



# Commentary on

## Policy Brief: Consent Options for Biobanks

Timothy Caulfield and Bartha Knoppers

**A researcher's perspective**

**Christina Wolfson**

**Co-PI Canadian Longitudinal Study on Aging**

**Neuroepidemiologist, McGill University**





# Outline

- The vision of the CLSA
- Design features of the CLSA
- Consent Process
- Some comments, questions

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# The Canadian Longitudinal Study on Aging (CLSA)

- ▶ A key strategic initiative of CIHR
  - ▶ The Canadian Longitudinal Study on Aging
- ▶ More than 160 researchers - 26 institutions
- ▶ Multidisciplinary - biology, genetics, medicine, psychology, sociology, demography, economics, epidemiology, nursing, nutrition, health services, biostatistics, population health

# The CLSA Concept

## The Aim

To study aging as a dynamic process and the inter-relationship among intrinsic and extrinsic factors from mid life to older age.

## The Vision

A research platform - - infrastructure to enable state-of-the-art interdisciplinary population based *research* and *evidenced-based* decision making.





# CLSA Program of Research

- Biological Function
  - Genetics/epigenetics
- Physical Function
  - Mobility/Chronic diseases/Injury
- Psychological Function
  - Cognition/Mental Health/Coping
- Social Function
  - Work and retirement/Social Participation/Housing

## Examples of Few Research questions in CLSA

- ❖ What is the relative importance of mid-life and later life risk factors on changes in neuromuscular, neuroendocrine, inflammation and immune functions that underlie aging and age-related diseases?
- ❖ Do exposures early in mid-life influence the development of social inequalities in older adults and how these social inequalities relate to disease, disability or psychosocial outcomes?
- ❖ Are there common risk factors and processes that promote the development and maintenance of cognitive and physical capability across the adult life course, reduce chronic disease risk and improve longevity?

# Core Set of Measurements

## Biomedical

- Health status, Quality of life, healthy aging
- Activities of daily living/disability/injuries
- Frailty/co-morbidities
- Function/Performance
- Physical measures
- Chronic diseases and symptoms
- Injuries
- **Cognitive function**
  - Depression, Psychological Distress
  - Oral health
  - Vision, hearing
  - Medications
  - Health and Social Services Use
  - Institutional care
  - Genetics/Biology
    - Disease susceptibility/longevity genes
    - Epigenetics
    - Biomarkers
  - Nutrition

## Psychosocial

- Social participation
- Lifestyle/behaviours
- Social networks and social support
- Care giving/Care receiving
- Coping, adaptation
- Mood, psychological distress
- Work to retirement transitions
- Workability
- Retirement Planning
- Job-Demand/Effort Reward
- Social inequalities
- Mobility-Life space
- Built environments/physical environment/Housing
- Economics/Wealth
- Demographics
- Linkage to “**secondary**” data bases
  - Health care use, homecare
  - Disease registries e.g. Cancer
  - Environmental (need development)
  - Contextual (need development)
  - Drugs

# Biological Samples

- **Blood based Sample Types**
  - Serum
  - Plasma, heparin
  - Plasma, EDTA
  - Plasma, citrate
  - Whole blood, EDTA
  - Buffy coat
  - Buffy Coat with Trizol
  - Whole Blood, Acid Citrate Dextrose + Dimethyl Sulfoxide
  - Peripheral Blood Mononuclear Cells
- Urine (no preservative)

