product has been obtained, remove any patient specific identifier or health information on the product label, and replace with the unique coded identifier label. The product will then be delivered frozen to the investigator for their research studies.

Dr. Derek Stirewalt and the Repository manager will be the primary gatekeepers of these cells and any cellular material derived from these cells. The samples may be examined by researchers at Fred Hutchinson Cancer Research Center, University of Washington, Seattle Children’s Hospital.

6. RECORDS

The Repository Database is stored in a protected folder on the FHCRC computer network. Access is restricted to the PI, the Repository manager and approved lab members. In the event of a staff change, the database password will be changed. Specimens are stored in locked freezers in Fairview Freezer Facility.

APPENDIX A – Examples of CTL Letters & Forms and Cell Storage Contract

1. Letter to patient and Patient Election Forms
2. 2nd Letter to patient, final contact attempt
3. Letter to next of kin and Product Disposition Form
4. Cell storage contract