

This template document helps the user to create a protocol describing their study as well as the mechanisms for obtaining biospecimens from a biobank.

Template Protocol for Research Project using Biospecimens Obtained from a Biobank

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Research Services (BBRS)*

Dear Researcher:

Before you create your ethics protocol for your study that intends to obtain biospecimens from a biobank, please read the following information about biobanks.

A “biobank” is collection of human biospecimens and their associated annotating data for research purposes. Biobanking in support of health research involves a set of connected activities or linked processes focused on participant enrollment, collection, processing, annotation, storage, release and distribution of biospecimens and data.

Biospecimens in research biobanks may be collected from:

- healthy individuals or from patients with disease.
- residual materials available and arising during the course of medical diagnosis or treatment (e.g. biopsies, surgery, blood tests).

Although the term biobank is usually restricted to refer to collections of intact biospecimens (e.g. tissue blocks) or components of biospecimens (e.g. plasma and serum), it can be extended to refer to collections of derivatives of biospecimens created by handling to maintain viability (e.g. cell lines and patient derived xenografts) or created by extraction of components (e.g. DNA, RNA and proteins).

The term ‘annotating data’ is used to describe specific information associated with a biospecimen in research biobanks such as:

- participant information (data provided by the participant e.g. lifestyle information).
- enrollment and biospecimen collection, handling, and processing information.
- participant health related clinical and outcome data (e.g. data about the participant’s diagnosis, treatment, and response).

Biobanks require ethical oversight and are governed by policies, including access and release policies. Many biobanks are certified or accredited to verify their activities.

The Ethics Research Board you are applying to will be aware of what a biobank is. **All you need to do is state that you will be obtaining your biospecimens from a biobank(s).**

The biospecimens and data that have been collected by the biobank will already have patient consent associated with them. **Therefore you do NOT need to recruit participants to your study.**

In any sections of the ethics application that refer to participant recruitment you can state that “the participants have already been recruited by the biobank and have given their consent to participate in research”.

The biobank’s access and release policy dictates that the biobank will review your application for biospecimens in a structured way and will also check whether you have ethics board approval before releasing biospecimens to your study.

TITLE PAGE

< Insert study title >

Protocol

Version < date >

Principal Investigator < name >

Template (v.1) created by

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1. SHORT SUMMARY

<Insert 2-3 sentence summary of study>

2. PURPOSE

<Insert paragraph describing the purpose of the study >

3. PREVIOUS DATA

<Describe any relevant, previous data>

4. GOAL & HYPOTHESIS

<Outline goals and hypotheses>

5. RESEARCH DESIGN

a. Cohorts

We plan to apply to <insert # of biobanks> biobanks for relevant cohorts of <insert disease of interest e.g. breast cancer patients> comprising <insert biospecimen of interest e.g. plasma and tumour tissue> and associated clinical-pathological, treatment and outcomes data. <State the names of the biobanks, whether they are certified or accredited, how many biospecimens will be requested from each one and the clinical data that will be requested>

b. Study plan

<Insert study plan>

c. Methods

<Insert methods>

6. ANALYSIS

< Describe how analysis will be conducted>

7. SIGNIFICANCE

<Describe the significance of study and predicted outcomes>

8. REFERENCES

<Insert references>