PARTNERS HUMAN RESEARCH COMMITTEE

TISSUE REPOSITORY PROTOCOL SUMMARY

Answer all questions accurately and completely in order to provide the PHRC with the relevant information. Do not leave sections blank.

# PRINCIPAL/OVERALL INVESTIGATOR

# PROTOCOL TITLE

# FUNDING

# VERSION DATE

### SPECIFIC AIMS

Concisely state the objectives or purpose of this tissue collection. State explicitly what diseases, conditions or processes will be studied.

### BACKGROUND

Justify why collection of these tissues is warranted scientifically. Summarize briefly the knowledge to date about the disorder, or condition under study. Describe the general directions for the research. If samples are stored for as yet undefined or general uses, please describe the *types* of research expected, providing examples.

### TYPES OF TISSUES TO BE BANKED

Explicitly list what types of tissues will be collected, listing all, for example: (a) excess material from clinical operative procedures (e.g., tumor after pathologist’s sampling completed); (b) prospectively collected human material/tissue, either normal or pathological, taken at the time of a clinically planned procedure (e.g., cardiac biopsy at catheterization or open heart surgery, extra biopsies at endoscopy, additional intestine at gastric bypass, or normal fat or skeletal muscle at surgery, extra CSF at LP, extra blood at phlebotomy); and/or (c) prospectively collected human material/tissue obtained during a procedures performed solely for research, e.g., blood, urine, saliva, breast milk, skin, muscle, semen samples, or cells from cheek swabs. Explicitly state whether immortalized lymphoblastoid cell lines, fibroblast cell lines or tumor cell lines are planned. Inexhaustible cell lines are considered of greater risk to confidentiality than finite samples like excess tumor that will be eventually consumed entirely by research.

### RECRUITMENT PROCEDURES

Explain in detail the specific methodology that will be used to recruit subjects who provide tissue samples at Partners performance sites. Specify how potential subjects will *initially* learn about the possibility that they could provide samples to this tissue repository. Specify how, when, where, and by whom, subjects will be approached about providing samples to this tissue repository.

Clarify whether there are existing collections or samples that will be “grandfathered” into this bank. Describe the “consent status” of those samples, i.e., what kind of consent was provided by those from whom such older stored samples were collected. Include a copy of the consent form, when applicable.

Provide details of remuneration of research subjects, when applicable.

### CONSENT PROCEDURES

Explain in detail how, where, and by whom informed consent is obtained from the subject providing samples. Describe timing of consent, i.e., how long subjects will be given to consider participation. Describe the qualifications and experience of the individuals who will be obtaining consent (e.g., genetic counselor, licensed physician, nurse practitioner). Describe how the principal investigator or a physician investigator will be available for consultation or questions, when informed consent is obtained by someone other than the principal investigator or physician investigator.

When applicable, explain how provision of samples to more than one repository is discussed with subjects. Typically each repository has a specific consent form.

In general, the PHRC requires researchers to obtain the informed consent of the individual from whom the human material/tissue was obtained. Surrogate consent is usually not appropriate since there are no direct benefits to the individual. If you propose to include subjects who are unable to give consent due to age (minors) or current physical/mental condition, discuss this issue in detail. Indicate from whom consent will be obtained, for example, from parents/guardians, legally authorized representative, next-of-kin, etc. If you choose to include such subjects, explicitly rationalize the inclusion of subjects unable to consent on their own behalf, based upon risk/benefit considerations. For guidance refer to the PHRC web document, Surrogate Consent to Research for Individuals with Impaired Decision-making Capacity:

[**http://intranet.partners.org/phrc/surrogate\_consent\_memo.pdf**](http://intranet.partners.org/phrc/surrogate_consent_memo.pdf)(PHS intranet link).

If *Partners investigators* will not be obtaining informed consent from all subjects, clarify how investigators who are obtaining consent will provide you with documentation of consent and IRB approval of the relevant protocol and consent forms. Provide a copy of the IRB approved-consent form(s), when applicable.

### WAIVER OF INFORMED CONSENT/AUTHORIZATION

If informed consent will not be obtained for the collection and storage of human material/tissue in the repository, address each of the following regulatory requirements to obtain a waiver of informed consent.

