

CLSA Phase 1 – Protocol Development

Study 1:

Exploring the Acceptability and Feasibility of Conducting a Large Longitudinal Population-based Study in Canada

Technical Report of the Study Findings

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Executive Summary

In recent years a number of longitudinal, population-based studies have been initiated, mostly in Europe and North America. Despite the growing number of such studies, there is a paucity of information on factors which influence the decision to participate, or not to participate, in multi-dimensional studies of this magnitude. The purpose of this feasibility study was to explore the views and acceptance of Canadians regarding a large, longitudinal, population-based study, such as the proposed Canadian Longitudinal Study on Aging. Focus groups were conducted in Vancouver, Calgary, Winnipeg, Hamilton, Montreal, and Halifax.

Understanding Healthy Aging

The concept of healthy aging is a central theme of the CLSA, underlying much of the proposed research. Focus group discussions generally revealed an evolution of thinking about healthy aging on the part of participants. Initial comments tended towards the physical and lifestyle aspects of healthy aging, while later comments moved into the social, emotional and spiritual aspects of healthy aging. In all, eight sub-themes were identified for healthy aging: physical, lifestyle, social, emotional, financial, contextual, spiritual, and independence.

Most discussions of healthy aging began with the physical aspects, including the notion of comfort. Closely linked to this concept was freedom from pain, illness, debilitation and medications. *“I think it’s living to a ripe old age without being incapacitated.”*

While some participants embraced the idea of healthy aging, others doubted that healthy aging was possible, citing the inevitability of some form of sickness or incapacity. Reflecting on intergenerational differences in lifestyle, participants pointed out differences in their lifestyle and that of their children or the younger generation in general. Several participants felt that because of the younger generation’s greater awareness of health concerns and their consequent healthy choices, they will likely remain healthier longer. Regular visits to the doctor and other health care professionals were considered to be a key aspect of staying healthy.

The importance of family and friends was identified as a key element of healthy aging; many participants gave examples of relatives who they felt had declined due to a lack of companionship. Friends of the same generation were also seen as important. *“Lots of friends and family, a support group; people you can talk to. Have a connection with the community, the people around you.”*

Participants talked about the need to enjoy life or to “get in as much as you can” rather than doing nothing or worrying about their health. It was important to have some purpose in life and to remain physically and mentally active and involved in the community and not merely surrender to old age.

Attitudes towards, and on the part, of the elderly have also changed. *“But we think differently about aging too. I remember my parents and my in-laws when they hit their 60’s, they didn’t do anything anymore.”* Some respondents talked about not feeling their age or feeling that their mind was younger than their body and expressed some level of frustration with the feeling of being in an older body, or with social expectations for people “their age”. *“You know what my biggest problem is with aging at 67 is that my mind is 29, my body’s just not.”*

For some participants, healthy aging had a financial component. They talked about the need for financial planning in order to have enough money for retirement and expressed concern about whether they would, in fact, have enough income to live comfortably in their old age. There was also discussion of government policy as it impacted seniors. Topics included the illegality of in-law suites, the need for better education on healthy living, more support for seniors to stay in their own homes, such as trained home caregivers, more monitoring of long term care facilities and incentives to encourage physical activity.

Some participants expressed their own fears of aging and death. *“...I think if I’m truthful with myself, I think I probably fear getting old...”* Others felt that society, itself, did not want to confront the reality of aging and death. In this context, participants discussed not only the ageism that exists in society but the change in their own perspectives, such as the change in attitude that comes with aging, from feeling immortal when you are young to feeling very vulnerable when you are older. Underlying this discussion was the sense of a society that values youth more than the elderly and which ignores, or covers up, the reality of aging and death.

Overall, participants demonstrated an understanding of aging as a complex multi-dimensional process which was worthy of study. *“too many people, when you say healthy aging, they think only physical health but healthy aging has to do with using yourself spiritually, your growth, your intellectual growth as well as your physical growth and also having the finances to maintain a lifestyle.”*

Importance of the Research

Generally, most participants understood, and could identify, the benefits of doing research on aging in Canada. It was felt that research of this type would be beneficial, if not to them, then to future generations. They also recognized the timeliness of a study on aging given the changing demographic profile of the Canadian population. Aging was a reality for most participants, either from their own personal experience, or that of close friends and relatives. It was not a great leap then, for them to want to participate in a study which has the potential to reduce the suffering often associated with old age. *“My first reaction is that this is very important and it should be happening right now. The aging population is the largest population in this country now, and growing... it’s a good thing, I highly approve of it.”*

Participants commented on the rising cost of health care and the need for individuals to take responsibility for their own health as a way of controlling these expenditures. The results of a study on aging were seen as a way of identifying lifestyle and other factors that would help promote healthy living. There was also considerable discussion about whether simply being in the study would make participants more conscious of their own health because it was being monitored. Some felt they would monitor their health more closely and try to pursue a healthier lifestyle while others felt that despite good intentions it would be very difficult to modify their behaviour. Participants were aware that most of the benefits of the study would accrue to society in general or future generations rather than to the individual participants themselves. *“Results after 20 years is not really for us but for the next generation.”*

The social policy implications of undertaking a study on aging were raised by participants who reasoned that it would provide valuable information to governments in terms of planning for future needs for seniors. Several participants expressed the view that the study would only have value if the results were put in the hands of policymakers. They expressed concern that, like so many other studies, this one might languish on a shelf somewhere. *“There are a lot of studies about this that are sitting on shelves. You can have the best study but if the government ignores it means nothing.”* Other topics touched on by participants included problems with the current health care system and geographic differences in health across the country. Participants thought that the study might discover differences in health or longevity based on diet or lifestyle in particular regions of the country.

Altruism as a Motivator for Participation

Altruism was a major motivating factor for most participants who indicated that they would be willing to take part in the study if it would “help others”. This motivation was repeated in all the focus groups in the context of many different discussions. Typically participants sought no other reward for their participation other than the knowledge that they could help someone else. *“I think that should be our goal, to be concerned about others and anything that we can do to help one another, we should. “...it’s a really serious thing to think about, as far as aging...there’s a lot of suffering out there... If we could accomplish something to ease that suffering, it would be a wonderful thing.”* For some others the motivation to participate had to do more with benefiting society as a whole. *“If it’s for the good of society, no problem.” “I would be content knowing I participated in a good social cause.”*

Some participants felt that there should be some form of recognition for their participation in the study. Generally participants eschewed monetary rewards but wanted to be thanked for their efforts and to know that their participation was helpful to others. *“...basically your primary reason for doing it would be to help others. So all of a sudden they come back and say, hey, what you’ve done has helped in this way; that would be kind of nice...”* For several participants,

however, their participation would be conditional on the results not being used for commercial purposes. While they were motivated to help others they did not want commercial entities profiting from a study for which they volunteered their time. *"...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... my wealth, by all means, you use it."*

Participants did want to know the types of tests they would be undergoing as part of the study and who would be administering them. Reimbursement for travel costs was expected but was not a motivation for participating. Rather, it was seen simply as compensation for out of pocket expenses. An important consideration for participants was flexibility in scheduling appointments and convenient data collection sites. There was an expectation that since participants would be volunteering their time, the study should accommodate their needs as much as practicable.

There was also an expectation that the study would provide information to participants about their own specific test results as well as more general research findings. This topic surfaced spontaneously in several groups during the discussion of blood, urine and DNA testing. Generally participants were interested in their own health and seemed eager to be able to have some additional means of monitoring it. While receiving test results was perceived as a benefit of participating, most participants also recognized that the distribution of routine results would be time consuming and were content to have only adverse results communicated. Some participants felt that the study had an ethical obligation to return individual results, especially adverse findings, while others felt that doing so would invalidate the study findings.

Providing Bio-samples

The majority of participants had no concerns about providing blood and urine samples in the context of a research study. A number indicated that they already do this on a regular basis for their family doctors so it would not bother them to do it for the study. Interestingly, there was the sense from participants that collecting blood and urine samples added credibility to the study. *"It adds credibility... You're going to see...where people are. Are they improving or not improving, that sort of thing? You know, nobody likes to get their blood taken but I'd say it's a good reason to have it done."* *"I think that would validate it, if they are taking actual medical information."*

Although most participants were willing to provide samples, a few had questions about why it was needed and what would be done with the samples. There was also the suggestion that the study could simply access this information by contacting participants' family doctors. Some participants asked about the type of tests that would be conducted and who would have access to their samples. *"I think a lot of people would question...what are you using it for? What are you testing for?"* In this context one group brought up the spectre of discrimination by insurance companies and also nursing homes based on the results of blood and

urine tests. A few participants said they would provide samples as long as it was “anonymous”. *“I just know that some things that have been found through testing, people have been discriminated against for it.”* A number felt that the testing might have diagnostic value for them, uncovering something of which they were unaware. *“Sometimes it’s a good thing to find out because if they find out in time they can cure it.”*

Using and Storing DNA

The potential value of DNA was recognized in furthering our understanding of many diseases, perhaps leading to treatments and even cures. *“...genetic material is the key...I think if you start studying stuff like that, then you’re starting to see things that people inherit... We know that there is a lot of diseases and stuff that people have that...if studied with a big enough population you might be able to see some kind of pattern and perhaps break the pattern...”*

Others wanted to know why DNA was needed as part of the study and what it would be used for. Many participants had an expectation that the study would offer a full explanation of why DNA was needed and what it would be used for. *“Well I don’t think anyone [would] ask that question without explaining why it was needed. I don’t think anyone would agree to it without being informed why. And if there were a benefit to it...I wouldn’t object in any way to it as long I was given a full explanation of why and if it would be of benefit and how.”*

Awareness of DNA seemed to be largely based on controversial images such as human cloning, eugenics and its use in law enforcement. Among some participants the mention of DNA evoked a negative response based on uneasiness or even fear. *“I would feel leery about it. Right away, I got my back up against the wall.”* There was considerable discussion of ethical questions surrounding the collection and use, or misuse of DNA. *“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.”* *“Would it be used for law enforcement, or any of that stuff or just in the study?”* Concern was expressed by one participant that some people might interpret the results of DNA testing in a manner that might indicate racial differences.

On multiple occasions participants indicated that only those with “something to hide” would be wary of a DNA test. *“But generally speaking, I think that the only people that are concerned about confidentiality issues are those with something to hide.”* *“I’m not planning any murders or anything in the future so they can keep my DNA.”* While some of the comments may have been made in jest, they clearly underlie some level of concern about who would have access to the data.

Despite some reservations, most participants would be agreeable to providing a sample of their DNA for research purposes providing that their questions and concerns were satisfactorily answered. However, this was the most controversial of any of the topics discussed. It is apparent that there is considerable lay

conjecture about the use of DNA in various settings. Individuals want assurances of how their DNA will be used for research and how their privacy will be protected. Generally, participants felt that knowing the project had been approved by an ethics review board would be an important consideration for them in deciding to participate in the study.

Privacy and Confidentiality

Most participants had no concerns about privacy and confidentiality and those that did focused mostly on the privacy of genetic material. Some participants wanted to know if the DNA samples would be completely anonymous while others spoke about the need for confidentiality and how certain diagnoses have been used to discriminate against people for services such as life insurance. There was an assumption among participants that their confidentiality would be protected and a trust in universities to make that guarantee. Participants did expect to be notified and asked for their consent if new tests, not originally planned as part of the study, were to be conducted using their biological samples. Most participants were not concerned about linkage to their provincial health records for research purposes and most felt that any data they provided as part of the study should remain with the study if they were to withdraw.

Communicating Personal Test Results

The provision of personal test results was seen as a benefit of participating in the study. Some participants wanted the information collected as part of the study to also be shared with their physicians indicating that, in some ways at least, they see participating in the study as a way of supplementing, if not substituting for, their own health care and health care providers. *“Because I think if you went into this study, I think your own personal doctor should be notified that you’re doing this and that they’re getting a report on how you’re doing...”*

Some participants were cognizant of the fact that returning individual test results could affect behaviour or lead to treatment which could potentially alter the outcomes of the study. This led to a debate in some groups between those favouring a “pure” study and those who wanted to receive their results, especially adverse results. *“...I’m hearing that the crowd here thinks that...there’s going to be some kind of benefit for themselves by doing this...is that, in fact, what’s going to happen? My understanding of the study is just taking a sample of the population and the feedback is not necessarily what’s going to happen.”*
“...but for you to step in and make decisions that will affect the results...will void the study.”

It was clear that some participants had knowledge of how clinical trials have been conducted and felt that the study should also proceed in this manner. Others felt that this study was different and individual results should be shared with participants. *“In the interest of science, I think it has to be cold-hearted myself...are we trying to fix people or are we just trying to figure out, is there a problem?”* *“...what you’re talking about is more like a double blind drug*

company study. This is more of a health and lifestyle study...and there's nothing wrong with knowing the results..."

There was general interest in receiving the results of individual tests but some felt that they already got this information from their doctors so it was not critical to know. The sense conveyed was that it was "nice to have" but not essential. However, participants were, quite naturally, much more concerned about receiving any adverse findings and felt that the study should be responsible for passing on such information either to the participants or their physicians. Most participants felt that only adverse findings should be reported back, reasoning that individuals were responsible for their own health, however a few thought that participants should get all test results. *"And I don't think the study should report back on everything they find, but if they find something serious, I think they should let you know."* *"Yeah, but ultimately our health is our own responsibility and it is up to us to go to our own doctor on a regular basis...so it shouldn't be their responsibility to...say, yeah you're healthy or you're not healthy, but if something big was found, then, yeah, I'd like to hear about it."*

Governance

Universities were clearly and overwhelmingly identified as the proper institutions to conduct this research. Participants were wary of government involvement in the conduct of the study but felt that government should fund the research. However, they were troubled by the prospect of private funding from commercial enterprises, especially pharmaceutical companies. Pharmaceutical companies were generally distrusted and participants were concerned about the prospect of a private company profiting from a study for which they volunteered their time. It was evident that private funding to the study from pharmaceutical companies would be a disincentive to participation for many.

When asked how they would feel if a discovery that came out of the study was used as the basis for a commercial treatment or diagnostic test, participants were initially distrustful and felt that commercial endeavours had no place in the study. However, there was an acknowledgement by some of the benefits of such treatments and tests and the reality of how new products are brought to the marketplace. Participants felt that the study itself should benefit from any discoveries which were commercialized through, for example, the payment of royalties.

1. *Purpose of the Research Project*

1.1. Introduction

The proposed Canadian Longitudinal Study on Aging (CLSA) is a broad, multi-disciplinary study of adult development and the aging process. A total of 50,000 men and women aged 40 and older will be assembled and followed over two decades as they enter into and comprise the senior population. The study takes a lifespan perspective and adopts a variation of the determinants of health framework to conceptualize the ways in which social and physical environments, genetic, biological and clinical factors, lifestyle and behavioural factors, social and societal factors, economic prosperity, and the health care system are inter-related to influence disease, function and well-being as individuals age. The identification of factors that determine the pathways to a range of outcomes, both positive and negative, will pave the way for the development of intervention strategies. Scheduled to be launched in 2008, the CLSA will require the long-term participation of volunteers drawn from the Canadian population and will entail a variety of data collection methods including telephone and face to face interviews, physical assessments, and the provision of biological samples such as blood and urine. This was the first of 11 feasibility studies funded as part of the initial CLSA development phase.

Given the magnitude, depth and complexity of the CLSA, it was imperative to understand the beliefs and attitudes of Canadians towards accepting and participating in such a study. This allows us to better design a study that simultaneously is most acceptable to study participants, maximizes recruitment, and minimizes attrition. The extended time period for participation in the CLSA, the different data collection modalities and the different types of questions to be asked (e.g., psychosocial, lifestyle, health) will all serve to create expectations and experiences that will have an impact on the willingness of Canadians to agree to participate initially, and to remain as part of the CLSA over time.

Surprisingly, given its importance to other similar types of studies, limited relevant literature exists on how Canadian adults feel about participating in a longitudinal study. What we do know is that a large majority of Canadians strongly support health research. National data from the 2003 Health Care in Canada survey show that 83% of Canadians value and support health research and 85% of Canadians believe that aiming to become a world leader in health research is something worth pursuing.¹ Canadians, according to a CIHR report, also recognize the connection between health research and improved health care.² However, there is no information that connects Canadians' thoughts and feelings toward health research to their ability and willingness to participate in a long-term, multifaceted study such as the CLSA. As such, the results of this

¹ Health Care in Canada Survey 2003: A national survey of health care providers, managers, and the public. http://www.mediresource.com/e/pages/hcc_survey/pdf/2003_hcic.pdf

² Canadian Institutes for Health Research. CIHR Performance Report. 2003.

study not only inform the future work of the CLSA, but are also beneficial to other Canadian researchers who undertake longitudinal studies.

