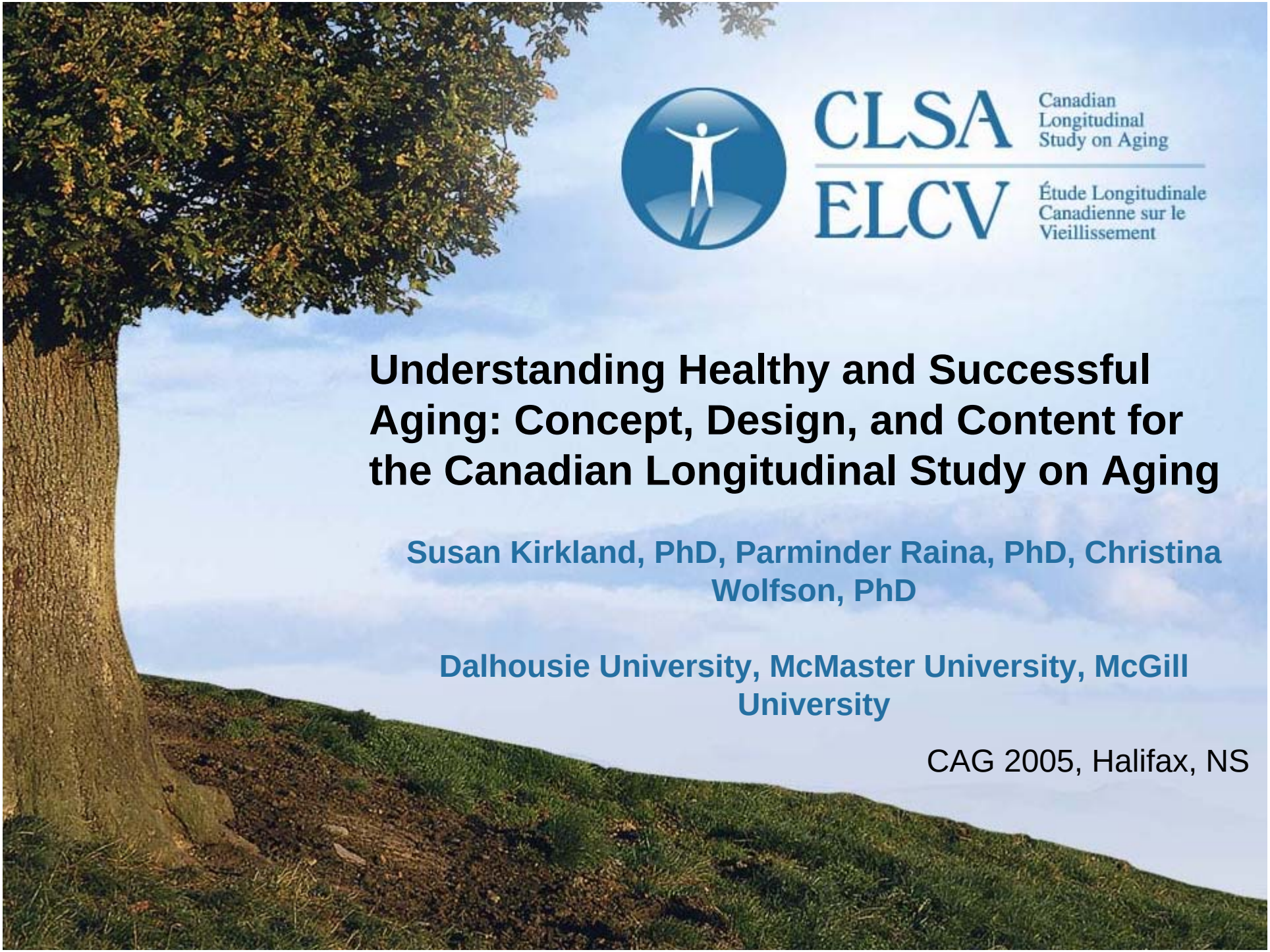

Understanding Healthy and Successful Aging: Concept, Design, and Content for the Canadian Longitudinal Study on Aging

Susan Kirkland, PhD, Parminder Raina, PhD, Christina Wolfson, PhD

Dalhousie University, McMaster University, McGill University

CAG 2005, Halifax, NS

What are the challenges?