1. Explain why the research could not practicably be conducted without access to and use of the identifiable health information/data.

2. Explain why the research involves no more than minimal risk to subjects. Specifically explain why the research involves no more than a minimal risk to the privacy of the individuals.

3. Explain why the waiver of consent/authorization will not adversely affect the rights and welfare of the individuals.

4. Explain how the identifiable health information that has been collected and stored will be protected.

5. Explain when the identifiers (such as the HIPAA identifiers listed above or the code linking the tissue to identifiable health information) will be destroyed at the earliest opportunity, for example, when the human material/tissue is used up.

### EQUITABLE SELECTION OF SUBJECTS

The risks and benefits of the research must be fairly distributed among the populations that stand to benefit from it. No group of persons, for example, men, women, pregnant women, children, and minorities, should be categorically excluded from the research without a good scientific or ethical reason to do so. List inclusion and exclusion criteria for subjects (bulleted lists are preferred). Please provide the basis for concluding that the study population is representative of the population that stands to potentially benefit from this research.

When enrollment is limited to specific groups (e.g., study of sickle cell anemia will not enroll Caucasian subjects), provide the scientific basis for the study population. When the medical condition under study exclusively or disproportionately affects one group of individuals, please describe this propensity. Describe how this will affect your enrollment of subjects across the diverse spectrum of patients cared for by our institutions. Address whether any one group will bear a disproportionate share of the burdens of research or, whether the benefits, to the extent anticipated, will be distributed fairly. Comment on efforts to enhance the enrollment of women and minorities, including subjects who do not understand English.

### OPERATING POLICIES AND PROCEDURES OF THE REPOSITORY

**Duration of storage, labeling of samples:** State how long you expect to maintain the repository. Describe the acquisition, logging in, and tracking of samples. Typically samples are labeled with a unique, random, identifying number or code, in order to protect the confidentiality of research subjects. Explicitly state whether samples will retain a key to the code linking the sample to the individual from whom the sample was obtained. Describe where the key to this code is kept and who has access to it. If, after obtaining identifiable tissue for a specific research goal, you plan to de-identify the remaining excess human material/tissue for further research, clarify how and when this occurs.

**Processes for distribution of tissues:** Clarify the process by which other investigators may request tissue from the repository, if proposed. Describe who oversees tissue requests (e.g., an individual, group of individuals, or board), provide their qualifications, and describe the process for determining the merits or acceptability of the request for tissue. Describe what materials are provided to requesting researchers, and what health/medical information accompanies tissue or samples distributed by the repository. If tissue/samples will not be provided to other investigators, but will be limited to one research group or laboratory, so state. Note that any release of *directly* *identifiable tissue or directly identifiable health information, or a key to the code linking the tissue directly to an individual* requires a separate, IRB-approved protocol. Clarify who at the repository will assess tissue requests and ensure that, where necessary, there is a current IRB-approved protocol covering the proposed research. Distribution of tissue that is coded, but not directly identifiable, when the recipient researcher will not seek to identify the individual from whom the tissue was obtained, is not considered *human subjects research*. However the recipient researcher must agree in writing to never attempt to access identifiable health/medical information or to attempt to identify the subject(s) who provided the sample(s). Such coded human material/tissue may be distributed *without separate, independent* IRB approval once the recipient researcher signs the agreement stating that s/he will not attempt to identify human subjects from whom the samples were derived. Provide a copy of a formal letter or form that recipient investigators will be asked to sign for such tissue distributions. For template agreement letters, refer to the following PHRC web documents:

Letter of Agreement for Transfer of Coded Samples

[**http://healthcare.partners.org/phsirb/Guidance/Policies\_Procedures/Tissue\_Uses\_Banking/Letter\_Transfer\_CodedTissue\_11.05.doc**](http://healthcare.partners.org/phsirb/Guidance/Policies_Procedures/Tissue_Uses_Banking/Letter_Transfer_CodedTissue_11.05.doc)**.**

Letter of Agreement for Transfer of Non-identifiable Samples

[**http://healthcare.partners.org/phsirb/Guidance/Policies\_Procedures/Tissue\_Uses\_Banking/Letter\_Transfer\_Non-identifiableTissue\_11.05.doc**](http://healthcare.partners.org/phsirb/Guidance/Policies_Procedures/Tissue_Uses_Banking/Letter_Transfer_Non-identifiableTissue_11.05.doc)