Many factors influence the attitudes and feelings of Canadians toward participating in a long-term study such as the CLSA. One very important emerging issue centers on privacy concerns. The increasing use of computers that can be used to store and retrieve large amounts of information has created concerns related to privacy that may be of particular interest to Canadians who will be asked to provide personal information about themselves, and in particular, genetic information. It will be important to ensure that the CLSA not only meets all ethical standards related to data storage and retrieval, but also meets the conditions that would make the public feel confident that any information they provide will remain confidential and safe. This issue is of such importance that in 2003 the Canadian Institutes of Health Research (CIHR) commissioned a paper intended to inform the work of the Canadian Lifelong Health Initiative (CLHI) Ethical Legal Social Issues (ELSI) Advisory Committee. ELSI was formed to advise the CLSA around issues pertaining to legal and ethical aspects of a long-term, population-based study. The paper, authored by Tim Caulfield and Nola Ries, explores some of the ethical and legal issues relevant to the CLSA.³ For the purposes of this feasibility study, we are concentrating on two important aspects of that paper: a) privacy and confidentiality and b) genetics.

1.2. Privacy and Confidentiality

The CLSA proposes to collect and store a broad range of data about its research participants. Canadian Federal and Provincial governments have recently introduced new types of legislation that govern the collection and use of personal information. These laws point to the importance of an individual's right to privacy and confidentiality of medical and other records collected for research purposes. Caulfield and Ries argue that "understanding and addressing the legal and ethical concerns in a thoughtful manner is essential to the long term success of these large cohort projects – especially in the context of public trust".³ There is an inherent tension between the need for information and the need for privacy and this feasibility study offers some insights into how Canadians view these issues. The CLSA will need to ensure that all information is handled in a way that maintains confidentiality and trust of both the public and research participants.

While there are important legal and ethical reasons to consider privacy and confidentiality, it is not clear that the Canadian public is aware of these issues. For example, a 2004 EKOS/Queen's University study found that:

People do not place a high priority on privacy of personal information, whether collected by governments, corporations, or employers. Moreover, few knew basic information about existing

³ Caulfield TA, Ries N Consent, Privacy and Confidentiality in Longitudinal, Population Health Research: The Canadian Legal Context. Health Law Journal 2004 (Supplement).

privacy legislations, and fewer still recognized the technologies used to collect, store, and transmit their personal information electronically.⁴

Interestingly, people endorsed the view that they should rely on themselves and not government to protect their personal information.

A recent Ontario study by Willison et al⁵ studied patients' preferred consent method for use of their electronic medical records and concluded that "most patients had given little or no prior thought about the use of their personal information for anything other than their own health care." On reflection, however, most wanted to be asked permission for the use of their health records, and expressed different levels of concern about sharing personal information depending on the funding source or the study: in qualitative interviews, they expressed distrust of drug and insurance companies, while in the survey they expressed distrust of government-sponsored research and insurance companies.⁵

1.3. Genetics

The proposed collection of biological samples to be used for genetic testing adds a layer of complexity to the CLSA. Genetic information tends to be perceived by some people as more personal than non-genetic information for a variety of reasons. For example, some understand genetic data as having predictive properties, and this could have an impact on someone's future behaviour and that of their offspring (i.e. decisions regarding having a child). In addition, it could have an impact on one's insurance status. A 2001 opinion poll found that 90% either strongly agree (61%) or agree (29%) that genetic information is different and that this type of information needs stronger protections than other types of personal and health data.⁶

Interestingly, a 2003 report prepared for the Government of Canada found that 78% of Canadians are willing to provide information from genetic testing to a data base used for medical research. The support increases to 90% when people are told that privacy protections will be applied and that there may be research benefits.⁷

⁴ Zureik E, What Canadians Think about Privacy. Queen's University Surveillance Project, 2004.

⁵ Willison DJ, Keshavjee K, Nair K, Goldsmith C, Holbrook AM, Patients' consent preferences for research uses of information in electronic medical records: interview and survey data. *BMJ* 2003;326(7385):373.

⁶ Pollara Research & Earncliffe Research and Communications. Public Opinion Research into Biotechnology Issues, Third Wave. 2001.

⁷ Pollara Research & Earncliffe Research and Communications. Public Opinion Research into Genetic Privacy Issues (Presented to the Biotechnology Assistant Deputy Minister Coordinating Committee (BACC)). Government of Canada, 2003.

The UK Biobank has also dealt extensively with the public's attitudes towards collecting and storing biological samples. Among their findings are a preference for understanding what their biological samples will be used for, a desire for reassurances of safeguarding confidentiality, and popular misconceptions about genetics and associations with worrisome uses of genetics, such as forensic DNA testing and cloning, resulting in a recommendation of particular care in explaining the use of genetic information.⁸

1.4. Study Goal and Objectives

The main goal of this study was to explore, through the use of focus groups, Canadians' beliefs and attitudes toward participating in a multifaceted, long-term study. To meet this goal, we formulated the following objectives:

1. Explore the attitudes of Canadian adults over 40 years of age towards providing health, psychosocial, lifestyle and biological data in a 20-year longitudinal study.
2. Explore Canadians' views on a long-term, multi-faceted study, addressing issues of willingness to participate, response burden, and the acceptability of the collection of various types of data including biological samples and a physical assessment.
3. Explore the beliefs and attitudes of Canadian adults around privacy issues associated with data collection and storage, including use of their archived CLSA data, particularly biological samples, for future research.

⁸ The Wellcome Trust, The Medical Research Council. Public Perceptions of the Collection of Human Biological Samples. 2000.

2. Study Design and Research Methodology

The research design comprised six focus groups of approximately 7 participants per focus group. The methodology for data collection and analysis is described in detail below. The six focus groups were held in six different cities across Canada, corresponding to the originally proposed regions for CLSA data collection. The six sites were: Halifax, Montreal, Hamilton, Winnipeg, Calgary and Vancouver.

2.1. Recruitment

Recruitment for all six focus groups was conducted by telephone. This was accomplished in a two-stage process. First, a commercial sampling firm was used to generate random telephone numbers. Second, a university based survey research institute was responsible for recruiting participants for the focus groups. The details of this process are outlined below.

The sample of telephone numbers was obtained from ASDE Inc., a firm that specializes in providing telephone samples for research studies. The sample was drawn by generating random telephone numbers based on the working residential telephone exchanges within the six study areas identified in the CLSA Protocol (defined as those areas within a 100 kilometre radius of Halifax, Montreal, Hamilton, Winnipeg, Calgary and Vancouver). The randomly drawn telephone numbers then were checked against published telephone listings in order to produce a Directory Listed (DL) sample. If this sample was designed to be representative of the population living in these areas a Directory Not Listed (DNL) sample would also have been drawn in an attempt to include unpublished and not yet listed telephone numbers. However, since these focus groups are, by definition, not representative, a directory listed sample was judged to be adequate for recruiting purposes.

Using this sample, the Institute for Social Research (ISR) at York University undertook the recruiting of participants from their Computer Assisted Telephone Interview (CATI) centre in Toronto. ISR is an established, reputable, research centre with trained, bilingual telephone interviewers, and the communication and information technology infrastructure necessary to undertake telephone recruiting. Because ISR is based in an academic institution and works extensively with the academic community, the organization is well apprised of, and adheres to, ethical principles typically required by university research ethics boards.

ISR recruited participants one to two weeks before the focus groups were scheduled to take place, using an established recruiting screener. Twelve participants were recruited for each focus group. However, due to attrition, this resulted in groups of between 4 and 10 participants. Since the CLSA will use participants 40 years and older, only those in this age group were eligible for

recruitment. When someone under the age of 40 answered the phone, s/he was asked if there was anyone in the household over the age of 40. In this study a gender balance within each focus group was desirable in order to obtain the views of both men and women. In order to ensure participants of all ages were included, recruits were also balanced by age group. Balanced groups were achieved by observing quotas. For example, once 6 females had been recruited for a 12 person focus group, only males were then eligible for inclusion. If a female answered the phone, she was asked if there were any males in the household over the age of 40. If there were none, the contact was thanked and the call terminated. Similarly once 6 participants from the 40 to 59 age group were recruited only those 60 and over were eligible for inclusion.

When a call resulted in contact with an individual eligible for the study, the person was provided with a brief description of the study and asked if s/he would be willing to participate. Those who indicated that they would be willing to participate in this study were given specific information about the date, time and location of the focus group. They were also asked to provide their mailing address so that a letter of confirmation could be sent.

Recruits were then mailed a brochure describing the CLSA study, a copy of the consent form and written confirmation of the date, time and location of the focus group. A reminder call the day before the focus group was also made to each recruit.

2.2. Informed Consent Process

As indicated above, the consent form was mailed to participants along with the brochure and focus group information. An accompanying letter requested that potential participants review the consent form prior to attending the focus group and indicated that it was not necessary to sign it beforehand. A toll-free telephone number and e-mail address were provided to allow potential participants to obtain additional information on the consent process or any other aspect of the focus group. Several participants availed themselves of this opportunity for clarification or used the toll-free number to indicate that they would be unable to attend the focus group. Providing the consent form in advance gave participants time to review and absorb the information contained in the consent form and facilitated the actual consent process. Participants were also given the opportunity to ask questions about the consent form and consent process immediately prior to the beginning of the focus group discussions.

In addition to the moderator, one additional person was present at each group to help expedite the signing of consent forms and take notes. The importance of confidentiality, including the fact that participants should keep information shared in the focus group confidential, was addressed by the moderator prior to the start of each group discussion. One other individual, typically a focus group facility host, was present to help process participants and to be available in case a

participant was unable to continue to take part in the discussion and needed to leave the room.

2.3. Subject Participation

All focus groups were conducted in English, with the exception of the Montreal group, which was conducted in French by a French speaking moderator.

The focus groups took place in dedicated focus group facilities in all cities except Halifax and Hamilton where centrally located university boardrooms were used for convenience and cost savings. Participants were seated around a table with the moderator and the note taker. The focus groups took approximately two hours to complete.

Focus group participants were asked to provide demographic information (i.e., age, sex, education, ethnicity, employment) through a brief questionnaire which was completed prior to the beginning of the focus group but after signing the consent form. Identifying information such as name and address was not included on the questionnaire. Participants received a \$40 honorarium intended to offset the costs associated with attending the group. The option to fill out a form requesting a summary of the research findings was also provided to participants. Focus group participants were then asked to participate in a guided discussion concerning their views on participating in a long-term study of healthy aging. Topics for discussion included general reactions to a study such as the CLSA, factors that would influence their participation in a study such as the CLSA, and privacy and confidentiality issues.

All focus groups were audio-taped and field notes taken. All audio-tapes were transcribed. Access to the audio-tapes was limited to the transcriber and CLSA staff involved in data analysis.

The type of information sought from participants was unlikely to cause significant emotional or mental anguish and, indeed this was the case. No participants left the discussion prematurely and most commented that they enjoyed participating in the discussion.

2.4. Data Analysis

The audio tapes from the six focus groups were transcribed verbatim. The transcript from the French Language focus group was translated into English and transcribed in one operation. Additionally, a CLSA staff member took notes of key points in the discussion. After each focus group, a debriefing session was conducted to share impressions, compare notes, interpret participants' comments and/or behaviour and make summary and reflection notes.

The primary purpose of these focus groups was to determine the factors that would influence the decision to participate in a population-based, longitudinal study such as the CLSA. To that end, the focus group topics were designed to elicit information around themes and concepts that are likely to be important factors in the decision to volunteer initially and then continue to participate in a long-term study. Themes believed to be important to participant recruitment and retention in the CLSA included general beliefs and attitudes toward a long-term study, views on healthy aging, attitudes toward the collection of bio-samples and genetic information, response burden, data collection, and attitudes toward the use of data/privacy. Using a thematic analysis^{9,10} approach, specifically framework analysis, data generated from the focus groups was coded and organized around these a priori identified themes. In addition to the identified themes, several emergent themes were identified.

After a thorough familiarization with the transcripts through both listening and reading, members of the research team identified 15 major themes. Two members of the research team then independently coded all the transcripts to these themes using NVivo qualitative software. The coding was then compared and any differences resolved through discussion. Next, sub-themes for most of the themes were developed by CLSA staff through review and discussion. Each theme was then sub-coded by the identified sub-themes. Based on this organizational structure study findings were summarized emphasizing factors that might influence the likelihood of participating in a long term study such as the CLSA. The study findings are enriched by direct quotes from focus group participants illustrating key points under each of the themes.

The final document will be used to help guide the development of the CLSA and in particular, in the design of a study protocol emphasizing those factors which will increase the likelihood of recruitment and retention of CLSA participants and minimize refusals and attrition. It is also intended that excerpts from this document will be disseminated to a research audience via publication in a scholarly journal. Additionally, an abbreviated summary will be available on the CLSA website for the lay public.

⁹ Taylor SJ, Bogdan R, Introduction to Qualitative Methods: A Guidebook and Resource. John Wiley and Sons Inc. 1998.

¹⁰ Strauss AL, Qualitative Analysis for Social Scientists. Cambridge University Press. 1987.

3. Study Findings

3.1. Profile of Focus Group Participants

Focus groups ranged in size from 4 to 10 participants with a total of 43 participants across all six groups. Individually, and in total, the groups were well balanced by gender and also age group. In all there were 22 males and 21 females. Participant age ranged from 41 to 79 with a mean of 59. Fifty-one percent of participants were in the 40 to 59 age group and 49% were in the 60 and older group. Participants varied considerably in terms of education with 37% having high school or less, 23% with vocational training or community college and 14% with some university. Twenty-five percent had one or more university degrees. The majority of participants (81%) were born in Canada. In terms of ethnicity, almost half of the responses (47%) indicated British Isles origins¹¹. Seventeen percent of responses indicated French origins and a further 23% other European origins. Only 1 participant indicated aboriginal origins. The remainder indicated African, Asian or Latin, Central or South American origins. Sixty percent of participants were married with 30% being widowed, separated or divorced; only 10% were never married. Forty-four percent of participants were employed either full or part-time and a further 42% were retired. The remaining 14% were unemployed, homemakers retired or disabled. Household income varied widely with 25% of participants reporting less than \$25,000 and 23% reporting \$75,000 or more with the remaining 52% between these levels. While no claims can be made for representativeness, it is evident from this profile that focus group participants were diverse in terms of their age, education, employment status and income. This also confirms the informal finding that there was significant variation in socio-economic status among participants. This is a significant finding for the CLSA because of concerns that only better educated Canadians would be interested in taking part in research on health and aging.

3.2. Healthy Aging

The concept of healthy aging is a central theme of the CLSA, underlying much of the proposed research. Although it is too broad a concept to easily operationalize in quantitative research, it provided an interesting and useful starting point for our focus group discussions on the acceptability and feasibility of conducting a national longitudinal study on aging. Participants were asked: "What first comes to mind when I say healthy aging?" and were very willing to offer their opinions. The focus group discussions generally revealed an evolution of thinking on the part of participants. Initial comments tended towards the physical and lifestyle aspects of healthy aging, while later comments moved into

¹¹ Participants were permitted to indicate a number of ethnic origins. The percentages are based on total responses, not cases.

the social, emotional and spiritual aspects of healthy aging. In all, eight sub-themes were identified for healthy aging.

3.2.1. Physical

Most discussions of healthy aging began with the physical aspects. Concepts identified by participants included the notion of comfort. Closely linked to this concept was freedom from pain, illness, debilitation and medications.

“I think it's living to a ripe old age without being incapacitated.”

Some participants felt that while aging was inevitable, it was important to reduce the suffering associated with aging and expressed fear of what aging might bring, in particular, mental or physical incapacity. While some participants embraced the idea of healthy aging, others doubted that healthy aging was possible, citing the inevitability of some form of sickness or incapacity. One participant thought that healthy aging was an oxymoron. Others felt that, despite our best efforts, we really have no control over what will happen as we age and that is, perhaps, a good thing.

“...whether we want it or not we will start to lose it physically and psychologically.”

Some discussion centered on looking after your health, or not looking after your health, when you are young and the consequences as you age. Some participants expressed regret that they had not taken better care of themselves when they were younger.

While almost all discussions of healthy aging started out with discussions of the physical aspects of good health, they quickly evolved to consideration of other factors. Physical health, it became clear was a necessary, but by no means sufficient, component of healthy aging.

3.2.2. Lifestyle

Many participants reflected on the contribution of proper diet and rest, maintaining a healthy weight, physical activity and not smoking or drinking to healthy aging. There was considerable discussion of the value of organic foods and the dangers associated with poor dietary choices.

“Eating as naturally as possible, organic preferably...”

Smoking was also the subject of much discussion of the negative health consequences and the difficulty encountered in trying to stop. Surprisingly, one participant attributed her decline in health to smoking cessation.