# Design Features

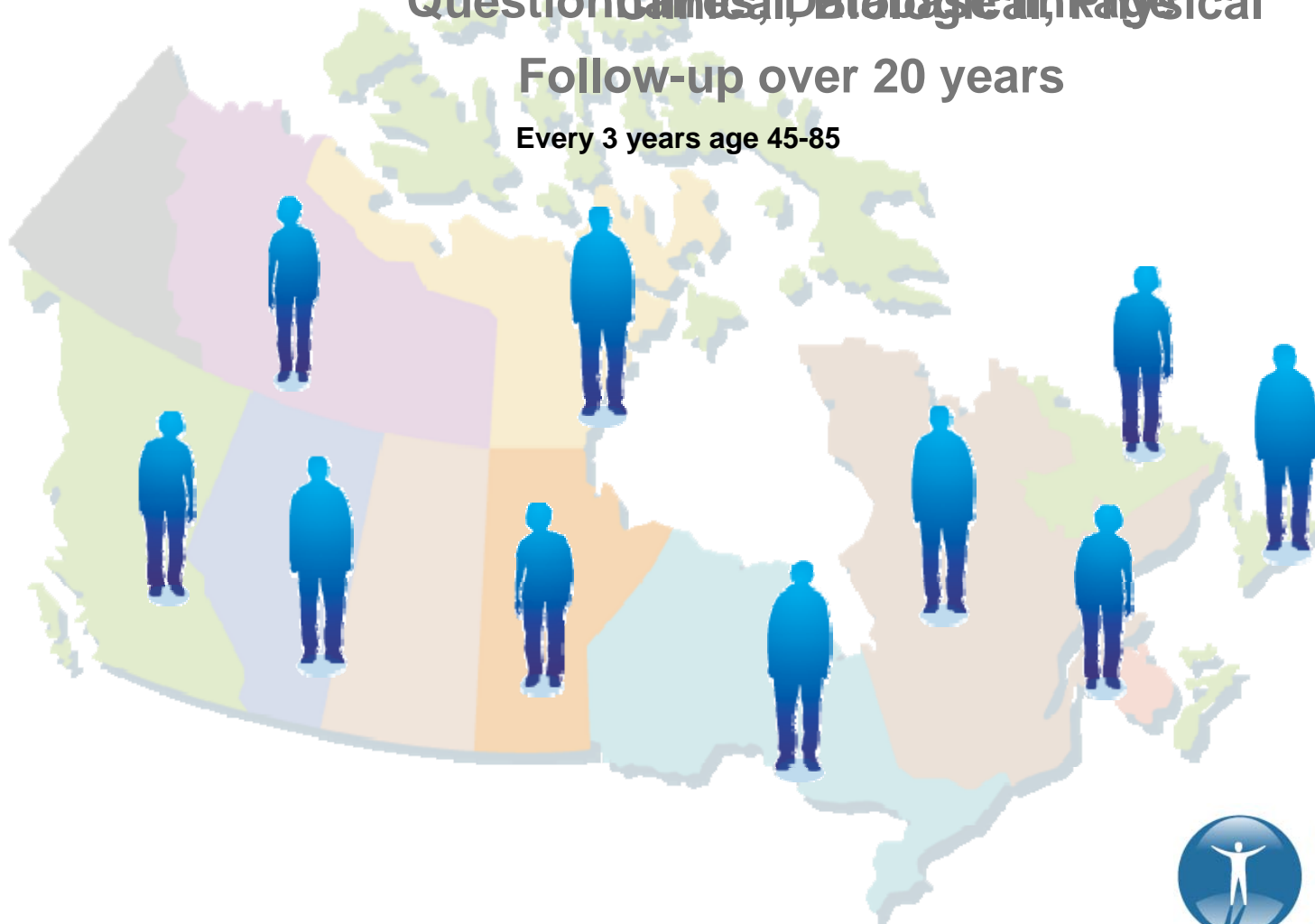


Initial Collection: 50,000 (at 10 sites)