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Ethical and Legal Issues

Informed consent

- Capacity to consent
  - Cognitive, other factors that impact capacity to consent
  - Proxy consent
- Full consent versus staged consent
  - 20 year duration
  - For biological samples, clinical assessment, questionnaire based information
  - Genetic and biochemical testing
  - For unspecified research projects in the future
    - issues related to re-consent
- Harmonization across provinces
  - Ethical approval from multiple REBs
- Privacy laws re use and disclosure of personal information across provinces

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Implementation Issues

- Is it possible to collect fasting blood?
- Is it possible to do Oral Glucose Tolerance Test?
- What are the best ways to collect blood?
  - Home
  - Private labs
  - CLSA-specific labs
  - Hospital lab
- Sample preparation and shipment
- Timing of bio-sample collection

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How are we dealing with the challenges?

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Ethical, Legal and Social Issues (ELSI)

ELSI Committee

- Lawyers
- Ethicists
- Philosophers
- Geneticists
- Epidemiologists
- Social scientists
- Privacy commissioner

Provides "arms length" advice

- Workshops
- Commissioned papers
- Expert panels to advise PIs on practical issues

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CLSA Development Phase

Phase I: April 1, 2004 to December 2005

- Refine the study content
- Conduct methodological feasibility studies

Phase II: January 2005 to December 2006

- Content related feasibility studies
- Validity, reliability testing and translation of selected measures

Phase III: January 2007 to March 2008

- Pilot full protocol

CLSA Launch: Fall 2008

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Participant Recruitment and Retention Studies

Study 1:	Views of Canadians towards participation in a longitudinal, population-based study
Study 2:	Test consent to release coordinates of participants in the CCHS
Study 3:	Identification of the optimal consent process
Study 4:	Identification of possible alternative sample frames
Study 5:	Evaluation of tools to assess capacity to consent to observational research
Study 6:	Development of optimal process for the baseline interview

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Data Collection and Data Flow Studies

Study 7: Feasibility of proposed blood and urine sample collection/shipping/storage and analysis strategies

Study 8: Strategies to enhance data linkage with health care utilization data bases and disease registries

Study 9: Development and evaluation of disease identification algorithms

Study 10: Issues related to the return of clinical information to study participants and/or general practitioners

Study 11: Assessment of logistics of data collection methods data transfer and security

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Preliminary Findings

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Views of Canadians

Objectives

- To explore Canadians' beliefs and attitudes toward a multi-faceted, long term study on aging
  - Provision of health, psychosocial, lifestyle and biological data
  - Willingness to participate, response burden
  - Privacy issues associated with data collection and storage, particularly biological samples, including DNA

Methods

- Focus groups conducted in six Canadian cities: Vancouver, Calgary, Winnipeg, Hamilton, Montreal, Halifax

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Views of Canadians

Themes

- Healthy aging
- Importance of research
- Benefits to participants
- Impact on participant behaviour
- Bio-samples
- DNA
- Unforeseen uses of data
- Data linkage
- Responsibility/ commercialization
- Privacy & confidentiality
- Participant requirements, response burden
- Conduct of the study

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Views of Canadians

Biosamples

- General willingness to provide blood and urine samples
- Some concern about providing a DNA sample
  - What will it be used for?
  - Adds credibility to the study

- Few concerns with respect to privacy and confidentiality
  - Assumption that confidentiality would be protected
  - Several participants indicated that only those with something to hide would be concerned about providing a DNA sample
  - Most concerns centered around the use of DNA
    - Information not be shared with insurance companies
    - Why do you need it
    - How would it be used
    - Who would have access to it

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Views of Canadians

Preliminary Findings

- Healthy aging seen as a complex multi-dimensional process
- Participants willing to provide bio-samples but had some concerns about providing DNA
- Universities are trusted to carry out the study; government to fund
- Participants do not feel that private companies should profit from the study results
- Most participants trust that their privacy will be protected
- Altruism is a key motivator for most participants