A number of participants mentioned exercise and active living as beneficial both in the physical sense but also in the sense of community involvement.

“I exercise daily, I try to be active and involved...my job is very fulfilling...and I try to get my proper rest.”

Mental stimulation was also mentioned by several participants as key to healthy aging, mostly in the context of reading books.

“I think healthy aging has to do with making good lifestyle change, or choices. It has to do with diet; it has to do with getting the correct amount of sleep, exercise...it includes mental stimulation too”

Another factor that was mentioned was environment, both in the context of toxins in the environment and in the food chain and also your surroundings, such as living in the country and having family and friends and other forms of social interaction.

“I...believe the better the environment you have, the better chances you have of having a better life and living a lot longer.”

Several participants also saw communication as a contributor to healthy aging both from the perspective of having someone to communicate with and also the mental stimulation involved in doing so. Stress was mentioned in several groups as a factor contributing to poor health.

“One thing that everybody has to learn to manage, I think, is stress because so many things are stress-related today that are causing so many deaths and if a study like this helped one manage their lifestyle and manage stress I think...it could be very beneficial.”

There was some discussion of intergenerational differences in lifestyle with participants pointing out differences in their lifestyle and that of their children or the younger generation in general. Several participants felt that because of the younger generation’s greater awareness of health concerns and their consequent healthy choices, they will likely remain healthier longer. One participant contrasted the technical knowledge of the younger generation with the wisdom of the older generation and felt that the older generation still had much to offer.

“...the young people look at the seniors as leaders, as a group that has a lot of experience, worldly experience, worldly wisdom... We are old but we have a lot to offer them.”

Some participants contrasted Canada with other countries or regions where there is greater longevity due to different lifestyles, particularly diet, activity and a cleaner environment.

“Now why in a certain nation like Japan, Okinawa, now why people with many years, they still can run, enjoy life? Now why in Canada, we tend to sit down when we retire?”

However, participant interest in longevity was predicated on good health.

“But if we’re going to live longer, I want to be healthier while I’m doing it.”

There was discussion in a number of groups about knowing the right lifestyle choices but failing to make them for a variety of reasons.

“...we all know what to do to be healthy. We all know there’s certain rules we have to obey but do we do that?”

Participants also talked about the importance of regular visits to the doctor and other health care professionals. Several participants advocated a role for the state in educating people about healthy lifestyle choices, especially not smoking.

“The state needs to concentrate on prevention. It would cost a lot less to tell people not to smoke than to care for them.”

Participants showed a keen awareness of the importance of lifestyle choices but also recognized the difficulty inherent in making the right choices. They also saw that longevity was of little consequence if it did not include good health.

3.2.3. Social

The importance of family and friends was a key element of healthy aging for many participants who gave examples of relatives who declined due to a lack of companionship. While family was important as well, a number of participants stressed the importance of friends who were of the same generation.

“...it was no disease that took my father; it was loneliness...because everybody, all his peers were gone...”

Some participants also spoke of the benefits of nursing home placement because of the social aspects of being part of such a community.

Community involvement was also seen as important by some participants.

“...a sense of contribution to the community as a whole.”

Social contact was clearly key to healthy aging for most participants. It is clear that some participants were expressing their own fear of being alone and their hope for companionship as they age. In expressing his views on healthy aging one participant summed it up well.

“Lots of friends and family, a support group; people you can talk to. Have a connection with the community, the people around you.”

Social interaction was identified as an essential component of healthy aging in all of the group discussions and social isolation or loneliness was seen as having profoundly negative consequences. This certainly supports the notion that we are all social beings who cannot be deprived of the company of others without suffering serious mental and physical consequences.

3.2.4. Emotional

Attitude emerged as a key concept in discussions of healthy aging. Participants talked about the deleterious effects of a negative attitude and the beneficial effects of a positive attitude on aging. There was also some talk of the depression that often comes with aging and the desire for happiness as we age.

“..I think life is the way we make it, really. We can make it happy or we can make it sad...by the things we do and say and the way we live”

“...I decided to have a positive outlook in life, personally and secondly, I should have a healthy lifestyle and enjoy the things in life God gave me.”

One participant felt that a positive attitude actually influenced the state of her physical health.

“...I believe that my health is a result of how I think about my health, what I believe about my health...”

Participants talked about the need to enjoy life or to “get in as much as you can” rather than doing nothing or worrying about their health. It was important to have some purpose in life and to remain physically and mentally active and involved in the community and not merely surrender to old age. There was also some discussion about how attitudes towards, and on the part, of the elderly have changed.

“But we think differently about aging too. I remember my parents and my in-laws when they hit their 60’s, they didn’t do anything anymore.”

Some respondents talked about not feeling their age or feeling that their mind was younger than their body and expressed some level of frustration with the feeling of being in an older body, or with social expectations for people “their age”.

“You know what my biggest problem is with aging at 67 is that my mind is 29, my body’s just not.”

Participants also talked about changing attitudes as we age, pointing out that young people often feel immortal while older people feel very frail and vulnerable. There was also some discussion about the act of placing parents in a nursing home indicating that you were next in line and the consequent need for planning.

“You can’t tell a young person about death or about anything because they don’t believe they’re ever going to see it. I didn’t. I’m still not sure.”

The wisdom that comes with age, or doesn’t come with age, was discussed in several groups. One participant felt that the wisdom and experience of seniors should be valued in an increasingly technological society.

“And I think a lot of people grow old but I don’t think that many people grow wise and use the common sense they’ve learned through life to make it easier and better for themselves.”

“They always look for us as a mentor so we should be vibrant like glowing embers...”

In almost all of the groups having a positive attitude towards life and aging figured prominently in discussions of healthy aging.

3.2.5. Financial

For some participants, healthy aging had a financial component. They talked about the need for financial planning in order to have enough money for retirement and expressed concern about whether they would, in fact, have enough income to live comfortably in their old age.

Some participants gave examples from their own experience of seniors who suffered due to lack of financial resources.

“There wasn’t a whole lot of money coming in and... I got the feeling... that she was scrimping on some things, maybe her diet wasn’t the best and I think in the long run it affected her health.”

Participants in several of the groups showed a keen awareness, not only that adequate financial resources were required for healthy aging, but also that the lack of such resources was potentially deleterious to health.

3.2.6. Contextual

Participants in several groups talked about nursing homes, especially about their prevalence and what was seen as the inevitability of being admitted to one, especially upon the death of a spouse. One participant felt that many of the elderly, once in a care setting, lived in fear and under threat of being admitted to a higher level of care if they got sick or if they were no longer ambulatory.

“...you moved into a condominium. Your next step is into a lodge. From the lodge is the nursing home, if you make it... and that seems to be the process. Now I’m not looking forward to that step.”

Many participants felt that the elderly would be better off in their own homes and that better supports should be in place to allow this. A comparison was made with Great Britain where, it was indicated, there was much greater support for seniors staying in their own homes. Some participants felt that there was no compassion in the institutional care system and even likened it to confinement. They felt that not only would the elderly have a much better quality of life in their own homes but it would be less expensive than admitting them to long-term care facilities.

“It would be far less expensive to hire someone to go and give the care that I’m going to need as I age than to put me in a home.”

However, one participant noted that many seniors are insecure and would be nervous having someone come into their home to assist with cooking, cleaning and personal care. Several participants also felt that seniors could be a danger to themselves in their own home.

There was also discussion of government policy as it impacted seniors. Topics included the illegality of in-law suites, the need for better education on healthy living, more support for seniors to stay in their own homes, such as trained home caregivers, more monitoring of long term care facilities and incentives to encourage physical activity. Participants held different views on the value of trying to educate the public about healthy choices.

“...we need to teach them that they need to keep in shape, alcohol, cigarettes, dope aren’t good. We need to speak loudly.”

“...to educate a 20 year old or educate a 30 year old about aging. That’s never going to happen... They don’t think they’re ever going to get older.”

In one group, participants proposed incentives to encourage seniors to be more physically active. They suggested seniors’ nights or other times during which facilities like swimming pools or ice surfaces could offer reduced or even free admission to seniors.

“There has to be things set up where...the healthy lifestyle is encouraged by making the price right for them.”

One participant even felt that those who made unhealthy choices, like smoking, should pay a premium for health care.

“Well, you’re a smoker and you have a lung ailment, if you don’t stop smoking we’re going to penalize your health care...”

Some participants also talked about negative attitudes in society towards the elderly indicating that it was part of a larger problem of lack of respect throughout society. Others felt that the elderly were not valued for what they could contribute to society. Comparisons were made with other cultures such as aboriginal peoples who were seen as having greater respect for the elderly.

“The older you get, the more devalued society sees you.”

“It’s this huge resource that’s being wasted; wisdom and knowledge just being shoved in the corners in nursing homes...”

Some participants also expressed their own fears of aging and death.

“...I think if I’m truthful with myself, I think I probably fear getting old...”

Others felt that society, itself, did not want to confront the reality of aging and death.

“...they’re reaching the end of the road and to help people understand that and help society...start dealing with the fact that death is a part of life, you know, and nobody wants to deal with it.”

In this context, participants discussed not only the ageism that exists in society but their own fears of loss of control, aging and death. Most felt that governments should do more to maintain seniors in their own homes and encourage healthy aging by providing incentives and education. They also

discussed the change in attitude that comes with aging, from feeling immortal when you are young to feeling very vulnerable when you are older. Underlying this discussion was the sense of a society that values youth more than the elderly and which ignores, or covers up, the reality of aging and death.

3.2.7. *Spiritual*

In several groups the spiritual side of healthy aging was discussed, especially in terms of spiritual growth as one ages. Some participants talked about the balance between several different components of healthy aging.

“I feel very healthy and... for me what it means is being physically, mentally, emotionally and spiritually balanced... My spiritual life is number one for me and I try to be of service to others wherever I can, whenever I can.”

“I think my strongest feelings are towards a balance between physical, emotional and spiritual.”

3.2.8. *Independence*

For several participants healthy aging was about independence of thought and action.

“Being able to do the things you want to do without any restriction; enjoying life to the fullest.”

“Being able to do what you want, when you want, how you want without suffering for it, that is being healthy.”

Participants exhibited considerable interest and engaged in spontaneous discussion on the topic of healthy aging. Their discussions covered many facets of aging and their thinking evolved to include more subtle aspects of aging such as the spiritual and even the financial side. Participants demonstrated an understanding of aging as a complex multi-dimensional process which was worthy of study.

“too many people, when you say healthy aging, they think only physical health but healthy aging has to do with using yourself spiritually, your growth, your intellectual growth as well as your physical growth and also having the finances to maintain a lifestyle.”

Considerable insight was shown into societal attitudes about aging, such as lack of respect for the elderly and what was seen as almost a denial of the reality of aging and death. Participants were very honest in expressing their own fears of growing old and the consequences, including death. While participants seemed to hold out hope that they would age in a healthy, enjoyable way, this hope was

tempered by reality for many who were already experiencing serious health problems and for others who feared them. There was a general sense of the value of a study such as the CLSA and a hope that the study would provide insights into aging that may not help them, but at least would benefit future generations.

Participants talked about suddenly realizing that they were old and wishing they had taken better care of their health when they were young. They talked about their attitudes changing, from thinking they would live forever to feeling very vulnerable. The death of friends and relatives was a key factor in increasing their awareness of their own mortality.

The discussion of healthy aging has several implications for the CLSA. It indicates considerable interest in the topic which may make recruiting easier. Participants are also interested in the study findings although many suspect they personally will not benefit. There is also interest in the public policy implications of the CLSA with many participants advocating a role for government in health promotion but also in providing better care for the elderly and maintaining them in their own homes longer. Most participants accepted responsibility for own health, recognizing that they knew what the right lifestyle choices were, even if they did not follow them. Participants were curious about the study and seemed pleased that there would be a study on aging. There was a general sense that aging should be celebrated and not denied or hidden away.

3.3. Importance of Research/Altruism

A key question which was posed in the focus groups revolved around the support participants had for research on aging. It was felt that Canadians would be much more likely to become involved initially, and continue to participate, in a study which they felt was worthwhile and which would produce beneficial results. Focus group participants were read a paragraph about the CLSA and asked for their first reaction to the study described. Probes included the importance of the research and the potential benefits to Canadians in general, and participants and their families in particular. Comments related to this theme also occurred in the context of other questions and are included here. Throughout the focus group discussions participants commented on their desire to help others by participating in a study such as the CLSA. These comments are also captured in this section.

3.3.1. Potential Research Benefits

Generally, most participants expressed their personal support for the research, using adjectives like “wonderful” “terrific” and “magnificent” to describe it and indicating the timeliness of the study given that the baby boom generation is beginning to enter their senior years. Some felt that the study should already be underway.

“My first reaction is that this is very important and it should be happening right now. The aging population is the largest population in this country now, and growing... it’s a good thing, I highly approve of it.”

“It’s also going to coincide with the period of time that the baby boomers are going to be hitting old age.”

Some participants also commented on the rising cost of health care and the need for individuals to take responsibility for their own health as a way of controlling these expenditures. The results of a study on aging were seen as a way of identifying lifestyle and other factors that would help promote healthy living.

“Hopefully we don’t tax the health care system as much, if we live a healthier lifestyle...that’s one of our biggest concerns, look at the amount of money we spend on health care...”

Many participants talked about the potential benefits of the study, citing examples from their own experience to illustrate the need for research on health and aging. Participants spoke of relatives who were suffering with, or had died of, various ailments and expressed their hope that research would be beneficial in reducing the suffering often associated with aging.

“My mother...and my grandmother...both died with breast cancer, so if something like this could benefit...my daughters or my granddaughters, then I think it would be a good thing.”

“...yes we have to age, we will die, that is part of life, but suffer less...”

Some participants felt that they, or their families, could benefit personally from participating in the study, particularly through genetic research but also in terms of identifying the components of a healthy lifestyle.

“...those people that are going in the study are doing so for a reason... Do you have personal reasons because you might help family members, you know, genetic things in your family that might be overcome because of participating in a study like this...”

“...as long as they gave me some results of what was happening...something that would be of interest to me to encourage me as an elderly person to be healthier...”

There was also considerable discussion about whether simply being in the study would make participants more conscious of their own health because it was being monitored. Participants were divided on this issue. Some felt they would

monitor their health more closely and try to pursue a healthier lifestyle while others felt that despite good intentions it would be very difficult to modify their behaviour.

For many participants most of the benefits of the study would accrue to society in general or future generations rather than to the individual participants themselves. A number of participants indicated that they wouldn't benefit from the study findings but future generations would.

“Results after 20 years is not really for us but for the next generation.”

In most groups there was discussion about various health problems such as cancer, heart disease and the effects of lifestyle and environment on disease and aging. There was also discussion about the benefits of medical research.

“The reason why people are living longer, I believe that it's because of research, medical research because of ideas people are coming up with... to become healthier... everybody knows that people are surviving with cancer. Diabetes, everything is improving and... it's because of studies and research...”

“It's only through research, I think, that we can really find out...what works and what aging is about and what we can do to make it better for everybody else.”

Some participants were also aware that not all participants would survive for the 20 year period of the study and still others would suffer physical and mental declines. However, they recognized that the ability to study decline and death in the context of a longitudinal study would be very valuable.

A number of participants also pointed out the social policy implications of undertaking a study on aging, reasoning that it would provide valuable information to governments in terms of planning for future needs for seniors.

“Well, out of this, needs will be shown, things that are lacking in the community, as well as information that will help the individual live a healthy life.”

“I mean, basically, I think they're looking down the road in terms of what the demands on the system are going to be because there's a lot of people...”

“Well, if it improves the medical system, provides more facilities, more money...to help people to be healthy...anything to keep people loved and active and honoured and respected for as long as possible, not shoved away.”

Several participants expressed the view that the study would only have value if the results were put in the hands of policymakers. They expressed concern that, like so many other studies, this one might languish on a shelf somewhere. Still others saw a role for the public in influencing government decision-making.

“There are a lot of studies about this that are sitting on shelves. You can have the best study but if the government ignores it means nothing.”

“It will also depend on what the public demands; it won’t be just the government who decides if we can garner some interest and we demand that our politicians do something in that area.”

There was also a concern that the results be made available to participants and ordinary Canadians in addition to health related organizations. There were also questions about whether the data would be shared and/or compared with other national longitudinal studies.

“I think they should reward us by providing education based on the findings; that would be a reward across Canada if they educated the population with the findings.”

One participant brought up the issues of stem cell research but put it in the context of the value of research in potentially saving lives.

“...you have the question of, not so much cloning, but stem cell research, which, as a God-fearing person, you may be very much against... But if you have a child that’s deathly ill that you have a chance of losing, all of a sudden...”

