

Using Proxies to Extend Opportunities for Research Participation in the Canadian Longitudinal Study on Aging

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I. Introduction to the CLSA

- Canada-wide, longitudinal study
- Data collection
 - occurs in 3-year waves;
 - started in 2011 and scheduled until at least 2032
 - information relevant for: physical, emotional and social functioning + onset of health conditions and diseases
- **2 arms**
 - ***Tracking***
 - **21,241 participants** recruited
 - data collected via **telephone interviews**
 - ***Comprehensive***
 - **30,097 participants** recruited
 - data collected via **interviews at in-home and data collection site visits**
 - blood and urine samples



Risks associated with a longitudinal study on aging

- participants in a longitudinal study on aging may over time be at **risk for cognitive decline**, experiencing diminished or fluctuating mental capacity
 - for the study this means: **risk of attrition**
 - for the participant this means: **risk loss of research participation**—a valued opportunity for research participants
- **attrition for the study involves**
 - a **loss of valuable information** for understanding health & aging processes
 - and, **participants are often lost to follow-up for the very reasons critical for our understanding of aging and health.**
 - *health conditions*
 - *transitions in living arrangements*
 - *use of health services*
- attrition for the study also involves
 - **risk of study bias**

II. The need for proxies and a sound protocol

- there are **motivating scientific concerns** to address these risks
 - obtaining information on study participants for as long as possible is **essential for the scientific validity** of a longitudinal study
- there are **motivating ethical concerns** to deal with these risks
 - consent is necessary for human subjects research (*TCPS II*, ch.3; *Declaration of Helsinki*)
 - on the one hand there is a **need to protect persons with diminished or fluctuating capacity** to consent from abuse and exploitation
 - on the other hand there is a **need to avoid default (unjust) exclusion of vulnerable populations from participating in research**
 - “*protective exclusion may undermine the human rights of the elderly and disabled to equal recognition, non-discrimination, and full participation in society*” (Thorogood et al., 2018:70)
 - **protective exclusion cuts off this population from (immediate and prospective) benefits of research**

II. The need for proxies and a sound protocol

- Motivating ethical concerns cont'd
 - Respect for Persons and the *Tri-Council Policy Statement II* (2018:pp.6-7):

“Respect for Persons ...encompasses the treatment of persons involved in research directly as participants and those who are participants because their data or human biological materials ... are used in research. **Respect for Persons incorporates the dual moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy.** ¶Autonomy includes the ability to deliberate about a decision and to act based on that deliberation. ...¶An important mechanism for respecting participants’ autonomy in research is the requirement to seek their free, informed and ongoing consent. ...¶Some people may be incapable of exercising autonomy because of youth, cognitive impairment, other mental health issues or illness. **While autonomy may be considered a necessary condition for participation in research, involving those who lack capacity to make their own decisions to participate can be valuable, just and even necessary. ...¶Where it is foreseeable that a participant may lose decision-making capacity during a research project ... it may be appropriate to ask participants to express their preferences and ensure that they have authorized a trusted person to make decisions on their behalf should they lose the capacity to decide whether to continue their research participation.”**



III. Types of proxies

- What is a proxy (in the context of research)?
 - **a proxy is an individual delegated**, almost always by the participant, **to take over the participant's responsibilities** associated with CLSA research participation.
- There are **2 roles for proxies**
 - **Proxy Decision Maker** assumes responsibility for making decisions on the participant's behalf concerning all matters relevant to participation in the study.
 - **Proxy Information Provider** assumes responsibility for providing questionnaire-based information about the participant to researchers when the participant cannot (or simply may not want to) do so on their own anymore.
- They **can be separate persons** for each role, **or the same person** for both roles
 - *most proxies with the CLSA fulfill both roles for the participant they represent*



The Proxy Process

- The proxy process has 3 stages
 - Stage 1: **Knowing that you want a proxy.**
 - participants are asked to **designate a proxy candidate and provide consent** for the CLSA to contact that person (when needed) to act as the participant's proxy.
 - Stage 2: **Knowing when to initiate the proxy process**
 - Stage 3: **Contacting designated proxy candidates and requesting their consent** to act as the participant's proxy