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Consent to Release Coordinates of Participants in the CCHS

- Require sampling strategy for the recruitment of a representative sample of the Canadian population
- Statistics Canada's Canadian Community Health Survey (CCHS) identified as a survey vehicle that could provide a sample frame for the CLSA

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Consent to Release Coordinates:

Objectives

- Determine the willingness of CCHS participants to share **personal coordinates** (contact information) with CLSA
- Determine the willingness of CCHS participants to share **survey responses** with CLSA
- Explore respondents' concerns in regards to their willingness to sharing either personal coordinates and/or survey responses

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Consent to Release Coordinates

Methods

- Additional content related to CLSA was added to the activities of the CCHS 3.1 Pilot Test
- Qualitative testing of the questionnaire and respondent material in one-on-one interviews (25 E 10 F)
- CCHS 3.1 Pilot (summer 2004) Computer Assisted Personal Interview (n=318)
- Content focused on health issues, replicating the context in which CLSA plans to operate.

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Consent to Release Coordinates:

Results

Qualitative

- Majority of respondents did not express concern over giving their consent HOWEVER many did not have a clear understanding of what they were actually agreeing to do
- Unsure of who/what CLHI is

Quantitative

- Interviews conducted in Vancouver, Montreal, Halifax

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Consent to Release Coordinates: Results by sex

	Males	Females	Total
Share contact info	64.7%	62.8%	63.8%
Share survey data	75.3%	76.4%	75.8%

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Consent to Release Coordinates: Results by age

	40-54	55-64	65-74	75+	Total
Share contact info	63.9%	76.8%	46.7%	55.3%	63.8%
Share CCHS data	73.7%	86.6%	64.4%	73.7%	75.8%

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Consent to Release Coordinates: Results by Location

	Vancouver	Montreal	Halifax	Total
Share contact info	44.2%	78.1%	69.7%	63.8%
Share CCHS info	62.5%	90.5%	74.2%	75.8%

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Consent to Release Coordinates

Caveat….

n=429	100% of eligible sample
n=319	74.1% of those eligible agreed to participate in CCHS
n= 298	94.9% of those who agreed to participate in CCHS agreed to share their data with the MOH
n=190	63.8% of those who agreed to share with MOH agreed to share contact info with CLSA
Therefore…	**44.3% of those originally eligible agreed to share contact info**

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Consent to Release Coordinates

Key Findings

- Little variation between sexes
- Considerable variation between age groups, geographic region
- Based on original eligible sample, response low
- 42% of all respondents reported no concerns or did not ask any questions in regards to the CLSA initiative
- Three most often reported concerns were confidentiality, privacy issues (16.4%), lack of interest (7.1%), and commitment issues (6.7%).

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Data Linkage with Health Care Utilization Data Bases

Objectives

- Examine barriers and facilitators to accessing and linking with health care utilization databases
- Explore the feasibility of using health insurance registries as CLSA's sampling frame
- Develop best practice guidelines for use of and access to health care utilization data

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Data Linkage with Health Care Utilization Data Bases

Methods

- Telephone interviews conducted with
  - Provincial and Territorial Data Stewards (N=20)
  - Provincial and Territorial Information Privacy Commissioners / Ombudsmen (N=13)

- Methodological & ethical issues of data linkage

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Data Linkage with Health Care Utilization Data Bases

Preliminary Findings

- Participant informed consent is key to success: Clarity of understanding essential
- Data access agreement key: Provincial/territorial MOH—unique challenges
- Provincial privacy legislation AND health information legislation—new or emerging—need to operationalize
- Need to develop and maintain strong ongoing relationships with data stewards and managers
- Complex process, but possible
- Requires extensive “up front” work

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Blood and Urine Sample Collection, Shipping, and Storage Strategies