While there was general support for the study and the many benefits of aging research that were identified, there were a few dissenting voices. Several participants felt that the study would not discover anything that wasn’t already known about aging. Still others questioned how the results would be used. One participant wanted to know if the results would be made available to commercial organizations like pharmaceutical companies. Several felt that because of their age they would only be in the study for a few years and doubted that their contribution would be useful.

“Are they really going to find anything out new that they didn’t already know about aging?”

A number of participants spoke about funding for the study, commenting on the cost and posing queries as to potential sources of funding. There were also

comments on government cutbacks in funding affecting not only research but health care funding, particularly de-insuring particular health care services.

“And what will be done with the information they get from this? I’m sure that it’ll be a tremendous amount of money spent on another research study and following people for 20 years. I sort of feel the information is all out there.”

Other topics touched on by participants included problems with the current health care system and geographic differences in health across the country. Participants thought that the study might discover differences in health or longevity based on diet or lifestyle in particular regions of the country.

3.3.2. Altruism

A prime motivation for most participants was the desire to help others. In all groups, a majority of participants expressed their desire to help both current and future generations, as a key factor influencing their participation in a study such as the CLSA.

“I think that should be our goal, to be concerned about others and anything that we can do to help one another, we should.”

“...if I thought for one minute that I could do one thing that would help one person with Alzheimer’s, 2 years down the road, 5 years down the road, 20 years down the road, I wouldn’t care what you asked me to do, I would be signing up for it left, right and centre.”

“...it’s a really serious thing to think about, as far as aging...there’s a lot of suffering out there... If we could accomplish something to ease that suffering, it would be a wonderful thing.”

For some others the motivation to participate was more indirect, having to do more with benefiting society as a whole through research on aging.

“If it’s for the good of society, no problem.”

“I would be content knowing I participated in a good social cause.”

Some participants felt that there should be some form of recognition for their participation in the study. Generally participants eschewed monetary rewards but wanted to be thanked for their efforts and to know that their participation was helpful to others.

“...basically your primary reason for doing it would be to help others. So all of a sudden they come back and say, hey, what you’ve done has helped in this way; that would be kind of nice...”

For several participants, however, their participation was conditional on the results not being used for commercial purposes. While they were motivated to help others they did not want commercial entities profiting from a study for which they volunteered their time.

“...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... my wealth, by all means, you use it.”

Generally, most participants understand, and can identify, the benefits of doing aging research in Canada. Not only do they recognize the timeliness of doing a study on aging, given the changing demographic profile of the Canadian population, but they also clearly see the need for such research. Aging is a reality for most participants, either from their own personal experience, or that of close friends and relatives. It is not a great leap then, for them to want to participate in a study which has the potential to reduce the suffering often associated with old age. Typically these focus group participants seek no other reward than the knowledge that they can help someone else. The appeal of this simple concept for participants cannot be overstated. The appeal of helping others should be emphasized in any material used for recruiting participants to the CLSA. Further, communications to participants must emphasize the value of their contribution to the research. This will help to ensure the high retention levels necessary for a successful longitudinal study.

3.4. Bio-samples

A key component of the CLSA will be the collection bio-samples including blood and urine. Participants were asked several questions about the collection of these samples. Initially, they were asked how they would feel about being asked to give a blood and urine sample for a research study. Subsequent probes asked if they had any concerns, if felt there would be any benefits and whether having to give bio-samples would change their mind about participating. In a subsequent question on privacy and confidentiality, they were asked if they had any concerns about the use and storage of blood and urine samples.

Most participants had no concerns about providing blood and urine samples in the context of a research study. A number indicated that they already do this on a regular basis for their family doctors so it would not bother them to do it for the study. Several participants felt that collecting blood and urine samples added credibility to the study

“It adds credibility... You’re going to see...where people are. Are they improving or not improving, that sort of thing? You know, nobody likes to get their blood taken but I’d say it’s a good reason to have it done.”

“I think that would validate it, if they are taking actual medical information.”

Although most participants were willing to provide samples, a few had questions about why it was needed and what would be done with the samples. There was also the suggestion that the study could simply access this information by contacting participants’ family doctors. Some participants asked about the type of tests that would be conducted and who would have access to their samples. In this context one group brought up the spectre of discrimination by insurance companies but also nursing homes based on the results of blood and urine tests. A few participants said they would provide samples as long as it was “anonymous”.

“I think a lot of people would question...what are you using it for? What are you testing for?”

“I just know that some things that have been found through testing, people have been discriminated against for it.”

In all of the groups only one participant refused outright to provide bio-samples.

“Absolutely not. That’s something I’ll do with my family doctor on a regular basis but there’s no way I’d do it for a study.”

A few participants indicated that some people have a fear of needles and this might present problems for the study. However, a number felt that the testing might have diagnostic value for them, uncovering something of which they were unaware.

“Sometimes it’s a good thing to find out because if they find out in time they can cure it.”

There was some discussion in several groups about the storage of both samples and data. It was not made clear in the questions that samples would likely be cryogenically stored for the duration of the study and a number of participants made the assumption that the actual samples would be destroyed and only the test results would be stored. This would, of course, have to be made clear in any consent form. One participant doubted that any data was in fact secure if someone wanted to access it.

While it is evident that participants will need to be informed of how their bio-samples will be used and given guarantees of confidentiality, giving a blood and urine sample would not inhibit participation for most of the group. In fact for a number of participants, it is an indication of the serious, in-depth nature of the study.

3.5. DNA Samples

A short paragraph describing the nature and potential uses of DNA was read to participants who were then asked how they would feel about having their genetic information use as part of a research study. Subsequent probes asked about concerns over what would be done with their genetic material, privacy and confidentiality of DNA information, the importance of written assurances of confidentiality and what would be done with the material, the importance of university ethics review and linkage of DNA information with other data provided by participants. Participants were also asked if they thought there would be any benefits of having their DNA taken and whether having to provide a DNA sample would change their mind about participating in the study.

A significant number of participants had a number of questions and concerns about DNA samples being used as part of a research study. This series of questions sparked considerable discussion and debate in the focus groups and pointed to a lack of understanding and, indeed, unease among some participants.

3.5.1. *Willingness to Provide Samples*

Some participants spoke about the potential value of DNA in furthering our understanding of many diseases, perhaps leading to treatments and even cures.

“...genetic material is the key...I think if you start studying stuff like that, then you’re starting to see things that people inherit... We know that there is a lot of diseases and stuff that people have that...if studied with a big enough population you might be able to see some kind of pattern and perhaps break the pattern...”

Others wanted to know why DNA was needed as part of the study and what it would be used for. Many participants had an expectation that the study would necessarily offer a full explanation of why DNA was needed and what it would be used for.

“I mean, specifically...why would you need it; what would you study in that area?”

“Well I don’t think anyone [would] ask that question without explaining why it was needed. I don’t think anyone would agree to it without being informed why. And if there were a benefit to

it...I wouldn't object in any way to it as long I was given a full explanation of why and if it would be of benefit and how."

There was considerable discussion of ethical questions surrounding the collection and use, or misuse of DNA. Participants brought up topics as diverse as cloning, forensics and eugenics in their discussions. There was also concern expressed by one participant that some people might interpret the results of DNA testing in a manner that might indicate racial differences.

"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."

"Would it be used for law enforcement, or any of that stuff or just in the study?"

"The big concern...that I would have is that they didn't start doing what Hitler did: trying to get all the blue-eyed kids with blonde hair and start putting them together..."

Several participants also mentioned that DNA would be relatively easy to obtain from an individual without their knowledge, perhaps indicating that they were fans of television crime dramas.

Speaker A: "You could get my DNA after I leave here without even my knowing it."

Speaker B: "You watch CSI don't you?"

Speaker A: "It's so easy to obtain."

Speaker B: "Yeah, that's true, but legally you'd have to have consent."

There was also discussion of the value of university ethics review. There was a comment that the ethics boards were only as good as their members, implying that they might have other motivations, other than the welfare of study participants. There was also an assumption in one group that ethics review would take place after the study rather than before. However, generally, participants felt that knowing the project had been approved by an ethics review board would be an important consideration for them in deciding to participate in the study.

There was also some question as to whether or not a person would want to be notified of a genetic predisposition.

"...there's a gene that most females carry that determines whether they will or will not have breast cancer...and my daughter, she brought that question up: Do you think I should

have my DNA tested? I said no thank you. If you want to, go ahead and do it but do you really want to know?"

A number of participants asked if they would receive the results of DNA testing if they were a part of the study and indicated that receiving such results would be a benefit of participating in the study.

3.5.2 Privacy and Confidentiality

A number of participants indicated that only those with "something to hide" would be wary of a DNA test.

"But generally speaking, I think that the only people that are concerned about confidentiality issues are those with something to hide."

"I'm not planning any murders or anything in the future so they can keep my DNA."

Implicit in this assumption is the notion that the study would somehow share information with the law enforcement community or that there would be some revelation made about the health, habits or disease state of participants. While some of the comments may have been made in jest, they clearly underlie some level of concern about who would have access to the data. Even after it was reinforced that the DNA samples would be used for research purposes only, one participant asked: "So if they found my blood at a murder scene they wouldn't be able to come back to you guys?" However, this does bring up the very valid point that promises of confidentiality to research study participants are not protected under Canadian law, opening the possibility, at least, of DNA samples being subpoenaed in a court case.

Several participants were clear that they would have to have more information before making a decision about providing a DNA sample and would have questions about how it would be used and confidentiality if asked to do so.

Moderator: "What are your feelings about a DNA sample?"
Speaker: "I'd have to know a lot more about it"

Privacy and confidentiality concerns were voiced by a number of participants especially regarding who would have access to the data. Some participants wanted to know if the DNA samples would be completely anonymous while others spoke about the need for confidentiality and how certain diagnoses have been used to discriminate against people for services such as life insurance. One participant felt that it was close to being an invasion of privacy.

"I really don't know much about DNA sampling but I think it's getting pretty close to being an invasion of your privacy..."

Despite some reservations, most participants were agreeable to providing a sample of their DNA for research purposes providing that their questions and concerns were satisfactorily answered. However, this was the most controversial of any of the topics and it is manifestly clear that participants are not well informed about DNA and that they want ironclad assurances of how their DNA will be used and how their privacy will be protected.

Participant awareness of DNA seemed to be largely based on negative images such as human cloning, eugenics and its use in law enforcement. It would be fair to say that among some participants the mention of DNA seems to evoke a negative response based on uneasiness or even fear.

“I would feel leery about it. Right away, I got my back up against the wall.”

While some of the concerns of participants, such as cloning or eugenics, seem unfounded or even ridiculous, it is important to note that they are real concerns for some participants, at least, and so need to be addressed. Based on the information gleaned from the focus groups, considerable time will need to be invested in providing potential participants with information and assurances about how their DNA will be used and their privacy protected.

3.6. Data Linkage

Participants were told that it was possible to link the various types of data collected by the CLSA with individual health records maintained by their provincial health care system. They were then asked how they would feel about having the information they would hypothetically provide, linked with their existing health care records. Although it was not clear in the question, the direction of the proposed data flow was from the provincial database to the study and not vice versa. This was clarified for participants if they asked.

3.6.1. Willingness to Permit Data Linkage

Generally this was not a controversial question but participants did have some questions. They wondered whether this information should not come from their doctor rather than the provincial system and also wanted to know if the information collected by the CLSA would also be shared with the provincial systems. Some participants talked about the disarray of their provincial health care systems and doubted that the information would be available.

Most participants had no problem with the concept of data linkage and even thought that it would be beneficial to the study. However, several participants found the idea somewhat troubling.

“Lets...you find the things that I forgot to tell you.”

“I don’t think that the government has all that much information and I don’t think that I would want a study like this linked to the government at all.”

Some participants thought that only those with something to hide would refuse to allow data linkage.

“Someone who may be abusing the system at the present time might be reluctant to have it done, like an excessive number of doctor’s visits...”

3.6.2. Clarification of Data Linkage

There was considerable discussion of the mechanics of data linkage, including the direction of data flow. Some participants were concerned that data from the study not be shared with provincial health authorities while others had no problem with this concept.

Speaker A: “Oh, which way is it going; from them to you or from you to them?”

Moderator: “...No, from them to the study...”

Speaker A: “But they don’t have access to what you get out of this?”

Moderator: “Right.”

Speaker A: “Okay, that’s my concern.”

Some participants did not understand why the study would want or need to access their health records reasoning that they could provide the necessary information. In some cases other participants addressed this concern arguing that people’s memories were not always accurate or the records might contain information that the person themselves was not aware of. One participant summed up the process in this way:

“Basically you’re taking a shortcut to get the information instead of going through it all yourself...you’re saving money, that’s still OK. It’s still confidential, just an accessible thing.”

3.6.3. Privacy and Confidentiality

Some participants were concerned about the confidentiality of their information and some confused confidentiality with anonymity, asking why their name had to be on the records. One participant brought up the fact that his medical files might contain references to his relatives and he could not consent to release that information, only his own data. There was some reluctance from a few participants to share confidential information with the study.

“I, perhaps, don’t want to tell those researchers things that I went through personally. There is confidential data. I won’t tell you which ones because it is confidential, but those researchers don’t need to know either.”

Generally data linkage was not a troublesome issue for most participants despite some concerns over the direction of the linkage and confidentiality. It will be important to explain the one way direction of data linkage and thoroughly explain why it is being used in order to allay participant concerns.

3.7. Unforeseen Uses of Data

Participants were read a short paragraph which stated that it is impossible to know at the beginning of a 20 year research study all the ways that the information provided by research participants will be used. They were then asked how they would feel if the information that they provided was used for future research that could not be foreseen at the time they agreed to participate. Probes asked if they would have any concerns about this, if there would be any benefits, whether they would want to be notified and whether this would change their mind about participating.

It would be fair to say that participants found this question somewhat confusing and, indeed, it is not a simple concept. There were a number of requests for clarification and, based on participant responses, it is clear that, initially, they thought that the question implied more than it did. Participants wanted to know if the further research would be health related; whether information would be passed on to other studies, other countries, or even patented or sold to pharmaceutical companies. Several participants wanted to know if any money would be changing hands.

Speaker A: “Who would let it be used for another purpose?”

Moderator: “Well, it would be a purpose that hadn’t been originally disclosed because it was something new that had been developed.”

Speaker A: “So again, would there be money changing hands in this?”

“...the objective of the project can’t change; for example, if the government, in fifteen years, said we are running out of money, but selling data to the pharmaceuticals would help us meet our budget... If you mean changes in the objectives I would refuse.”

Despite the initial confusion, most participants understood, or came to understand, the nature of the question and were agreeable, albeit with some caveats.

“Has anybody got a crystal ball? ...the parameters of the study may very well change five years into the study, simply because of medical advances.”

“I would expect it because the idea of this study is to learn.”

“...if you’re going to find something different, or you want to use it for something different, it...extends the validity of the study and how far the study can go, then why would they say no?”

Much of the concern over unforeseen uses of the data was based on the assumption that the data would be given to other studies or other organizations rather than stay within the original study and be used for different purposes.

“...you don’t know where it’s going and then all of a sudden these people [are] no longer involved in the study and some group from the United States are involved in this study and then the whole integrity part of that is gone.”

Even many of those who understood that new tests might be developed and applied to data that had been previously collected, expected to be notified and, in most cases asked for their consent.

“The thing is, if I sign on for something, to go into a study, and understanding what the study is and you want to change the parameters, then you should ask me for permission.”

“You don’t agree to carte blanche and say do what you want to do with it. You agree to: this is the study as I understand it. I’m going to sign and that is the study I’m doing. If you want to do something else with my information, you have to come to me and explain to me what you’re trying to do.”

Most participants found the idea of using their data for purposes that were not disclosed to them initially, troubling at some level. This concept seemed to arouse suspicions which, in some groups, led to speculation about whether participant data would be sold or exported to other countries. While some participants understood right away that medical advances would mean that new tests would inevitably be developed, most did not. Even those who did understand expected to be notified and, in most cases, asked for their consent. It is evident that this concept would have to be carefully explained to participants at the time of recruitment. A central concept would be strong guarantees of the confidentiality of all participant data and the fact that it would not be shared with or sold to any other organization.

3.8. Return of Clinical Results

The return of clinical results to participants was not a specific question in the moderator guide, although one probe did deal with this topic by asking: “What about getting back the results of tests such as cholesterol levels or blood pressure readings?” However, this topic emerged spontaneously in a number of the focus groups without any prompting. Participants asked whether the results of blood or DNA tests would be available to them and even engaged in discussions about the validity of the study if results were returned. Key points of interest were whether all results should be returned or only adverse results and who should receive the results.

