

# **POLICY BRIEF: CONSENT OPTIONS FOR BIOBANKS I. CONTEXT**

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Study name	Target or final number of participants	Age, Min, (Max)	Country of residence	Current study status
Million Women Study	1 300 000	50, (64)	United Kingdom	Follow-up
NIH-AARP Diet and Health Study	567 000	50, (69)	United States	Follow-up
European Prospective Investigation into Cancer and Nutrition	520 000	30, (70)	Sweden, Italy, Netherlands, United Kingdom, Germany, Norway, France, Greece, Spain, Denmark	Follow-up
Cancer Prevention Study - 3	500 000	30, (65)	United States	Recruitment
Kadoorie Study of Chronic Disease in China	500 000	35, (74)	China	Follow-up
LifeGene	500 000	N/A, (55)	Sweden	Development
UK Biobank: a large-scale prospective epidemiological resource	500 000	40, (69)	United Kingdom	Recruitment
Norwegian Mother and Child Cohort Study (The)	260 000	N/A	Norway	Follow-up
45 and Up Study (The)	250 000	45, (N/A)	Australia	Follow-up
Multiethnic Cohort Study	215 000	45, (75)	United States	Follow-up
National Guard Health Affairs Bio-bank	200 000	N/A	Saudi Arabia	Development



# PROSPECTIVE HARMONIZATION PROJECT

- Canadian Partnership for Tomorrow
- Questionnaires, physical and cognitive measures, procedures and quality control, biochemical measures, registries (administrative information, outcomes, environment), etc...



# CPTP: DRAFT INFORMATION PAMPHLET AND CONSENT FORM PROPOSED TO PROVINCIAL COHORTS

## 1. What is the purpose of the study?

The **[Insert name of study]** is designed:

- To enrol up to **[Insert number]**, **[Insert name of province]** residents over the next **[Insert number of years]** years into a cohort for long-term follow up.. A cohort is defined as a designated group of persons who are followed over a period of time. The aim will be to follow participants over the next **[Insert number of years]** as some remain healthy and others develop diseases such as cancer. The study will uncover prior environmental, occupational, infectious or lifestyle exposures in order to understand their relationship to health or disease. **[Insert name of study]** is a long-term study which will run until **[Insert year, indefinitely, etc.]**.
- To partner with the other provinces in the Canadian Partnership for Tomorrow Project, a national cohort which will provide the large numbers needed (300,000 Canadians) to examine the role of environmental factors, lifestyle, and genetics with the development of rare cancers and other diseases.



### 3.3 Re-contact for follow-up research

It is important in this type of a long-term study to be able to re-contact you so that you can provide lifestyle, health, dietary and environmental information at different stages of your life, we will therefore ask for your permission to re-contact you in the future to invite you to participate in follow-up research (e.g., providing additional samples or answering additional questionnaires). We also require contact information of a relative or friend in case you move and forget to provide us with your new contact information.



The **[Insert name of study]** expects to receive requests and, if approved, provide access to data and samples to Canadian and overseas researchers and international collaborators. Approved researchers who request access will not be given any information that would enable them to identify you. Independent bodies will oversee these processes.





European network for genetic and genomic  
epidemiology

Website: [www.euengage.org](http://www.euengage.org)



## Mission/Aim

To translate the wealth of data emerging from large-scale efforts in genetic and genomic epidemiology conducted in well-characterized European (and other) samples into information of relevance to future clinical advances.



# DISEASE SPECIFIC CONSENT


## Psoriasis and psoriatic arthritis (*National Psoriasis Victor Henschel BioBank*)

« Qualified scientists will request samples from the BioBank to use in their research to identify the genes that cause psoriasis and psoriatic arthritis. This BioBank collection will be used to evaluate individuals' disease over time in a way no other collection has done to date. This allows scientists to ask additional, sophisticated questions about the disease's process. »

## Cancer (*Victorian Cancer Biobank*) Broad Disease Consent

« The Biobank provides tissue samples to scientists who are involved in various aspects of cancer research, so we cannot say exactly what projects your tissue samples will be used for now or in the future. Some scientists may study the genetic material inside your cells while others may study the proteins produced by those cells. Regardless of the specific details of the project, your tissue samples will be used to study the causes of cancer and/or develop improved methods for the detection, diagnosis, monitoring and/or treatment of cancer. Other scientists may want to study how diseases are passed on in families by comparing the genetic material (proteins or genes) present in both normal and cancer cells within similar groups of patients; this is called genetic research. »