Objective

- Document the infrastructure of existing clinical laboratory services in 6 cities across Canada
- Compare the feasibility, logistics and cost of collecting blood and urine specimens in private community-based and hospital-based clinical laboratories
- Assess the ability of select clinical laboratory sites to accommodate study participants, and to execute standardized “best practice” protocols for the collection, processing, on-site storage and shipment of specimens for the CLSA

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Blood and Urine Sample Collection, Shipping, and Storage Strategies

Methods

40 participants per site, randomized to:

- Private (community based) lab (n=20)
- Public (hospital based) lab (n=20)
  - Randomized to:
  - Collection of 93mL of (fasting) blood and a urine specimen (n=10) OR
  - Collection of 93mL of (fasting) blood and a urine specimen AND Oral Glucose Tolerance Test (OGTT) (n=10)

- Processing time approximately 1 hour, to be conducted within a 2 hour window
- Frozen, stored, shipped to central location in batches

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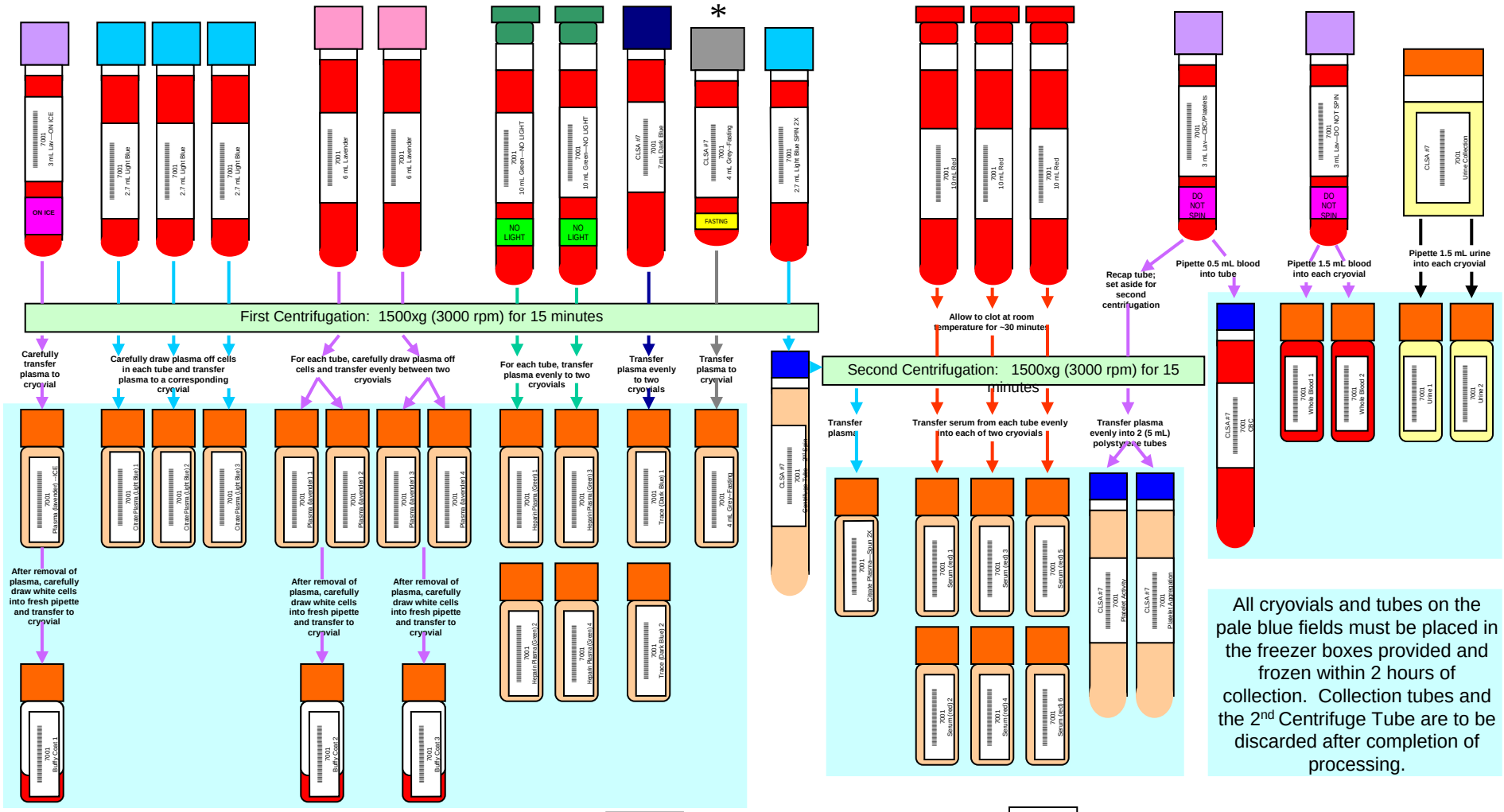
Specimen Processing for the **C**anadian **L**ongitudinal **S**tudy on **A**ging: Biological Specimen Collection Feasibility Study