IV. Stage 1: Designating and consenting to have someone act as one's proxy

Stage 1

- those participants **aged ≥ 70 at baseline**;
- those **aged ≥ 70 at the time of being contacted during any wave** of data collection;
- those **requesting the use of proxy** (regardless of their age)
 - all are given,
 - i. **an information package** (explaining why they might consider designating a proxy decision maker and/or information provider), and
 - ii. **a consent form** to fill out for designating a

proxy

IV. Stage 1: Designating and consenting to have someone act as one's proxy

- **Providing a designated proxy candidate is encouraged, not required**
- Participants opting *for* using a proxy are encouraged to notify their proxy candidate
- **The proxy's contact information is re-confirmed with the participant at each wave of the study**
- **Participants can change their choices** (whether to use a proxy; what kind of proxy to use; and who is to be their proxy decision-maker and/or information provider) at any time

V. Stage 2: Knowing when to initiate the proxy process

- For those ≥ 70 , **at the beginning of each Follow-Up interview a cognitive screening test** (validated 6 item screener) is used:
 - delayed recall of 3 words ('penny', 'table', 'apple')
 - What year, month, day of the week is it?
- for **participants who recall $\leq 3/6$, the interviewer initiates a conversation about** the participant's interest and self-perceived capacity to continue the interview on their own, or **interest to move to using a proxy**
- at any time by way of a request from the participant or at the discretion of the interviewer, **the interviewer may initiate a discussion about using a proxy** to extend research participation
- As a rule, the **CLSA does not contact a proxy candidate until the participant confirms to do so**
- However, **a concerned caregiver or relative may contact the CLSA to suggest not contacting the participant for interviewing anymore**

V. Stage 2: Knowing when to initiate the proxy process

- either at the **participant's request** (standard) **or** in response to **challenges with interviewing**, the CLSA will undertake the ***Proxy Initiation Script* interview** with the participant
- the script seeks to identify and **confirm participant's present need or wish to transition to using a proxy.**
- **in such cases**—as well as any case where the participant proves unable to complete the script but has already provided consent to the use of a proxy—the CLSA will **initiate contact with the designated proxy candidate.**

VI. Stage 3: Contacting the designated proxy candidate and requesting their consent to act as the participant's proxy

- **Initial contact with the designated proxy candidate is established by mail.** Items sent include:
 - *Letter of Introduction and Invitation to be a Proxy*
 - copy of *Participant Study Information Package & Summary*
 - *Information Pages for Proxy Decision Maker / Information Provider*
 - *Consent Form for a Proxy Decision Maker / Information Provider*

Summary: Multi-step, proxy protocol

Stage 1:

- **Provide participant with information and identify participant interest** to use a proxy to ensure future study participation in the event of participant's inability (or desire not to continue) to interview anymore.
- **Receive participant consent** (from those interested to use a proxy) and record contact information of designated proxy candidate.

Stage 2:

- **Identify and confirm participant's need/wish to initiate a proxy.**

Stage 3:

- **Contact designated proxy candidate to establish consent** or refusal to act as a proxy.
- **Inform participant** via letter of the results of step 2.
- **Contact confirmed proxy to schedule interview.**

VII. Next steps: The need for proxies and developing verbal consent protocols

For **Comprehensive Participants**

- **consent form** to use a proxy is **completed at the in-person interview**
- rate of **uptake is 87%**

For **Tracking Participants**

- **consent form** to use a proxy is **completed (on their own)** and mailed in to the CLSA
- rate of **uptake is 47%**

Verbal consent protocols are in development

- [Article 3.12](#), TCPS 2, 2018
- *Script to obtain Verbal Consent for Designating a Proxy* (telephone)
- **target**
 - **mainly Tracking Participants**
 - **Comprehensive Participants who cannot visit a Data Collection Site**

In Conclusion ...

The CLSA's **sound, proxy protocol** is designed to be both **responsive and anticipatory**

Enabling proxies to help research participants continue participation in the study (past the point of diminished or fluctuating capacity) **meets the study's needs.**

- Doing so avoids attrition and bias
- Doing so also upholds scientific validity

Enabling proxies also meets participants' needs and wishes. This includes:

- respect for persons | participant autonomy
- continued participation and inclusion in research | equal recognition and non-discrimination
- immediate and future access to the benefits of research





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