**BIOVU –  
COMBINING EMR AND  
RESIDUAL BLOOD  
SAMPLES FOR NON  
HUMAN SUBJECTS  
RESEARCH**

# DATA CERTIFICATION

- The data derived from Vanderbilt's DNA Databank program do not qualify as "human subject" research under §46.102(f)(1)(2)
- The research data being deposited have been de-identified
- All future uses of these data that are deemed acceptable and approved per NIH policy and follow the dbGaP procedures for access are allowable
- There is no associated informed consent for which restrictions carry forward to future uses, nor are there any restrictions or exclusions on types of research that can be conducted (provided the studies are not intended to re-identify)
- No identities of participants are collected, so none will be disclosed to dbGaP
- **Big challenge is potential identifiability**



# NON-HUMAN SUBJECTS MODEL + OPT OUT

## VI. USE, RETENTION AND DISPOSAL OF TISSUE AND BLOOD

I understand and agree that any specimens or tissues normally removed from my body by VUMC in the course of any diagnostic procedures, surgery, or medical treatment that would otherwise be disposed of may be retained, used for educational purposes or research, including research on the genetic material (DNA) or other information contained in those tissues or specimens.

I acknowledge that such research by VUMC may result in new inventions that may have commercial value and I understand that there are no plans to compensate me should this occur, regardless of the value of any such invention.

I understand that any research using these leftover specimens or tissues will be done in a way that will not identify me or my medical information.

I also understand that if I do not want DNA research to be done using my leftover blood, I need to check the box shown below. If you have questions, please call 1-866-436-4710.

*Do not use my leftover blood for the DNA Databank*

# leftover blood

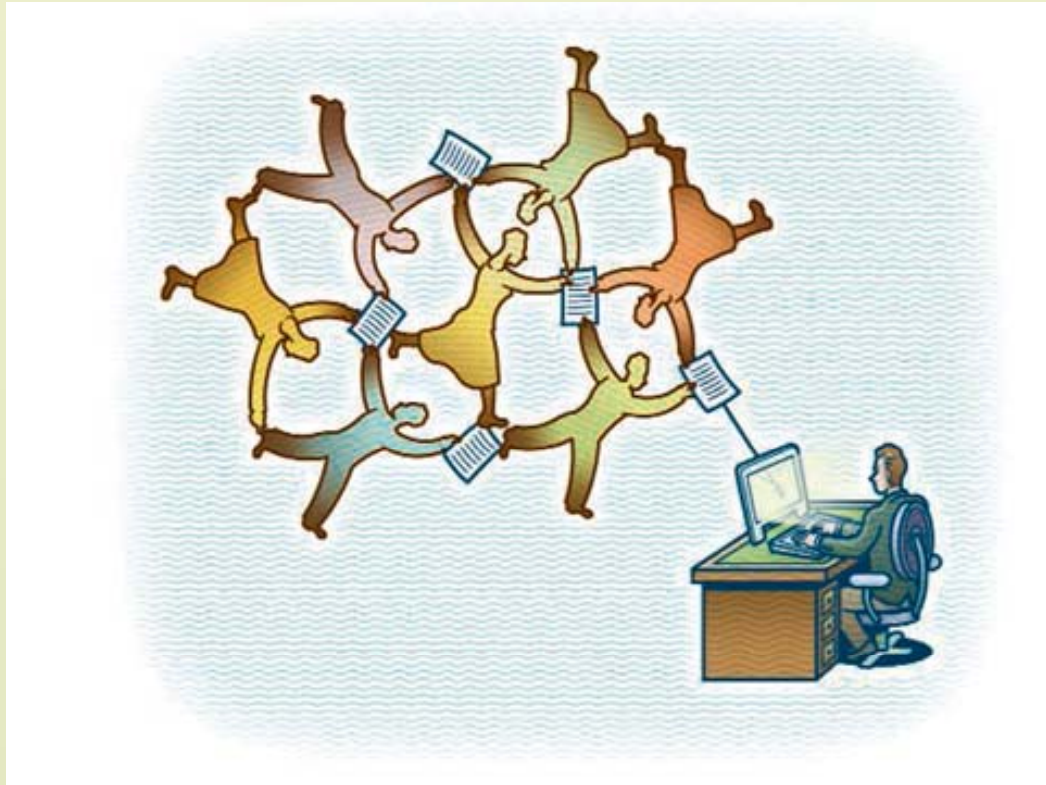
***PLEASE READ THIS ENTIRE AUTHORIZATION PRIOR TO SIGNING.***

Patient/  
Legal Representative \_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_ A.M. P.M.

(Relationship to Patient) \_\_\_\_\_

- + multiple mechanisms of communication
- On average ~3% of patients opt out







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