3.8.1. Benefits/Desire of Returning Clinical Results

In the course of discussing such things as providing blood, urine or DNA samples, a number of participants asked if study participants would receive the results of these tests. In most cases the moderator asked if they would, in fact, like to receive these results. In all cases, participants responded in the affirmative.

Speaker A: “Would we learn the results of our own tests?”

Moderator: “Would that be important to you?”

Speaker A: “Well, it would save me going to the doctor once a year...”

Moderator: “...is that how you see it?”

Speaker A: “Well, I’m being silly, but, well, it’s information, you know, why wouldn’t I want it? I mean, yes, I would want it.”

Speaker B: “I would too”

Speaker C: “Yes, I would like a record of that...”

Participants also perceived the communication of personal test results as a benefit of participating in the study.

Speaker A: “Yeah, I would like to know the results.”

Moderator: “Would that be a benefit to you in terms of participating?”

Speaker B: “Yes, definitely.”

Speaker C: “Well, it would mean that you could follow up with your own doctor.”

Speaker D: “You’d feel more involved”

Speaker E: “You’d feel like you’re not just a guinea pig.”

“But you’re saying: what would the benefits of being in a study like this be? That could very well be one of the benefits, to have more information, more broader information, more precise information about your and your family’s health.”

Some participants wanted the information collected as part of the study to be shared with their physicians indicating that, in some ways at least, they see participating in the study as a way of supplementing, if not substituting for, their own health care and health care providers.

“Because I think if you went into this study, I think your own personal doctor should be notified that you’re doing this and that they’re getting a report on how you’re doing...”

3.8.2. Concerns about Impact on the Study

Some participants were cognizant of the fact that returning individual test results could affect behaviour or lead to treatment which could potentially alter the outcomes of the study. This led to a debate in some groups between those favouring a “pure” study and those who wanted to receive their results, especially adverse results.

“...I’m hearing that the crowd here thinks that...there’s going to be some kind of benefit for themselves by doing this...is that, in fact, what’s going to happen? My understanding of the study is just taking a sample of the population and the feedback is not necessarily what’s going to happen.”

“...but for you to step in and make decisions that will affect the results...will void the study.”

Some participants were concerned that even general results would not be released before the end of the study.

“But if after five years you find out that 10% of the people...are ending up getting some disease or whatever, would you wait until the 20 years is up to say we’ve found something...?”

It was clear that some participants had knowledge of how clinical trials have been conducted and felt that the study should also proceed in this manner. Others felt that this study was different and individual results should be shared with participants.

“In the interest of science, I think it has to be cold-hearted myself...are we trying to fix people or are we just trying to figure out, is there a problem?”

“...what you’re talking about is more like a double blind drug company study. This is more of a health and lifestyle study...and there’s nothing wrong with knowing the results...”

3.8.3. Adverse vs. Routine Results

Participants were generally interested in receiving the results of individual tests but some felt that they already got this information from their doctors so it was not critical to know. The sense conveyed was that it was “nice to have” but not essential. However, participants were, quite naturally, much more concerned about receiving any adverse findings and felt that the study should be responsible for passing on such information either to the participants or their physicians.

“If they did do a blood test and they found something abnormal, would they let you know?”

“I think if my blood pressure was high and I was ready to pop a valve and they found out about it, they should let me know...”

Most participants felt that only adverse findings should be reported reasoning that individuals were responsible for their own health but a few thought that participants should get all test results.

“And I don’t think the study should report back on everything they find, but if they find something serious, I think they should let you know.”

Speaker A: “Yeah, but ultimately our health is our own responsibility and it is up to us to go to our own doctor on a regular basis...so it shouldn’t be their responsibility to...say, yeah you’re healthy or you’re not healthy, but if something big was found, then, yeah, I’d like to hear about it.”

Speaker B: “Yeah, but they’re getting the results anyway. All they’re giving you is like a print-out of whatever it is. It’s not like they’re doing extra work. They’re not.”

Participants also wondered whether test results could be passed on to their physicians.

“Would there be anything... in the study that any abnormalities detected in the blood work that the participant had... signed a release so the information could be passed on to their own doctor?”

“...I would think that this would cover the individual whose doctor hadn’t found it.”

There was considerable interest among participants in receiving individual test results. Indeed, this topic surfaced spontaneously in several groups during the discussion of blood, urine and DNA testing. Generally participants were

interested in their own health and seemed eager to be able to have some additional means of monitoring it. While receiving test results was perceived as a benefit of participating, most participants also recognized that the distribution of routine results would be time consuming and were content to have only adverse results communicated. In some groups participants engaged in a debate about ethics vs. science. Some felt that the study had an ethical obligation to return individual results, especially adverse findings, while others felt that if participants changed their behaviour or lived longer or healthier lives as a result of interventions brought about by participating in the study, the study would not be valid. It is interesting that focus group participants engaged in the same ethical debate as researchers about returning clinical information. It is also evident that there is an expectation that a study like this would return clinical results to participants or their physicians, especially if they were adverse.

3.9. Responsibility for the Study

Participants were asked: “Who do you think should be responsible for conducting a study like this?” Probes to this question included: “Is it important to you to be able to recognize the name of the organization that is conducting the study?” and “Is there a particular organization, or type of organization, that would make you feel more comfortable about participating in a study like this?” While the purpose of this question was to assess the comfort level of participants with a university sponsored research study, the question also elicited a number of other comments on the role of the government and pharmaceutical companies.

Some participants spoke of general characteristics such as integrity or reputation, but most identified universities, which clearly emerged as the top choice, and indeed the only choice, in all the focus groups. Universities were seen as credible organizations to carry out the research and trusted to do so in an ethical manner. It should be noted that in the recruiting process, the university affiliations of this research study were noted and this may have played a role in the overwhelming endorsement given to universities. However, a number of participants indicated that the only reason they agreed to attend the focus group at all was because of the university connection, and in particular recognizing the name of a university with which they were familiar.

Speaker A: “That’s why I was here tonight because I said to the young lady that was on the phone: “who are you with?” and she said who she was with; then I was willing to listen.”

Speaker B: “I would have turned it down otherwise.”

Moderator: “And that was?”

Speaker A: “Dalhousie.”

Speaker B: “Mine was McGill.”

“Now if it was a name I didn’t recognize, I wouldn’t be here.”

Recognizing the name of a particular university was important for a number of participants but for others it was not an issue.

“...I may not know the name but I’m sure they’d have the credentials...to do this research.”

Most participants identified universities as the appropriate organizations to undertake this research either in general, or citing specifically Dalhousie, McGill or McMaster, the universities identified with this phase of the study.

“I think when you put three names like that across the top of your letterhead that lends a lot of credibility, you know, McGill, McMaster, Dalhousie.”

“It has to be a university. That’s where the most brains are. McGill has such a good name as Dalhousie.”

It was interesting to note that in several groups, one participant suggested that the government conduct the study but quickly changed their minds upon reflection or as a result of the comments of other participants.

Moderator: “Who do you think should be responsible for conducting a study like this?”

Speaker A: “The federal government.”

Speaker B: “I don’t know. Gotta be a better option than the federal government... Granted, you might be able to get some grants or something from them...”

Speaker A: “She’s right, I take mine back.”

“Alright, scrap the government and go with the university, absolutely.”

“Not the government, the university people who designed it. They’re the ones who understand what they want to find out about and have some idea where it’s going.”

A number of participants were openly distrustful of governments in general and the federal government in particular.

“And I certainly wouldn’t trust...I would look for ulterior motives from the government.”

“Because I’m really leery about government just as you are leery about pharmaceutical companies. I feel the same way about government.”

While government was not seen as a suitable entity to carry out the study, most participants identified it as the logical entity to fund the study.

Speaker A: "...how are they going to get the funding if there isn't some association with government?"

Speaker B: "Well, the government does fund things and, as long as they're not dictating."

"...so I feel it should be done through the universities, but the federal government fund it for them."

"...that's what I say, get the money from them. Don't put it in their hands."

Participants were also concerned that pharmaceutical companies not be involved in funding the study and some were concerned that these companies might become involved and this fact would not be disclosed to participants.

"So perhaps these are pharmaceutical companies behind McGill or Dalhousie; I don't know if you can provide the names, otherwise we can't really know can we? Getting the names of the universities is reassuring, but at the same time, pharmaceuticals could be the major power behind these studies."

"I think it's a bit naïve to think the research departments don't get the money from major pharmaceutical companies, that's where they get their research grants, you know."

Speaker A: "Are we talking about the pharmaceutical companies? Are we saying, yeah, let's get them on board or let's exclude them? Is it that sort of thing?"

Moderator: "...do you feel that they should be responsible for doing the study..."

Speaker B: "No."

Speaker A: "No, I'd say definitely not."

Speaker C: "No, definitely not."

Speaker D: "I'd ban them."

Moderator: "You'd like to ban them?"

Speaker D: "Yeah."

Speaker C: "Yes, I'd say they'd be the most unethical to have on board, frankly."

There was concern among participants that whoever conducted the study, it should be a non-profit organization and the study should not be done for commercial gain.

“The most important thing is the organization that forms this survey study should be non-profit organization...”

“People that have a commercial interest, definitely not.”

Universities were the clear choice to conduct the study among participants in all focus groups. Universities are perceived as having credibility and knowing the name of a university was an important consideration, for some participants, in making the decision to attend the focus group. Participants were wary of government involvement in the conduct of the study but felt that government was the appropriate body to fund the study. There was particular suspicion of pharmaceutical companies being involved but also recognition, on the part of some participants that a lot of medical research was funded by pharmaceutical companies. Distrust of government and “Big Pharma” has implications for the CLSA. It is clear that recruitment and retention would be compromised by any involvement from pharmaceutical companies. Government involvement is also suspect and it is likely that recruiting participants would be more successful if it was done on behalf of the universities involved in the study than if there were any government involvement, such as “piggybacking” recruitment on a study carried out by Statistics Canada.

3.10. Commercialization

Participants were read a paragraph about the possible commercialization of study discoveries. They were then asked how they would feel if research findings from a study they participated in were used as the basis for commercial products. As probes, participants were asked if they would want to be notified about this and if they expected any compensation. They were also asked if the potential for commercialization would affect their willingness to participate in the study.

Participants in some groups were initially somewhat wary of this question, sensing that someone might be deriving a benefit from their voluntary participation in a research study. There were also a number of participants who recognized that without commercialization of discoveries, there would be no avenue for new products to reach the marketplace. In most of the groups, both points of view were represented and while there was no consensus on the issue, there did appear to be an evolution of opinions in some groups from suspicion to reluctant acceptance of this process. Once again, distrust of pharmaceutical companies was evident.

Some participants had no problem with this concept initially, or after clarification that commercialization was limited to medical treatments or diagnostic tests. They even saw the potential for new medical discoveries as an important part of the study.

“Well, if something didn’t come out of it, I would be disappointed. The reason for the study is to come to a conclusion and discover something. How exciting is that?”

Speaker A: “I’d say great. If they were able to use the information to improve health...”

Speaker B: “That was the reason for the study in the first place.”

Some participants were wary of the idea of commercializing research discoveries and gave conditional acceptance while others had mixed feelings, recognizing the potential benefits, but concerned about the greed of pharmaceutical companies.

“It would depend on what that product was and what the purpose of it was. There might be something that I disagree with strongly, in which case I wouldn’t agree to it...so it depends.”

Speaker A: “It’s mixed because I guess I listen to the radio too much on drug companies making a ton of money and I don’t know whether they’re...If somebody’s going to benefit from it then I’m happy for that but I’m just...”

Speaker B: “You just don’t want the drug company to make money.”

Speaker A: “Yeah, because the drug company represents...a very small portion of people. I would rather see a large portion of people benefit from it, but if the general population is going to benefit, wonderful.”

Speaker A: “...I’ve just read too much about the manipulations done by the drug companies. They’re very powerful.”

Speaker B: “But you know, on the other hand, the drugs that we have today are saving lives...”

There were other concerns expressed by participants about the commercialization of research discoveries, including fears of pharmaceutical companies funding the study and thereby gaining control of it and also the possibility of participant data being patented or sold.

“Well, I guess I’m a little concerned that if...they’re using whatever samples, and some drug company is involved, then does the drug company start funding and manipulating your study?”

“I mean, how do we know when we give blood into a lab, if they find something specific you would never know if that blood you donated has been...patented or sold.”

Most Participants wanted to be notified if research discoveries made as a result of a study they participated in were commercialized. The primary motivation for this was acknowledgement of their contribution to the study. A few others felt that notification, especially if it involved approval, would be impractical.

“You should be notified. You should know you’ve been a benefit to the cause.”

“...your primary reason for doing it would be to help others. So all of a sudden they come back and say, hey what you’ve done has helped in this way; that would be kind of nice...”

“...but I think if I’m agreeing to the study, I also can’t expect somebody to be calling me up every few months to say: we’ve produced this drug, do you agree with it? I think at some point I’d have to trust that... whatever you do with the results is up to you...”

There was considerable discussion in all groups about the disposition of royalties that might accrue as a result of scientific discoveries. There was some discussion that participants should receive a share but, in most cases, this was suggested facetiously or seen as impractical. There was, however, the suggestion in several groups that participants should receive any new drugs free or at reduced cost. Most participants who addressed this issue felt that the study itself should benefit from any scientific discoveries.

“But if you want to slide me a cheque along the road, well you know my address...”

“Everybody seems to be jumping on the bandwagon saying no, we don’t need compensation but if...they take that information and they make 500,000,000 dollars selling some kind of pill or process, I think I should get something out of that.”

“I like the idea that if it was attributable directly to this study, yeah, use it for ongoing research, put it back; roll it back into the study.”

“You would hope that if some commercial venture came out of it, that some of the profits could be directed to the three universities...”

There were numerous comments about “greedy drug companies” and a general sentiment that pharmaceutical companies should not profit, or at least not profit too much, from discoveries made in the course of the study. Some participants

seemed to make a distinction between medical devices or diagnostic tests and pharmaceutical products.

“How a company deals with that... if it was just in it for the greed and the profits, then I don’t want to be a part of it. I want to help somebody.”

“...if you’re going to create some kind of diagnostic tool that’s going to help someone, I have no problem with that but if you’re going to create a pill that one pharmaceutical company can make hundreds of millions dollars off of when I’m already upset with the way they act and the way they make money on other people’s pain...so I wouldn’t want it to go that way. But if it’s something medical that’s going to help, that’s a different story.”

“Because if they used the findings to develop a drug, if it is good for the population, if the price is affordable, I would agree, but if you give them your data and they kill you with the price, then it is not right.”

“But in this case, the research is free. They’re taking advantage of research that was gathered and freely given by people and actually sponsored by the Canadian taxpayer, so if they’re going to capitalize on it, I would expect that anything that was done would be the property, or at least the taxpayer would be partial owners of that, and so, instead of paying, I would expect some kind of a benefit. If they discovered a new drug, you know, because of this research, I would expect instead of paying \$50 for a pill, you know, giving it a reasonable price, then that’s what I would expect. Like, they shouldn’t be allowed to make millions because of free research.”

However, some participants accepted that without some return on investment pharmaceutical companies would not invest in producing and testing a new product and it would not become available to the population.

Speaker A: “If they do make a pill and people are going to benefit from it, what’s the harm in it? Somebody’s going to make money off of it.”

Speaker B: “That’s right. If it wasn’t for the study, they wouldn’t be able to make that pill.”

Speaker C: “The drug to help people.”

Speaker B: “I can’t see a problem with that.”

Speaker A: “People are going to make money from it, yes. You can’t do nothing about it.”

Speaker B: “But that’s what the study’s all about isn’t it? That somebody is going to benefit one way or another.”

Several participants felt that there was no way of preventing the commercialization of research results because those results would be published in medical journals. Others felt that this would level the playing field to some extent by not allowing one pharmaceutical company to benefit through a special relationship with the study.

“I don’t see how you can stop that from happening because your research is going to be published. Anybody can read it. Anybody can say: hey, I’ve got a great business idea. I can take that research you’ve done and develop this from it and start selling it, so that’s the normal way we do things.”

“It would be alright for me as long as the study findings are also available to different companies wanting to use them, not because there is an agreement between the company and the government.”

Commercialization was one of the more contentious topics discussed in the focus groups and produced a diversity of opinions. Initial reactions tended to be negative and there is no doubt that this view was coloured by perceptions of pharmaceutical companies as powerful and greedy entities which profit from the misery of others. A number of participants, however, recognized the necessary role of pharmaceutical companies in bringing new products to the marketplace, but still felt that there had to be a balance between the public good and the profit motive of commercial enterprises. This was especially true in the hypothetical circumstance presented because the pharmaceutical company was only testing and marketing a discovery made by others. Participants were concerned that the study benefit from these discoveries through the payment of royalties. While there was some discussion of participants receiving some compensation for their participation this was largely, although not entirely, facetious. Participants do, however want to be notified of any new discoveries and see this as a “pat on the back” for their participation. They were also concerned that there be a level playing field with all pharmaceutical companies having the same access to study discoveries. It is evident that focus group participants view pharmaceutical companies with a high degree of suspicion and would likely balk at participating in any study in which they played a part. Even the potential involvement of pharmaceutical companies in marketing a new product would have to be carefully explained to participants.