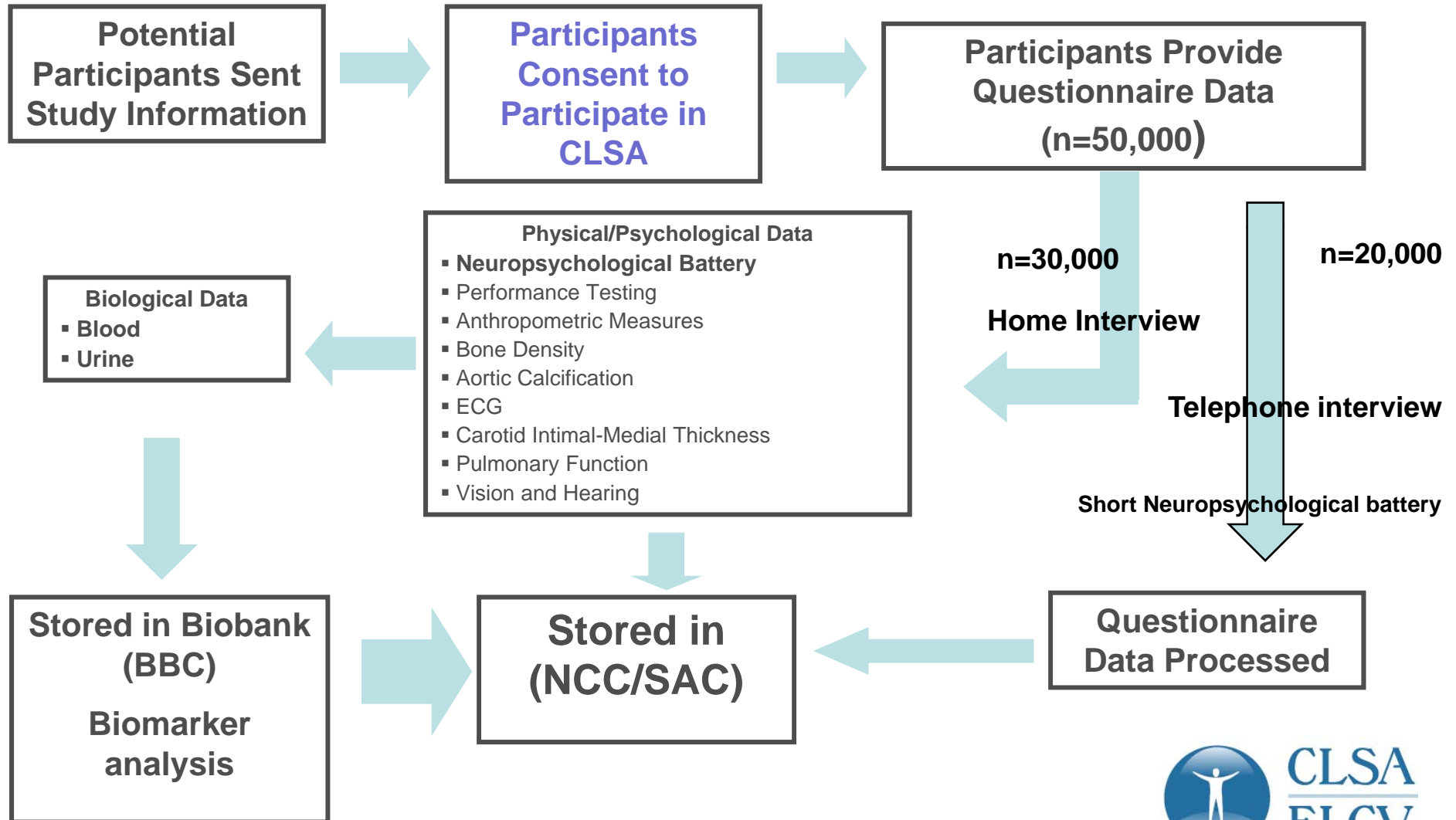
Questionnaires: Clinical, Biological, Physical