All cryovials and tubes on the pale blue fields must be placed in the freezer boxes provided and frozen within 2 hours of collection. Collection tubes and the 2nd Centrifuge Tube are to be discarded after completion of processing.

* For Grey tube labeled CLSA #7 7001 4 mL Grey Post 2 hr OGTT, processing is identical; plasma is transferred to cryovial labeled CLSA #7 7001 4 mL Grey—2 hr OGTT

Blood and Urine Sample Collection, Shipping, and Storage Strategies

Analysis

- Participant questionnaire: Convenience, acceptability, discomfort, privacy etc.
- Laboratory Requisition: confirm fasting, time marks in specimen collection etc.
- Lab feedback Questionnaire: problems in execution, suggestions for improvement etc.
- Specimen evaluation: central lab evaluation of specimen quality (no analysis of blood samples)

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Blood and Urine Sample Collection, Shipping, and Storage Strategies

Preliminary Findings

- Not all provinces have private labs
- Instability in private sector
- Considerable variation in capacity among hospital based labs

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Return of Clinical Information

Objective

To explore the issues involved in returning individual clinical rest results to research participants and/or their family physicians

Methods

- Survey of other relevant longitudinal studies.
- Focus groups to explore potential participants' views of the importance of the return of individual information, the type of information they would like to receive, and how they would like to receive it.
- Expert workshop of clinicians, epidemiologists, bioethicists and family physicians to guide decisions regarding returning clinically relevant test results to participants and/or family physicians.

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Return of Clinical Information

Web-Based Survey

- Invitation to participate sent to 68 principal investigators or identified contact persons of longitudinal studies on aging
- Selected from CIHR and NIH publicly available database lists, supplemented by disease-specific longitudinal studies
- The web survey assessed:
  - characteristics of the study
  - types of health measures collected and whether individualized information was returned to participants
  - factors that impacted on the decision whether or not to return individualized information to participants

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Return of Clinical Information

Data Type	%
Physiological	60%
Genetic	60%
Functional health	85%
Lifestyle	100%
Psychological	90%
Cognitive abilities	75%
Social	90%
Health services utilization	70%

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Return of Clinical Information

Type of measure	Collected	Returned if collected
Anthropomorphic measures	85%	35%
Functional ability	50%	20%
Neuropsych exam	45%	33%
Blood pressure	75%	63%
EKG	65%	75%
Advanced clinical tests	22%	83%
Vision	32%	63%
Hearing	42%	67%
Oral	10%	50%
Blood biomarkers	70%	79%
Urine biomarkers	45%	44%
Biosample for genetics	60%	0%

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Return of Clinical Information

Preliminary Findings (n=20)

- Majority of studies returned some individualized information to study participants
- Results were most often returned through mail
- Ethical considerations identified as most important factor in deciding whether or not to return individualized test results
- 75% of respondents recommended return of individualized test results; 25% recommended no return
- Reasons in favour of returning individualized results: ethical considerations, participant retention, benefits to participants
- Reasons against returning individualized results: ethical considerations, tests not done in clinical settings, reliability too low, results not readily interpretable

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In conclusion…

Common threads:

- Complexity
- Necessity (and appreciation) of “up front” work required for such a large scale study
- General sense of enthusiasm and support

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