3.11. Privacy and Confidentiality

Privacy and confidentiality has already been discussed in the context of questions in which it emerged as a particular sub-theme. However, there was

also a specific question in the moderator guide that dealt with issues surrounding privacy and confidentiality. Participants were read a short paragraph and given an assurance that their privacy and confidentiality would be protected if they participated in the study. They were then asked if they would have any concerns about the protection of their privacy if they were to participate. Probes to this question included concerns about the release of personal information and medical information and also the use and storage of blood, urine and DNA samples.

Most participants expressed little concern about the protection of their privacy. There were a few questions about how privacy would be assured but generally participants seemed to have an expectation that their privacy would be protected in a study like this. This may have been due to the complex consent form that they had to sign in order to participate in the focus group itself, and also the guarantees of confidentiality that were extended to them in this regard.

“You walk into something like this, your expectation of privacy; you believe it’s going to be confidential because that’s the surrounding you’re in.”

“It is all based on the credibility of the agency directing the study. Since I decided it was a credible agency, I would not be worried.”

“You actually can tell when we walked in; you...signed so many papers and understanding stuff. I mean that’s just right off the bat. You understand that...you took all the precaution already obviously.”

Other participants felt that they could trust universities in general and the three universities undertaking this research in particular.

“That’s why I think if the research is done by a credible group like a university, I think you can rely that they will keep it confidential.”

“Yeah, but if it was them, Dalhousie or Mac doing this, I can’t see that you’d be reading about it in Maclean’s magazine and see your name come up.”

“Like I can’t see that if it’s you guys that are doing it...I don’t see that it’s a problem.”

A few participants had some concerns about who would have access to the data or expressed the view that they would like more information about how their privacy would be protected. One participant reserved the right to refuse to answer any questions that dealt with private matters.

“I think things would stay pretty private but, you know, if information goes then to... another company, then it’s not private anymore.”

“I suppose it would all be within the hands of the study. I presume it’s not for sale.”

“If I were...getting involved in this study, I’d want to know how that was being done.”

“There are private things that I would not want to share...so if I had that right I would not be worried.”

A few participants were confused about the meaning of confidentiality, assuming that it was synonymous with anonymity.

“...How can they ensure confidentiality...they know who you are; they have your name, telephone, address...how can it be confidential?”

Most participants had no concerns about the protection of their privacy. In fact, in one group, participants became impatient when this question was asked, indicating that they had already said they had no concerns about privacy and confidentiality.

Speaker A: “I think we already answered that...”

Speaker B: “Yeah, I think we already had that one.”

Speaker C: “It’s no biggie.”

Participants were not greatly concerned about the protection of their privacy in a research study such as the CLSA. Some had concerns, such as whether anyone outside the study would have access to it while others wanted more specific information on how the confidentiality of their data would be assured, but, in general, there was an expectation that their privacy would be protected and most trusted universities to make and honour this guarantee. Some participants were reassured by the consent process for the focus groups and the guarantees of confidentiality that were given for the data collected in these groups. While it is essential that potential participants for the CLSA be fully informed of the confidential nature of any data they contribute and how their privacy will be protected, it does not appear to be a worrisome issue for these focus group participants.

3.12. Participant Requirements, Response Burden, Feelings about Participation

Participants were asked a number of questions which probed their willingness to participate in a study which imposed a relatively high level of response burden on them. They were asked their feelings about committing to a 20 year study, visiting a clinic for a four hour physical assessment and interview every 3 years, and their motivations for participating or not participating in the study. As a final question, participants were asked if they would agree to participate if asked at that moment. All of these questions and their attendant probes were designed to elicit responses which would help to determine if the proposed study design would impose an unreasonable burden on participants and if there were particular elements of the research design which might make participants less likely to want to participate in the study.

3.12.1. Response Burden

Participants were read a short paragraph indicating that the proposed study would last 20 years and they would likely be contacted every three years and asked to provide a variety of information. They were then asked how they would feel about being asked to participate in a long term study such as this. Probes dealt with any concerns they might have, if they perceived any benefits to participating, and if the length of study would change their mind about participating.

The length of the study did not seem to concern most participants. One or two indicated that they would want to know more about the study and its parameters before agreeing to participate but, generally, most were not bothered by the prospect of undertaking a 20 year study. Several indicated that they did not expect to be around in 20 years or facetiously suggested that they would sign up for the study if doing so would guarantee them another 20 years.

“I would like it to be less but whatever it takes to reach a goal, okay. If it means to be committed to an issue that is going to better lives, well then there’s no time limit.”

“I think if one is being asked to participate in a 20-year study...you would expect to be contacted regularly, otherwise there’s not going to be much studying done.”

“If you can promise me that I will live for another 20 years, no problem.”

“...you know you might not get 20 years, but you might get 10 years out of me. I can pretty well guarantee that you wouldn’t get 20, but anything is something that may help someone else...”

“Like an added goal; I want to finish this. I want to be around in 20 years.”

Several participants astutely pointed out that not everyone who started the study would make it to the end but this, in itself, would form an integral part of the study findings.

“It would be of interest to this study if any of us kicked off anyways, to be honest.”

A number of participants affirmed their interest in participating in such a study with some indicating that they would enjoy being part of a long term study, especially if they felt that the results would help others.

“I would like to be chosen to participate in it in hopes of perhaps helping someone else, or some of the information you gather will benefit the future aged.”

Several participants wanted to know if they would receive feedback on the overall results of the study before it concluded and indicated that this would be a beneficial aspect of participating.

“...I guess it would have to be going for a few years before you could see some results, and it would be perhaps interesting for the participants to know...what you're seeing, in a general way.”

Participants were eager to offer comments on the conduct of the study. Several felt that the follow-ups needed to be more frequent than three years in order to track changes among participants but also to ensure that contact information was kept up to date and participants would remain in the study.

“...I'd say it would have to be done at least every two years, a contact, because a lot of health related issues can come up in two years, I mean, even a year you know.”

“...I think you might have to keep in contact more than that, because in three years time, I'm not sure whether I'll be at the address that I'm at now...”

Participants were also told that study members would likely have to come to a central location, such as a clinic or a university, for a physical assessment and asked how they would feel about this. Additional probes dealt with topics such as the effect of distance on their decision, the effect of a particular location such as a clinic or university, and the effect that the amount they were reimbursed for travel would have on their decision to participate. As a follow-up to this question, participants were told that this assessment, along with a personal interview,

could take up to hour hours of their time. Again, they were asked how they would feel about participating in these activities over this time period. Probes focused on any concerns they might have, any benefits of participating and whether or not having to take part in these activities over a four hour period would change their mind about participating.

Although some participants had a number of questions and wanted clarification on some issues, coming to a central location for a physical assessment and interview that could last four hours was not problematic for most.

“I’d be disappointed if it didn’t happen that way. I think that if you’re going to do the study, then you should know the subject...”

“I think that’s part of the study. You know that before you go in don’t you? You don’t expect just to have somebody mail you a letter and fill out the questionnaire and send it back.”

Speaker A: “I would expect to have to go to a clinic somewhere...”

Speaker B: “Yes, it’s got to be done.”

Some of the specific concerns mentioned by participants included: the types of testing and physical measures that would be performed, who would be conducting the testing, if the testing could be done by their own doctors, the difficulty elderly participants might encounter in getting to a central location and what would happen to participants if they moved during the study.

“But I’d have to know what kind of tests you’re going to run me through. One thing, I couldn’t go in some Goddamn machine, just stick you right in the hole...I get claustrophobic, right? I ain’t going in that thing.”

“Well, I wouldn’t mind if it was going to be done by a medical doctor. I would not really be comfortable if it wasn’t an MD.”

“A lot of people that are older can’t get around on their own. They’re going to be relying on their support group...friends or family so a lot more people would be involved in these studies than just these people who’ve consented.”

The distance they would have to travel was not problematic for participants as long as it was not another city. Participants in most cases expected that they would have to travel to a central location for this type of assessment. However, this did not prevent several from asking if the assessment could be done closer to their own community.

“Within limits; I mean this is fine...if you want us to travel to Montreal say, then there would have to be some type of...compensation.”

The particular location, be it a hospital, a clinic or a university was not an issue for most although some participants favoured a convenient, private location which was easy to find and which had abundant parking.

“I don’t think it would make much difference between a clinic and a university here, as long as it’s an area you’re able to get to... It’s got to be something that’s pretty straightforward to find.”

“As convenient as possible I suppose, as central as possible.”

For the most part participants expected to be reimbursed for their out-of-pocket expenses and considered the amount they received to cover the expense of coming to the focus group (\$40) to be a reasonable amount. However, there were a few who didn’t feel the need for compensation and even felt guilty about taking the \$40 which was offered to offset the costs associated with attending the focus group.

Moderator: “Would the amount that you were reimbursed for your travel affect your decision to participate?”

Speaker A: “Sure.”

Speaker B: “If you’re not paying, I’m not going.”

Speaker C: “If you’re reasonable.”

Speaker D: “I think it was fair tonight.”

Moderator: “Okay.”

Speaker A: “I mean I sure didn’t come here for 40 bucks, that’s for darn sure.”

Speaker C: “I don’t think anyone did.”

Speaker D: “so the money’s not an issue...you can learn from the study.”

“Well, it makes it more difficult when you have to...come quite a distance, it’s costly and your time and all this...”

“...if it works with my work schedule and if they paid transportation and parking, it would motivate, yes.”

“I wouldn’t think so. I feel guilty about taking the 40 dollars...”

Although, for the most part they were agreeable, a number of participants did not comprehend how the assessment and interview could take four hours and this produced some consternation. While no one refused outright to commit to a four hour session, a few seemed genuinely puzzled as to what could possibly take

that amount of time. Several suggested that the interview portion could be done by mail or over the phone as a way of cutting down the time they would spend at the central location.

“If you ever had to go into a hospital, you probably spent four hours.”

“If it’s going to be better for people...making them healthier, living longer... If it’s going to take four hours out of my life now, I may not have to lose that four hours ten years down the road.”

“...if it’s a year or two years...then you know four hours is very little time...I think four hours of your time, to get a benefit out of all this too, is a small sacrifice.”

“I think four hours is too long for one session; two hours is long enough.”

“...if you could see the questions ahead of time so that you know and you could answer by e-mail, perhaps then it could take just one hour or two to do the other tests...”

An important consideration that was mentioned in almost all the groups was flexibility in scheduling these appointments. Participants did not want to be given a date and time with the expectation that they would appear, but rather, expected to be consulted and a mutually agreeable date and time set. Participants also wanted the flexibility of night and weekend appointments and the ability to split the assessment and interview over more than one session.

“You know that they’re going to be accommodating or whatever and they’re going to say a time or a place and it’s not going to be behind the alley at midnight.”

“It would depend on whether they tell you to come in on a Monday at 2 o’clock or whether they, say, give us a call and make an appointment and set something up.”

Speaker A: “It would be nice if it was, say, on a weekend because most of us work through the week, and have weekends off, so we wouldn’t have to take a day off work.”

Speaker B: “Or evening maybe.”

Speaker C: “But if you schedule the time, some people can go in the evening; some people can go during the day. I mean you just schedule it.”

Some participants perceived that there would be a benefit to a thorough physical assessment, reasoning that it would likely be more complete than anything their doctor would do, and might even uncover something of which they, and their doctor, were unaware. Participants also expressed interest in receiving the results of their tests and saw this as a benefit of participating.

“It is really interesting; if it gives me a chance to know more about myself, if I have the opportunity to participate in a study I can give many hours.”

“It’s important to know myself. I give information to you, I want to know what my physical condition is, it’s important.”

3.12.2. *Willingness to Participate*

The last two questions in the Moderator Guide dealt directly with the question of how participants would feel about participating in the CLSA and whether, hypothetically, they would agree to participate if asked. Probes to the first question included motivating and de-motivating factors, expectations as to rewards for participating, the value of receiving individual test results as a specific benefit, and any other factors that would make participants feel good about participating. The only probe to the second question asked what would ultimately influence the decision to participate or not participate.

Most participants were interested in volunteering for the study. In a few cases and in one group in particular, participants wanted more information about the study and their role in it before making a decision, but no one refused outright to participate. Several participants made the interesting comment that those who wouldn’t participate had already been screened out by not agreeing to participate in the focus groups.

“I have no problem either. I’d gladly participate. I think that it’s a wonderful study.”

“I think the guys who wouldn’t participate; I don’t think they’re in this room.”

“I would want to have as much information as possible. I’d want it laid out in black and white and on paper telling me exactly what was expected, how many times I was going to be contacted; some ideas as to when they would be and who they would be.”

“I’m pretty sure I would do it but I’d like to have something before I agree that says this is exactly what we’re going to do and this is what we expect of you.”

However, there were some reservations expressed by participants. In some cases this was in the context of factors that would likely prevent them from participating.

“It was possibly sold out to another study...outside the university to a pharmaceutical company then that would be a deterrent but if it’s still kept in this type of study and institution...I’d see no problem with that.”

A prime motivation for participating was the desire to help others. Participants spoke generally about helping others and also in some cases about specific people such as children and grandchildren.

“I would hope it would bring results...some kind of results that would be profitable for all Canadians.”

“Knowing that we can save lives.”

“If it was for the good of society, no problem.”

“I don’t know how many years I got left right? But I got two nephews and they got two little boys. If I can do anything for them, I’d do anything for them or anybody else too, any other kid, anybody.”

Another motivation for participation was receiving individual test results. Most participants were interested in receiving any personal health information that the study could provide.

“I think at least the information, the knowledge at least. If we’re not going to get paid out of this at least the information. I think it’s very important.”

There was also a suggestion in several groups that the study communicate overall results to participants, especially important findings. Coupled with this was an expectation that the study keep in contact with participants through such means as newsletters or a web site.

Speaker A: “Perhaps they could publish a magazine you know...just get a free copy of it in the mail and find out what they’re doing, what they discovered...”

Speaker B: “Or just a newsletter.”

Speaker C: “Yeah, a newsletter.”

Speaker D: “An interim report.”

Speaker F: “Put it on the Internet.”

Participants reiterated their desire for the study to allow participants flexibility in scheduling appointments and take into account their busy schedules. There was also the concern expressed that the data collection be organized efficiently so as not to waste participants' time.

“To be as accommodating as possible for us. I mean, we understand that you can't come to the house...but if we have to go to a location make it accommodating for our schedules and for location, but not out of pocket because, obviously, that's going to be a big deterrent.”

“As long as it's productive time; If I'm waiting, then it's not a very good thing.”

Participants did not expect to be paid for their participation but did expect to be compensated for their direct expenses incurred in participating in the study. Many felt that their reward would be knowing that they had helped others.

“If they paid for my travel expenses when I went there every three years that is fine with me. I would not expect to be paid later on. I would be content knowing I participated in a good social cause.”

“We're not here to get rich. We're here to benefit people behind us...”

“I wouldn't like to think you'd have to get an extra ten million dollars in funding so that you could pay each of us 40 bucks every time we showed up.”

“I think they should reward us by providing education based on the findings. That would be a reward across Canada if they educated the population with the findings.”

Several participants were ready to sign up on the spot and others wanted to know if they would be part of the actual CLSA when it begins. One participant was quite insistent that the study recruit the people who participated in the focus groups and could not be convinced otherwise.

Almost all participants expressed positive interest in the CLSA and were not inhibited by the length of the study or the requirements to come to a central location for a physical assessment. In fact they seemed eager to be a part of the study, even suggesting ways to retain participants through more frequent contacts and feedback of study results.

However, participants do want to know the types of tests they will be undergoing and who will be administering them. Reimbursement is expected but is not a motivation for participating. Rather, it is seen only as compensation for out of pocket expenses. An important consideration for participants was flexibility in

scheduling appointments. There is an expectation that since participants are volunteering their time, the study should accommodate their needs as much as practicable and organize the data collection so that participants are not forced to wait too long.

Participants were willing in most cases and even eager to participate in the CLSA. While some felt that they needed more information about the study before making a decision, not a single participant refused to consider the prospect. Participants related a few conditions that would inhibit their participation, chiefly the involvement of pharmaceutical companies. When asked about their motivations for participating, most indicated that it was a desire to contribute to a good cause or help others, either society in general, future generations, or specific individuals. Virtually all participants agreed that receiving the results of their individual tests would motivate them to participate in the study. Participants were very interested in learning the overall results of the study and suggested that regular communication occur. Once again, participants did not want to lose money because of their participation but also did not want to be paid.

