

PREVENTION CENTER APPLICATION—Step by Step Instructions

Please meet with Prevention Center Administrative Manager Prior to Completion of Application

Requestor Information

Services and use of the Prevention Center are open to FHCRC divisions, affiliates and Consortium members. Dependent upon the Hutch relationship, type of research, and/or funding agency some applicants will incur additional costs above the established service rate. Please refer to the FHCRC website <http://www.fhcrc.org/admin/grants/docs/indirect.htm> to review F&A costs.

Facility Resource Request

In addition to requestor information, those wishing to have study staff perform procedures in the Prevention Center must identify which of the facilities they wish to use in the execution of their protocol. Due to the sensitivity and regular calibration of exercise equipment, and training requirements in the use of some nutrition lab equipment, the use of some resource equipment will require the presence of Prevention Center staff. Please make certain to discuss particulars of study use request with the appropriate facility manager prior to making application.

Study Information

To be accepted by review of the Oversight Committee, all applications require the signature of the Principal Investigator. By design, the Prevention Center performs minimal risk procedures on healthy volunteers where those procedures are not considered treatment as part of the study intervention. Research subjects under treatment may engage in intervention procedures conducted in one of the Prevention Center facilities. However, participants identified as immune compromised are restricted from use of these facilities until their status is changed, the change in status has been certified by a research MD, Prevention Center staff is notified by research personnel of the change in status, and health risks to the participant or other facility users are eliminated. The Prevention Center accepts applications that involve treatment interventions using FDA approved or experimental drugs where the Prevention Center environment or the study participant does not raise the level of risk for either the participant or others within the environment, as determined by the study investigator and/or the Prevention Center Director and confirmed by the Oversight Committee.

Study Personnel

It is a Prevention Center requirement that study staff performing any procedures in the Prevention Center must provide documentation of appropriate current health care certifications and training. Certifications must be sponsored by a Washington state licensed MD within the FHCRC, UW, CHRMC or SCCA Consortium. Appropriate training includes current bloodborne pathogens, Adult First Aid/CPR/AED, Human Subjects and AIDS training prior to the extension of Prevention Center privileges. In some instances, Prevention Center Phlebotomy/Laboratory Technician certification may be required to satisfy minimal proficiency in the performance of clinic tasks. All contact information for staff must be provided. Study personnel must keep the Prevention Center informed of any changes in personnel. Failure to do so may result in the cancellation of Prevention Center privileges.

Study Summary

Information should include sample size, recruitment, demographic (e.g. gender, age range), inclusion and exclusion criteria, length of (proposed) study. IRB documents may be attached in lieu of reproducing this information.

Study Objectives

Information should include protocol intervention activities and the expected (primary and secondary) outcomes related to those activities (list all protocol hypotheses). IRB documents may be attached in lieu of reproducing this information.

Inclusive Years of Study

List the expected study begin date and the expected study end date and identify total number of years (e.g. July 1, 1998 – January 31, 2008 [9.5 years]). Specify years that the Prevention Center will be used.

Research Participant Profile

Identify the characteristics of the participants enrolled in the study (e.g. ages, number of participants by gender, whether participants are minors or elderly). Participant health status pertain to whether participants met the health criterion at the time of study enrollment. Participants from other Divisions or institutions who are in treatment should meet the health criteria status agreed upon between the Prevention Center Director and the Division Administrator, and approved by the Oversight Committee prior to having procedures performed in the Prevention Center.

Research Procedures

Any activities related to the protocol must be identified, whether or not procedures related to those activities will be performed in the Prevention Center. Ensure any procedures performed in the Prevention Center, whether by Center staff or study staff, are listed by procedures per project year. In addition, for each type of procedure performed the number and specifics of the procedure must be included for each of the facilities used. Ensure inclusion of the following statement in IRB submission and consent forms to note use of the Prevention Center in the performance of intervention procedures.

“Some procedures related to study protocol interventions may be performed in the FHCRC Prevention Center by study or Prevention Center staff.”

For HIPAA compliance where required, the Prevention Center should be listed among the groups that may have access to participant medical records information.

Checklist

Additional forms may be required as attachments to the application. The Prevention Center staff will forward copies of those documents to the inquiring study for completion prior to forwarding applications for review by the Prevention Center Director or the Oversight Committee.

Questions regarding this application, and the completed application, should be addressed to:

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