OHRS Information Sheet
Blood Draws from Healthy Volunteers for Use in Research

This OHRS Information Sheet provides guidance to investigators whose research protocols require the use of blood samples drawn from healthy volunteers.

The DFCI IRB must review all protocols that propose to enlist healthy volunteers for one or more blood draws for use in the research. HHS regulations at 45 CFR 46.102(d) define research as a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge. The regulations define human subject as a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or private identifiable information. This regulatory framework applies equally to participants receiving an investigational agent and to the collection of blood samples from healthy volunteers.

Research involving volunteers who are under the direct supervision of the investigator(s) or who are the investigator's students will, in most instances, not be approved by the IRB. The relationship, at the very least, creates the perception of coercion and raises confidentiality concerns. Advertising for volunteers within the department, hospital or another lab is an acceptable solution.

As with all research subjects, healthy volunteers must be fully informed of the scope of the research, given an adequate description of the risks and benefits to subjects or others as a result of the research, a description of how confidentiality and privacy will be maintained, an explanation of whom to contact for answers to questions about research subjects' rights other than the investigator and whom to contact in the event of a subject injury. The informed consent document should not contain exculpatory language such as "I hereby relinquish all rights, title and interest to such fluids or tissues." The consent templates on the OHRS website can be modified for use with this population.

The IRB will evaluate the proposed compensation, if any, for the participation of the healthy volunteer/participant. The remuneration may serve as a direct reimbursement for expenses or compensation for time and effort but should not be undue incentive for participation.

It is also possible for investigators to obtain de-identified blood samples from the Kraft Blood Donor Center. This would need to be pre-arranged with the Administrative Director, Mardi Ellis and comply with the guidelines below.

Guidelines for investigators needing human leukocytes for research

There are two ways for you to get human leukocytes for research. These are described below:

Option 1: Recruit blood donors for your study. The details depend on the needs of your study. In brief, you write a protocol that must be approved by your institution's IRB (Investigational Review Board). Depending on the needs of your study, members of the Joint Program in Transfusion Medicine may be able to assist you by collecting leukocytes by apheresis. If your study requires assistance from a blood donor center operated by the Joint Program in Transfusion Medicine, please contact the Medical Director of one of the Blood Donor Centers to assist you in developing and conducting the blood collection aspects of your study. Collection costs are as follows:

	1-2 volume procedure (~ 2 hrs)	3 volume procedure ($\geq$3hrs)
Donor	$500	$900

Requirements for Leukopheresis:

Investigators Responsibility	**Blood Donor Center's Responsibility**
Complete Order/Billing form	MD coverage during collection procedure
Fax copy of IRB to 617-632-3255	Pheresis orders including calcium gluconate
Donor History and Physical	Pre and post CBC
Donor Informed Consent related to IRB	Infectious Disease Marker testing on day of collection.
Pick up product after collection	Perform Health History Questionnaire prior to collection procedure.
	Care of donor during collection procedure
	Label product

Option 2: Use white cells collected from volunteer blood donors. This is a service provided by the Joint Program in Transfusion Medicine for the research community. These white cells are byproducts of platelet donations. This approach reduces the work and expense to the investigator. Some important points to consider are:

- These are released for research purposes untested for diseases and may contain viruses such HIV and Hepatitis C. Hence, universal precautions should be used when handling these products.

- The estimates as to the number of cells present in each product are based on past experience. There is no guarantee concerning the contents of any product.

- Collars are available for pick up in person (on a first come first served basis) only at 12:30 p.m. and 4:30 p.m. Monday – Thursday in the Kraft Blood Donor Center. On Fridays, collars will be available for pick up in person only at 12:30 p.m.

- No special requests or I.D. information of donors will be granted. We will not identify collars that are A2's or provide any reference to HLA typing. It is imperative that the collars remain anonymous.

- When picking up a collar, please print your name, your lab and how many collars you are taking on a log sheet – before taking the collars. The log sheet is located near the collar pick up area.

Product	Contents	Availability	Price
Trima Collar	(15 ml) 6-14 X 10^8	Monday-Friday. Availability based on Donations that are not totally predictable.	$25.00