These questions give a strong indication that the level of response burden anticipated for the CLSA would not discourage these focus group participants. Their comments also indicate the factors that would motivate them to participate and continue to participate in the study. It is clear that participants in research study can be asked to give a great deal but they also have expectations which have been clearly articulated. Ignoring these expectations would be likely to negatively affect recruitment and retention. However, as several participants pointed out, the people who would be unlikely to participate in the study were also not present in the focus groups. This underlies the necessity of following up this series of focus groups with a quantitative survey to determine with a high degree of accuracy, the proportion of the Canadian populace willing to participate in a longitudinal study on aging.

3.13. Benefits to Participants

While there was no single question on the benefits of participating in a study like the CLSA, a number of questions included probes which explored this topic in the context of the various requirements of the study. For example, when asked about providing blood and urine samples as part of the study, participants were asked if they thought there would be any benefits. It was not explicitly stated to whom these benefits would accrue but in many cases the perception was that participants, themselves, would benefit in various ways.

3.13.1. Direct and Indirect Benefits

Some participants felt that the overall study findings might prove useful to them. Participants were interested in being informed about the general findings of the study in the hope that information on factors that might influence health and aging could prove useful to them. Participants talked specifically about

geographic factors as well as a number of lifestyle factors. There was also the perception that participants could learn from each other.

“I’d be interested in seeing how your study differed from...Halifax...and...Hamilton...just to see what the difference is...and you would find out that those people are living longer or not living longer. I think that that would help because obviously lifestyle on the east coast is different than here and you could say, maybe fish. I don’t know.”

“...if the follow-ups were done on an individual basis, and there were regular updates, then you could learn from the updates. If somebody else had this problem and they did this...exposure to other people who have been through something is a whole lot more valuable in a lot of cases than puttering around on your own.”

A few participants expressed interest in learning more about any genetic predispositions they might have.

“Well, definitely, sure...I mean I had one sister die from cancer, you know, so it would be interesting to know if you do have some gene that is...”

A number of participants perceived the receipt of individual clinical results as a benefit of participating in the study and this has been discussed under “Return of Clinical Results”. Based on the responses in the focus groups, the return of clinical results is the most significant benefits of participating in the study. While routine results are desirable participants clearly had an expectation that adverse results would be shared with them or their physicians.

“If you’re going to die, I’d like to know.”

“...I think a lot of people would like to have that open door...okay, you need your empirical data for your study, but if something is found then we’d like to hear it.”

For some participants, being part of the study was seen as a substitute for regular health care or as a potential enhancement to their regular health care. Some participants talked about the difficulty of getting to see a physician, the short amount of time allotted to patients, and the difficulty in even getting a family physician in some areas.

“You’d have a guaranteed doctor...”

“...the other thing too, with the physical alone, you’re not going to get one like that in a doctor’s office, so if you were in this study, you’d get a free four hour physical.”

“This way, if they’re keeping track of you, they might be tracking a few other things that you haven’t thought of...”

3.13.2. Impact on Participant Behaviour

Some participants felt that by participating in a study on health and aging they would become more conscious of their own health and this awareness would then motivate them towards a healthier lifestyle. For others, the motivation to become healthier seemed to be linked to wanting to well on the physical assessment.

“I think it would make you more aware, like if you’re in the study, you’re going to look at yourself and your lifestyle and everything a lot closer than if you weren’t...”

“Knowing more about me, if you share the results, even if it is every three years, perhaps you will find something even my doctor did not find.”

“I think the biggest thing for me is the way it will affect me; the way I will change all my habits because in this amount of time I have to go and show how my health is and what I’m doing to maintain my health and somebody’s going to be monitoring that so it’s going to affect the way I act and my lifestyle.”

“It would force me to stay healthy. I’d have something to prove, wouldn’t I?”

Other participants were concerned that such behaviour would skew the study results.

“Yeah, but that would be affecting the study. They’re interfering. Are they allowed to do that?”

Participants perceive that there would be benefits of participating in a study like the CLSA. Many felt it would make them more health conscious simply because their health was being monitored. Some others seemed to view participation as a contest of sorts in which they had to “do well” on the physical assessments by modifying their behaviour. There was also a recognition by some participants that behavioural changes brought about by study participation might skew the results. While it is doubtful that these good intentions would be realized by significant numbers of participants, it is a consideration for the study as to whether or not participants are given any specific instructions or simply asked to

record or recall any lifestyle changes. Some participants do see participation in the study as a form of enhanced medical care if not a substitute for medical care. This notion represents something of a conundrum. Obviously the study is not designed and cannot function as a form of medical care and care must be taken that participants do not enter the study with any false notions. At the same time, the receipt of clinical data is perceived as a positive benefit and in all likelihood adverse results would not be withheld. Most participants do not view the study as a substitute for their health care providers, but do recognize that the study may find something of which they, and their health care provider, were unaware. Communicating to potential participants that adverse results will be made available within specified time limitations to specified parties, such as health care providers, could enhance recruitment and retention.

3.14. Withdrawing from a Long-Term Study

One of the probes to the question on privacy and confidentiality explored participant expectations about their data should they withdraw from the study. The question specified both questionnaire data and also bio-samples. Participants had mixed views on this question. In three of the groups participants did not feel that any information should be returned to those who withdrew from the study. However, in the other three groups the question of returning participant data was raised and there was discussion about the circumstances which might engender such a request.

Most participants thought that the data of someone who withdrew from the study should remain with the study. There was even the suggestion that this should be a requirement of participation and concerns were expressed that the study would be compromised if data were to be removed.

Speaker A: "I think it should stay with the study. If you've been in it to that point, and you decide to get out, I think what you done up to that point should stay with the study."

(General agreement)

Speaker A: "I don't think it should be given back to, whatever; I mean that's useless."

Speaker B: "We should be obligated to agree to leave it there."

Speaker A: "Oh yeah, 100%."

Speaker C: "Why would you want it back? Why would anyone want it back?"

"I think...the study would go under the gun if you had the option of taking it back."

"I think you gave them in good faith...so I can't see you guys saying: "Oh, here's your 12 test tubes" or whatever."

In other groups some participants thought they might want their information back, depending on the reasons for their withdrawal. These participants felt that if they moved away or otherwise could not continue they would not want their data back. However, if they withdrew for moral or ethical reasons they would want their data back.

“...but if it comes to a point where I have a reason to withdraw and whatever that reason is, it’s got to be strong enough that I don’t want to give you more information. If I felt that way I’d want my information back.”

“If I was P.O.’d for some reason of how things were going and thought that it was not a credible study or something, I’d want it all back and I’d want a total pull-out.”

If I left on a negative note, I’d like it returned. If it was because of a choice I had to make, whether it was because I had to move away or whatever other reason, then I would say, just leave it. It’s dependent on which way you parted.

Some participants pointed out specific circumstances in which they would leave and expect their data to be returned.

“...it doesn’t really matter too much unless you are deceived. You thought it was something and then it wasn’t and they lied to you and you...withdraw everything and try to even sue them or something but...there’s no reason to believe that such a case here might...”

“If the material or the information was used in a manner that was inappropriate, and I have a choice to leave then I should have the access; I should be able to retain the samples and the information.”

In several groups participants brought up the fact that some people might withdraw from the study because of fear over what testing might reveal. In one group the prospect of alcohol consumption was raised while in another a positive AIDS test was mentioned.

“...they got drunk last and have to give a urine and blood sample today: “Oh, I gotta do that? Heck with it, I’m quitting.”

“...if I get into a study like this...and I find out I have AIDS and I’m afraid they’re going to find out, I’m going to say forget it. I don’t want anyone to know I have it.”

While most participants felt that information previously contributed should stay with the study, there was enough discussion about expectations that it would or could be returned under certain circumstances to warrant careful examination of this issue. As one participant pointed out, the requirement for data to remain with the study could be disclosed during the consent process and participants asked to agree with this provision. While Freedom of Information legislation ensures access to data, it is unclear in what circumstances the legislation extends the right to retrieve or destroy information. Participants also felt that some people might withdraw from the study out of fear about what testing might reveal about them. It is obvious that the study has to make guarantees of confidentiality but exceptional circumstances must also be taken into account. Examples would include the obligation to report certain diseases to Public Health authorities and the possibility of data, specifically DNA samples, being subpoenaed by a court of law.

3.15. Conduct of the Study

Although no specific questions explored this topic, participants in most groups asked numerous questions about how the study would be conducted, and also offered a number of suggestions as to how they thought the study should best proceed. Although there is some overlap, this theme was designed to capture comments related to the design and structure of the study as opposed to the personal preferences of participants. However, these suggestions also relate to elements which could make the study more complete, efficient or more attractive to participants.

3.15.1. Understanding the Study

Participants had numerous questions about the study, inquiring about the length, format, start date, frequency of contact, eligibility requirements, and whether they would be part of the larger study. Participants wanted to know why the study would last for 20 years and what was meant by “longitudinal”. There was considerable curiosity about the study with participants inquiring how the study was to be funded and how much it would cost; how the results would be used and how participants would be chosen. Several participants wanted to see the study’s mission statement.

“That’s what I’m kind of curious about, the parameters of your study; how it’s getting developed.”

“And who provides the funding for this research, for this study?”

Speaker A: “What are you talking about: 20 million dollars over the 20 years?”

Moderator: “Oh, I think it would probably be a bit more than that.”

Speaker B: “A lot more than that.”

“I think a lot of people would question: okay, what are you using it for? What are you testing for?”

“Yeah, where’s your mission statement? I was trying to find one, and I couldn’t find one anywhere. ...because that tells me a lot about who you are, what you represent.”

3.15.2. Testing

When informed that the study would include a physical assessment including the provision of bio-samples, participants had a number of questions, concerns and suggestions. In several groups participants wanted to know if an M.D. would be conducting the assessments and expressed discomfort with researchers or medical students undertaking this task. However, when informed that the assessment could be conducted by another health professional, such as a nurse, most participants seemed satisfied.

“Well, I wouldn’t mind if it’s going to be done by a medical doctor. I would not really be comfortable if it wasn’t an M.D.”

“Well, I think they should have a doctor...I don’t give my information to anybody...but a doctor.”

“Well, I mean it’s just got to be someone qualified...not a first year student, that’s all I’m saying.”

A number of participants questioned the need to come to a central location for a physical assessment, reasoning that the study could simply obtain this information from their physicians once consent had been given. However, some other participants were also cognizant that the study would need consistency and so would likely employ its own staff to undertake these procedures. There were also several suggestions that the study come to participants’ homes rather than participants coming to a central location. Some participants also felt that their own doctors should be notified that they were in the study and should receive information on them from the study.

“Does it have to be a face-to-face kind of study? Is it something that you could fill out like a questionnaire and mail in?”

“...they could write me and I could turn around and give my doctor permission to send them the results from the last thing. It would do the same thing without having them get it directly.”

“So would this study be more beneficial to you if you had your own staff doing the check-ups, instead of asking me how my health has been and I could fudge the results?”

“I think it makes it more difficult if they start farming out the procedures whether it’s taking blood or whatever job...it allows for more contamination or more problems within the study. I think they have to do it in-house.”

“What would be the chance of having it go to them?”

“Because I think if you went into this study, I think your own personal doctor should be notified that you’re doing this and that they’re getting a report on how you’re doing...”

Some participants even made suggestions about the types of tests the study should employ.

“One thing I think you should do if you go into the health aspect of it...everyone should have an MRI done.”

There was considerable discussion about the frequency of the testing with a number of participants suggesting it be more often than once every three years. Some participants also expressed concern with the length of the testing and interview process, estimated at four hours.

“...personally, I’d say it would have to be done at least every two years...because a lot of health related issues can come up in two years, I mean even a year...”

“...three years does seem like a long time. It would depend on the person too...how old they are, how well they are, and how able they are to provide continuity...”

“...four hours answering questions, that’s a bit harsh. At the beginning they take your blood, then they ask questions, so if it is two or three hours even, or e-mail or by mail; if you could see the questions ahead of time...and you can answer by e-mail., perhaps then it can take just one hour or two to do the other tests...”

“...so each individual is going to be...like a whole new can of worms. You’re not going to get two individuals...to take the same length of time...might take one person 6 hours...and it might only have to take him 15 minutes...”

“...the person that takes four hours got to be a walking medical book.”

3.15.3. Selection and Participation

Participants commented extensively on factors that would affect selection and on-going participation in the study. Topics included diminished capacity to consent, participants dying or moving to other countries or other parts of Canada, the effects of potential budget cuts on the study, factors which would affect the validity of the study and also the possibility of cooperation with longitudinal studies in other countries. It was clear from these comments that participants had no difficulty in placing themselves in the role of a study participant and anticipating the type of issues that could potentially arise.

“...how are the people chosen? Is it completely at random?”

Speaker A: “So what happens to the people who are unable to continue this because of their mental capacity?”

Moderator: “What do you think should happen if somebody’s...no longer competent...?”

Speaker A: “They should be dropped. It shouldn’t be something that should be passed on to their kids.”

“...three years is a fair old whack, and I’m not quite sure, you know, where I’d be, so perhaps a space where one could say...I’m off to wherever, however, this is how you could contact me...”

“So what if, in the course of our aging here...people end up...moving out to Victoria or something like that...Then if we let you know would we get switched to another...?”

“Twenty years is a long time to track the same people so you guess some people would drop off and some people might not want to be involved anymore...so I guess you build in the reliability and the validity into that somehow.”

“...if the budget’s cut and you can’t do it... There’s all kind so complications here isn’t there over a period of 20 years?”

“If you only have me, I cannot represent my cultural heritage, but if there are lots of people in the studies, then the results work.”

“For the study it would be important to know if there is a relationship between education, social standing and all that so I suppose that is part of the study...”

“Would you share the information with other countries? Because I know they’re doing something similar in the UK...so it’d be useful, I think, for a country like Canada...to share with other

countries information on what's happening here. Is that foreseen as part of what you're doing?"

3.15.4. Organization of the Study

A number of suggestions for carrying out the study were put forward by participants. Discussions included how to organize participants into different groups, what should happen when a participant dies and how clinical results should be returned to participants. The discussion of the organizational structure of the study reflects a significant degree of interest the project among participants.

"Well, I think first of all you got to have six groups...on different subjects...one group should be working with people who smoke. Another one should be working with people who are drinking all the time and so on because all of those are factors in the aging situation, right?"

"You break your study up into health, environment and accommodations...and...then you'll have something to sell not only to the government, but to the people that participate."

Participants seemed particularly concerned about what would happen to participants in the study after they died. They correctly reasoned that the study would be interested in the cause of death and would want particulars. There was even a suggestion that participants agree to donate their bodies to science when they died.

"...if I died six months into this study...would there be some way of having a card...that says you're in this study, the study would be notified upon my death."

"You know it would be kind of stupid for me to work ten years on a study, and all of a sudden I drop out, and the reason why I've dropped out, I'm dead, and no one notifies you. That's kind of stupid. You'd have to be notified."

"But there's another thing...you can do with this study, is get people to sign sort of a waiver that turns their body over to science, to Dal science."

Participants also expressed interest in receiving updates on the study findings and felt that the study should find ways to reward individuals for their participation.

"I hope that they won't have the results in 20 years because there are a few people who won't be around to get the results; they

should have the results every three or four years to see what is happening.”

“...the people who organize this study should find a way to reward the participants.”

Other comments recommended that the study take a holistic approach to health and aging and to look at geographic determinants of health.

“...because if you’re looking into physical health and aspects like blood pressure and cholesterol...it’s related to your entire person, including your spirit and everything...I guess I’m concerned that it doesn’t compartmentalize things.”

“...you’re going to do this all across Canada, right? So all of those things like geography, the type of work you do, all of these things, how much stress we deal with and at what ages...”

The questions posed by focus group participants point to topics about which participants wanted more information. The answers to these questions need to be included in information packages sent to potential participants in the CLSA. It is clear that focus group participants are generally well informed and expect full disclosure on all aspects of the study. Some participants were concerned about the physical assessment they were told would be part of the CLSA being done by someone other than a physician. Participants are familiar with conveying medical details to their own doctor but some of them seem concerned about being examined by, or relating personal health matters to, anyone but a practicing physician. It is clear that participants expect a health care professional, preferably a physician. The how, why, and who of the physical assessment process needs to be carefully and completely explained to participants.

Participants would like the physical assessment and associated interview done in as painless a way as possible. While some wanted the study to come to them or to have their doctor send in their health records, there was recognition by some, at least, of the need for consistency in what tests were performed and the conditions under which this would be done. A number of participants felt that testing should be done more frequently than every three years and there was also concern expressed about the four hour time requirement for the physical assessment and interview. These concerns don’t mean that participants would be unwilling to take part in the CLSA but, rather, that they need to be informed why it is necessary and given flexibility in scheduling appointments.