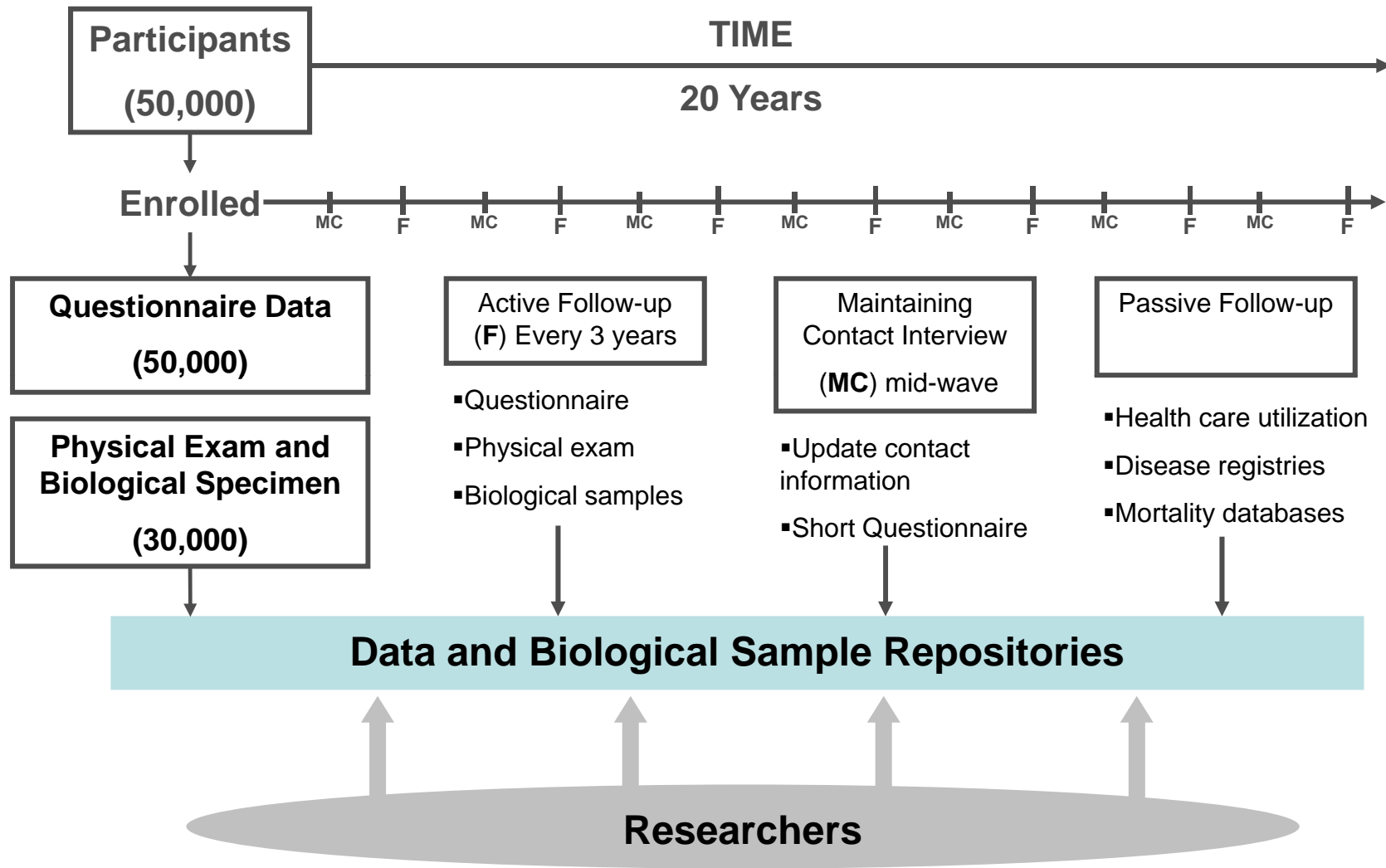
Follow-up over 20 years

Every 3 years age 45-85

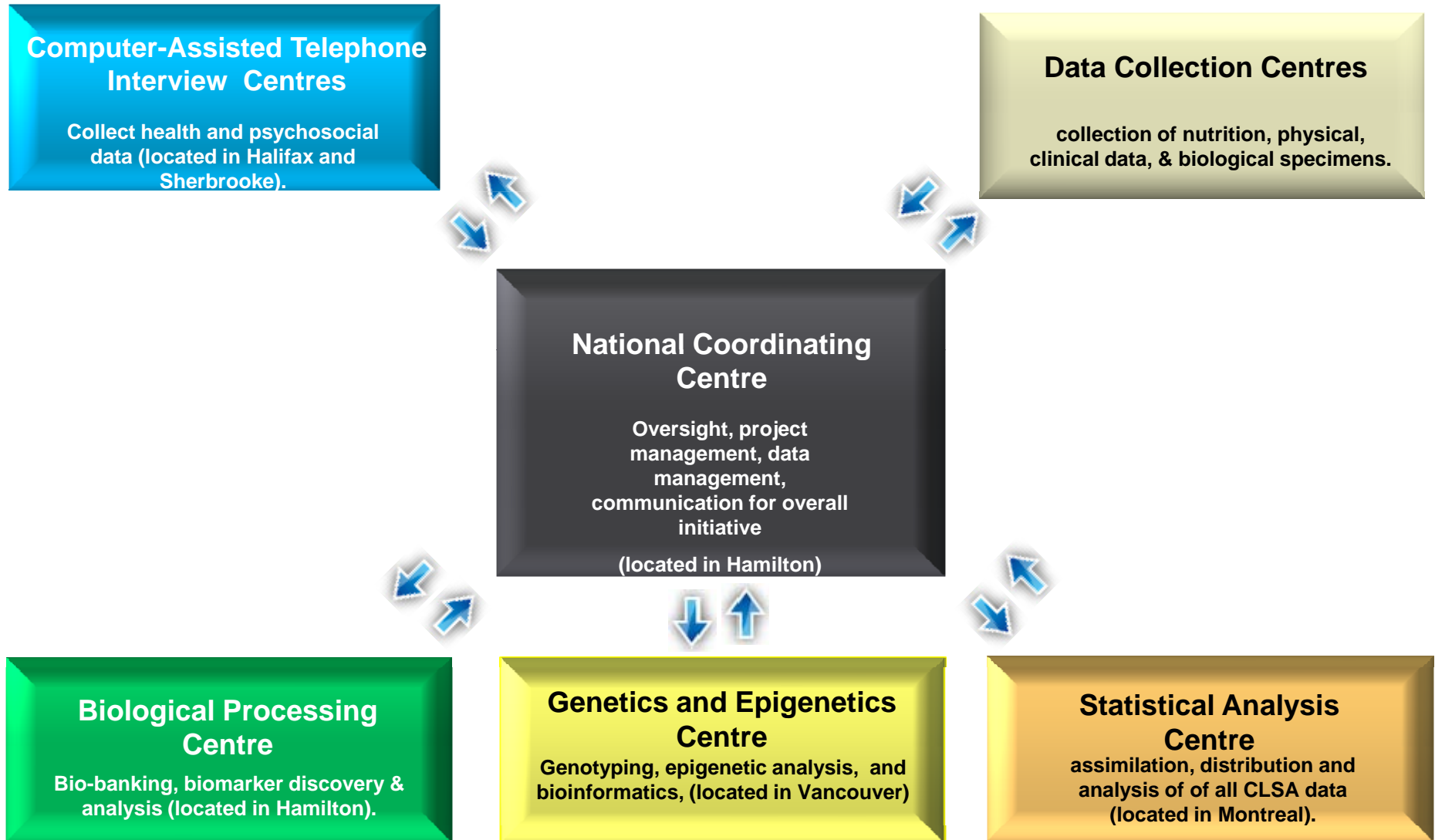


# Data Collection Overview





# Equipment and Infrastructure Supporting Research on Aging





# Consent options contained in the policy brief

1. Require specific and fully informed consent for each project
2. Broad initial consent accompanied by appropriate governance
3. Opt-out model



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# CLSA Consent

- Consent is sought from the perspective of a research study that will make the data available to researchers NOT from the perspective of asking individuals to agree to be part of a databank or a biobank
- Individuals agree to participate in **the study**

# Two Consent Forms

- One for the cohort members who are followed through telephone interviews
- One for the cohort members who will also undergo physical assessment and biological specimen collection
  - Agreement to provide biological samples not required for participation
- No specific consent requested *to be part of a biobank*
- Separate consent requested for linkage with provincial health records
  - not required for participation

# Comments - 1

- The CLSA will have scheduled follow-ups and thus will have the opportunity to inform participants of new studies as they arise
  - Is this a time to review consent?
- Consideration needs to be given to what happens to data/samples when individuals die or if they withdraw their consent
  - Will the data/samples remain in the databank/biobank?
  - Should participants be given choices at recruitment?

# Comments - 2

- In the CLSA as with other large studies, we will put in place a data and sample access and utilization committee – this committee in some sense plays the role of guardian of the data and samples
  - This committee is then charged with oversight of proper use of the samples, security etc
  - This committee is mentioned in the consent information
  - It would be useful to have some guidelines and principles for the conduct (and composition) of these committees as they play a very important role

# Comments -3

- With large databases there is an increasing opportunity for identifiability even with de-identified data
  - Do we need to re-examine identifiability?
- How do we sustain governance procedures for these large studies when these activities are generally not included in grant funding?

# CLSA pilot study Focus Groups

- *“...I don’t mind doing anything for the benefit of mankind. But if the information that I provide, you use it for commercial use for the corporation gain, that’s another thing. This I vehemently object, but if I can contribute...my body or my knowledge... , by all means, you use it.”*
- *“Hopefully, you’re not doing Frankenstein type stuff with my DNA. If I see someone that looks like me walking...I know who to come after.”*



CLSA  
ELCV

christina.wolfson@mcgill.ca

Website: [www.CLSA-ELCV.ca](http://www.CLSA-ELCV.ca)