**Re-contact of subjects providing biological samples to a repository:** In general, investigators are advised to plan ahead carefully and describe potential uses and sharing of repository materials, so that approved research that subjects have agreed to may proceed without the need to re-contact subjects. Re-contact of subjects to obtain consent for new types of research, collect additional samples, or provide clinically relevant information is not prohibited, but it may be time consuming, and may or may not be practical, welcomed by, or useful to, subjects. Research results may not be clinically useful or validated, and may not be ready for return to patients or physicians. It is often most acceptable to describe the types of research that will be performed and indicate that research results will not be returned to subjects or physicians. If it is anticipated that subjects will be re-contacted by representatives of the tissue repository, please describe in detail: (1) reasons for re-contact; (2) how and when re-contact would occur, or might occur, if not obligatory; (3) how subjects will provide updated contact information, if necessary; (4) whether an option for “no re-contact” is possible and reasonable; (5) what research information would be released to subjects or placed in medical records; (6) what counseling would be provided, and what notification of subject’s physicians would be undertaken, if any.

Clarify with whom tissues samples will be shared. Possible options include: (a) only within Partners; (b) only with academic collaborators; (c) with academic and commercial (for-profit) collaborators. If samples will be shared with collaborators at for-profit companies, please state this explicitly. Investigators are reminded that provision of samples to for-profit collaborators requires the existence of a bona fide intellectual collaboration between the Partners investigator and an individual or group at the for-profit site, and a Materials Transfer Agreement executed by Corporate Sponsored Research and Licensing. Comment upon fees assessed for shipping or preparing samples, and justify these charges.

### PRIVACY AND CONFIDENTIALITY

Describe methods used to protect the privacy of subjects and maintain confidentiality. Clarify whether special attention to confidentiality is necessary because of the nature of the research (i.e., the research involves collection of particularly sensitive personal information, for example, HIV status, reproductive history, data on illegal activities or drug use, or other potentially stigmatizing behaviors). Comment on whether a Certificate of Confidentiality has been obtained, if relevant. Specifically address where individually identifiable information will be stored and who will have access to such data. Explain how the potential for breaches of confidentiality and resultant risks to dignity, insurability and employment are minimized. Because genetic data may affect not only the individuals providing samples, but also their family members, or social groups, comment on potential psychosocial risks of genetic studies or DNA repositories to these extended groups also.

### EXPECTED BENEFITS

It is not expected that subjects providing tissue for repositories will derive personal health benefits as a result of their contributions to tissue repositories. However, explain any specific future benefits that might be expected to accrue to individuals, families or groups of affected individuals. Indicate what medical, scientific, and societal benefits are likely to accrue as a result of research performed on tissues in this repository.

### FORESEEABLE RISKS AND DISCOMFORTS

Risks to privacy and confidentiality should be discussed above. Clarify in this section any medical risks to subjects (e.g., risks of phlebotomy, or bleeding, infection, or scarring as a result of a biopsy performed solely for research purposes). Although uncommonly undertaken, if health/medical information from the research is returned to subjects or their physicians, discuss the potential risks, such as anxiety, or of false positive or false negative results.

### MINIMIZATION OF RISKS

Minimization of risks to privacy and confidentiality should be discussed above. Describe here how any additional risks to subjects are minimized, for example, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk or by using procedures already being performed on the subject for diagnostic or treatment purposes.

### DATA AND SAFETY MONITORING

Describe who reviews and analyzes reports of any adverse events, breaches of confidentiality or complaints and forwards them to the IRB, and how and when these events are reported to the IRB. Describe how unanticipated problems involving risks to subjects or others (e.g., staff, families of subjects etc) will be reported to the IRB. Comment on whether any other regulatory bodies (e.g., FDA, NIH, or other IRBs) will also receive reports or such events, if this is relevant. For more information on unanticipated problems, refer to the PHRC web page regarding Reporting Unanticipated Problems (including Adverse Events):

[**http://healthcare.partners.org/phsirb/guidance.htm#7**](http://healthcare.partners.org/phsirb/guidance.htm#7)**.**