Participants had a number of other suggestions for the study, including the types of tests to be performed and the need to reward participants for their efforts. There was a significant amount of discussion about what would happen if a study

participant died during the course of the study. Most participants agreed that this would be important information for the study to be made aware of.

3.16. Intergenerational Differences

In some groups participants discussed intergenerational differences either between themselves and their parents or themselves and their children. Many of these comments illustrated the fact that the current generation was living longer and better lives than the previous generation and the younger generation would likely live longer and healthier lives than their parents. However, participants also noted some negative effects of generational changes as well. There was also discussion about how attitudes towards aging vary with age.

Participants talked about generational differences in lifestyle and nutrition in both their parents and their own children.

“Dad was retired...and his lifestyle and my lifestyle, just one generation apart, are drastically different so...I can see my children are going to be different in their lifestyles and what they do...”

“I have a son who’s 19, and I know his lifestyle is completely different than mine, and I do look at the two of them and their eating habits; they’re very conscious about what they eat.”

There was also some discussion about the negative effects of generational changes such as stress, lack of time and inactivity among children. There were also some comments to the effect that the next generation will have it easier due to the efforts of their parents

“...my mother stayed home and my wife never went out to work...until the last ten [years] and I look at my kids now and both of them, their spouses, everybody’s working and they’re saying I wish I could stay at home...it doesn’t look to me as if they have more leisure time that what we did.”

“...the kids are having a big problem with the children today. They’re not going out playing in the field and they’re sitting watching video games...in my day...we didn’t have that. We were outside.”

“These kids, they just walk down to the end of the street and they all get bussed and so our society makes things easy but, on the other hand, it’s robbing our kids...”

“...the younger generation is going to take it easier because they know this is coming to them. We work long hours, at some times I had two jobs, just to make a go, and from the younger people, I see they work too, but they enjoy life more than we did.”

Participants also commented on different attitudes towards aging among their parents and their children from thinking you will never age to putting your parents in a nursing home and realizing you're next in line.

“...to educate a 20 year old or educate a 30 year old about aging: that's never going to happen to them...because at 30 you don't think you're ever going to age.”

“...they can see it through example though...the big shift for me was putting parents on into a nursing home. Wow, we're the next step going there, we'd better start planning for that now...”

Speaker A: “But we think differently about aging too. I remember my parents and my in-laws when they hit their 60's, it's like they didn't do anything anymore.”

Moderator: “How has that changed your view?”

Speaker A: “I'm almost 60. I took up golf. I'm taking up Tai Chi and I'm doing all this stuff. I'm having a great time...my in-laws would never have done that.”

Speaker B: “When our parents were our ages, there was no enlightenment as far as what women's rights and what people can do and now there are so many opportunities for everyone to go out and find different ways to grow and become more...”

Speaker A: “And you've got more money that hopefully you can afford to do it.”

Several participants equated better health with increased knowledge available through many sources including the Internet.

“...I think today people are very fortunate where they can go to the Internet and...find out something about cholesterol or you wanted to find out something about high blood pressure or even cancer prevention, you can tune into the Internet...”

“...I never knew anything about cholesterol till I probably was in my late 50's whereas today everything is so readily available which I think has a lot of advantages for the young generations so I think the health things down the road for them will be very different...”

One participant commented on the narrowing of the generation gap as beneficial to the aging process.

“Generation gaps are closing. I mean it was Mr. and Mrs. And they lived in a house, they had a suit and tie and the kids showed respect...and they listened to different music. Music’s become the same. Everything’s become the same. The generation is becoming closer and closer together and because of that, I’m not getting older as fast as I thought I was going to be. ...you’re not growing older because your generation gap is not as wide as it used to be...”

Participants generally showed a sophisticated understanding of intergenerational issues such as the relationship between research, improved communications and improved lifestyle. They were aware of how attitude towards aging change as one grows older but were unwilling to surrender to old age as their parents had. There was a general optimism among these participants that largely due to lifestyle choices and advances in medicine, future generations would benefit from research being done today and planned for the future. The CLSA was embraced as an important potential contributor to that research in Canada.

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Appendix A

Moderator Guide

Canadian Longitudinal Study on Aging Feasibility Study 1

June 2005

Introduction

Hello everyone, welcome, my name is **Geoff Strople** and I'm the moderator for tonight's group discussion. Helping me is **Olga Kits**, who will be taking notes during the discussion.

We appreciate you taking time to participate in tonight's session. The goal of this discussion is to "get" your perspective on a number of topics related to the Canadian Longitudinal Study on Aging. This is a proposed national study on healthy aging that will follow a large group of Canadians over a 20-year period. We have some questions for you about how you would feel if you were asked to participate in a study like this.

Before we get started I want to review some information and go over your role in the group discussion.

Disclosures

Confidentiality: All persons involved in carrying out this research will keep everything you say here confidential. Nothing you say will be associated with any individual by name. We also want to emphasize that it is very important that you also maintain the confidentiality of what is said by others during the discussion. You can talk about the focus group with other people in general terms, but you should not reveal any personal information that may come up during tonight's discussion to anyone outside this focus group.

Voluntary Participation: Your participation in this group is entirely voluntary. You may stop participating or withdraw at any time. You do not have to speak about any topic that you do not wish to discuss.

Audio-taping: This session is being audio-taped so that we can write an accurate report about the issues raised during the discussion, not to identify who said what.

Participant roles

1. Only one person should talk at a time. Please speak in a voice as loud as mine. This is so we can record everything that is said
2. Avoid side conversations with your neighbours.
3. We would like to hear from everyone during the course of the evening but you don't have to respond to every topic.
4. Feel free to respond to someone directly. You don't have to address your comments to me.
5. All points of view are welcome. We want to hear your personal views whether or not anyone else shares them. We are not looking for everyone to agree.
6. Finally a note on my role. I'm here to ask questions and guide the discussion but not to participate in the discussion. We are here to listen and learn from you. However, we do have a number of topics we need to cover so I may need to interrupt in order to move the discussion to a new topic or keep us on track. If you have specific questions about the study there will be an opportunity to ask them at the end.

Group Introductions

Please introduce yourself by telling everyone your first name only, and a little about yourself.

Background

First of all, has everyone had a chance to read the brochure? Is there anything in the brochure you would like to ask about?

Questions

10

1. What first comes to mind when I say "healthy aging"?

Probe, if necessary:

- a. Do you think healthy aging is possible?
- b. What would it look like?

15

Now I'd like to read you a paragraph about the Canadian Longitudinal Study on Aging. It's fairly similar to what you have already read in the brochure.

The Canadian Longitudinal Study on Aging is a proposed research project set to begin in 2008 that will follow a group of 50,000 Canadians, all over the age of 40, for 20 years. It will be one of the largest studies of aging ever undertaken in Canada. The study is taking a very broad view of health and aging. In addition to medical factors such as cholesterol levels, blood pressure and genetics, the study will also examine factors like physical environment, lifestyle, economic and social status as well as use of the health care system, and their relationship to disease, health and well being. The aim of the study is to better understand the process of aging but, more importantly, how to encourage healthy aging. A better understanding of this process will help us all remain healthy longer into our senior years.

2. What's your first reaction to the study I've just described?

Probe, if necessary:

- a. Do you think this is important research to undertake? Why? Why not?
- b. Do you think Canadians, in general will benefit from this research? Why? Why not?
- c. Do you think you or your family could personally benefit from this research? Why? Why not?

20

3. Participating in a study like this is not like agreeing to do a single survey. Because participants will be followed over 20 years, they will likely be contacted every three years and asked to provide health related information.

- a. How would you feel about being asked to participate in a long-term study such as this?

Probe, if necessary:

- b. Would you have any concerns? What are they?
- c. Do you think there would be any benefits? What are they?
- d. Would the length of the study change your mind about participating? Why? Why not?

25

4. The study could also involve giving a blood and urine sample once every few years in order to determine things like cholesterol and blood sugar levels.

- a. How would you feel about being asked to give a blood and urine sample for a research study?

Probe, if necessary:

- b. Would you have any concerns? What are they?
- c. Do you think there would be any benefits? What are they?
- d. Would having to give a blood or urine sample change your mind about participating? Why? Why not?

30

5. As you may know, genes are the blueprint for all life and have the potential to tell us a lot. For example, in the future, genes may be able to tell us why certain people are more likely to develop a certain disease, or even why certain people are more likely to live longer. It is possible to get genetic information, known as DNA, from a blood sample.

a. How would you feel about having your genetic information used as part of a research study?

1. Would you be concerned about what would be done with the genetic material?
2. What about issues concerning confidentiality and privacy?
3. How important would written assurances be about how your privacy and the genetic material itself would be protected?
4. Would knowing the study was reviewed by a university ethics board, whose job it is to protect the rights of study participants, make a difference to you?
5. Would knowing that your genetic information will be linked to other information you provide, such as the results of medical tests and questionnaires you fill out, make any difference to you?

Probe, if necessary:

- b. Would you have any concerns? What are they?
- c. Do you think there would be any benefits? What are they?
- d. Would having your genetic information used as part of a research study change your mind about participating? Why? Why not?

40

6. Because of the type of information that needs to be collected in a study such as this, it is likely that participants will be asked to come to a central location such as a clinic or a university to have a physical assessment.

a. How would you feel about coming to a central location for a physical assessment?

Probe, if necessary:

- b. Would the distance you had to travel affect your decision to participate?

- c. Would the particular location, e.g. a clinic or a university, affect your decision to participate?
- d. Would the amount you were reimbursed for travel expenses affect your decision to participate?

45

7. Each time participants come to the central location for *the* physical assessment they will also meet face to face with an interviewer who will ask health related questions. Together, these activities could require up to four hours of participants' time.

- a. How would you feel about having a physical assessment that required up to four hours of your time?**

Probe, if necessary:

- b. Would you have any concerns? What are they?
- c. Do you think there would be any benefits? What are they?
- d. Would having to come to a central location for four hours change your mind about participating? Why? Why not?
- e. What would be the maximum amount of time you would be willing to spend?

50

8. It is possible to link information that people provide in a research study with data from existing health databases such as provincial health records associated with visits to a doctor or a hospital.

- a. How would you feel about having the information you provide linked to other existing health databases?**

Probe, if necessary:

- b. Would you have any concerns? What are they?
- c. Do you think there would be any benefits? What are they?
- d. Would linking your data to existing data bases change your mind about participating? Why? Why not?

9. In a research study that lasts for 20 years, it is not possible to know at the beginning, all of the ways that the information participants provide, will be used.

- a. How would you feel about having the information you provide used for future research that we cannot foresee, and therefore, cannot tell you about right now?**

Probe, if necessary:

- b. Would you have any concerns? What are they?
- c. Do you think there would be any benefits? What are they?
- d. Would you expect to be notified?

- e. Would storing your information for future use change your mind about participating? Why? Why not?

60

10. Who do you think should be responsible for conducting a study like this?

Probe, if necessary:

- a. Is it important to you to be able to recognize the name of the organization that is conducting the study?
- b. Is there a particular organization, or a type of organization that would make you feel more comfortable about participating in a study like this?

1:05

11. A particularly important issue that has come up over the past few years is the protection of people's privacy. Participants in a study such as this would be assured that any information they provided would be kept confidential.

- a. **Would you have any concerns about the protection of your privacy if you were asked to participate in a study such as this?**

Probe, if necessary:

- b. Would you be concerned about the release of personal information such as name address and telephone number?
- c. Would you be concerned about the release of medical information?
- d. Would you be concerned about the use and storage of blood and urine samples?
- e. Would you be concerned about the use and storage of genetic samples or genetic information?
- f. Participants can withdraw from this study at any time. If you withdrew, what would be your expectations about the information and samples you had already provided?

1:15

12. There is a lot of discussion about commercializing the discoveries that come out of academic research. In other words, research findings could be used as the basis for commercial products. Examples include: diagnostic tests, treatments or even combinations of tests and treatments.

- a. **How would you feel if research findings from a study you participated in were used as the basis for commercial products?**

Probe, if necessary:

- b. Does this raise any concerns?

- c. How would this affect your willingness to participate in such a study?
- d. Would you expect to be notified?
- e. Would you expect to be compensated in any way?

1:20

13. Knowing what I've told you about the study, how would you feel if you were asked to participate in a study like this?

Probe, if necessary:

- a. What would motivate you to participate? Why wouldn't you participate? Is there anything that would make you change your mind?
- b. Would you expect to get anything in return for your efforts? (Probe: What about something more tangible?)
- c. What about getting back the results of your tests such as cholesterol levels or blood pressure readings? Would that be useful to you?
- d. Is there anything else that would make you feel good about participating in a study like this?

1:25

14. Based on all of the information you now have, how likely would you be to agree to participate in a study like this if you were asked right now?

Probe, if necessary:

- a. Ultimately, what would influence your decision?

15. Is there anything else you would like to tell us about this proposed study that you haven't had a chance to say so far?

1:30

Appendix B

Consent Form for Focus Group Participants

Exploring the acceptability and feasibility of conducting a large longitudinal population-based study in Canada

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2. Introduction

We invite you to take part in a study being conducted by Susan Kirkland, Ph.D., who is an Associate Professor at Dalhousie in the Departments of Community Health and Epidemiology, and Medicine, Christina Wolfson, Ph.D., Professor at McGill University in the Departments of Epidemiology & Biostatistics, and Medicine, and Parminder Raina, Ph.D., Associate Professor at McMaster University in the Department of Clinical Epidemiology and Biostatistics. Your participation in this study is voluntary and you may withdraw from the study at any time. The study is described below. This description tells you about the risks, inconvenience, or discomfort which you might experience. Participating in this study will likely not benefit you, but we might learn things that will benefit others. You should discuss any questions you have about this study with (the CLSA staff person).

3. Purpose of the Study

The purpose of this research study is to explore the ideas of Canadians 40 years and older about issues concerning participating in a long-term study of health and aging. The information provided will be used primarily to help develop the Canadian Longitudinal Study on Aging.

4. Study Design

This study will consist of six focus groups conducted in six different regions of the country. You have been asked to participate in one of these focus groups. The focus group will consist of a discussion guided by a moderator. Discussion topics will include asking you about your thoughts and feelings concerning a number of issues related to conducting a long-term study of aging. There are no right or wrong answers.

5. Who can participate in the Study

You can participate in this study if you are an adult living in Canada who is 40 years or older.

6. Who will be conducting the Research

The Principal Investigators for this study are Susan Kirkland, Ph.D. (Dalhousie University), Parminder Raina, Ph.D. (McMaster University), and Christina Wolfson Ph.D. (McGill University). The focus group you will be taking part in will be guided by _____. Field notes will be taken by _____.

7. What you will be asked to do

You will be asked to take part in a group discussion about issues related to conducting a long-term study of health and aging. A moderator will guide the discussion through a series of topics. During the discussion, you will be asked to share your thoughts and feelings about each of these topics. Because we are asking for your opinions, there are no right or wrong answers. It is expected that the discussion will last for approximately two hours. Prior to the focus group

discussion, you will be asked to complete a very brief written questionnaire to provide some background information on yourself. The information you provide will remain anonymous, that is, we will not ask for your name or any other identifying information.

The focus group will be audio-taped and field notes taken. The focus group is audio-taped to ensure that we do not miss any information and to ensure that we report all information accurately.

8. Possible Risks and Discomforts

There are no known serious risks or hazards involved in this study. However, all participants will be asked to respect the confidentiality of the information shared during the focus group.

Participants will be encouraged not to disclose any information of a personal nature, but it is possible that this may happen. For this reason, you will only be identified by your first name during the focus group. There is also the possibility that you may feel some stress or negative emotion if a topic is discussed that is of a highly personal nature to you. If this happens, or you wish to leave the focus group at any time for any other reason, you may do so.

9. Possible Benefits

There is unlikely to be any direct benefit to you for participating in this study, although you may learn about issues related to health research. The main benefit will be to researchers who use the information you provide to help develop better long-term research studies.

10. Compensation / Reimbursement

If you choose to become involved in this research study you will receive \$40.00 to assist you with 'out of pocket' expenses for travel, or other related expenses such as child care or elder care. If during the focus group you decide that you do not want to continue, you may withdraw from the study without penalty and will still receive the same amount (\$40.00).

11. Confidentiality & Anonymity

All information, which you provide, will be held in strict confidence. Only persons involved in transcribing the audio-tapes and analyzing the results of the focus groups will have access to and be able to listen to the tapes or read the transcripts. Audio-tapes, transcripts, questionnaires and field notes will be stored in locked cabinets in locked rooms at CLSA offices in the Department of Community Health and Epidemiology at Dalhousie University. Electronic files will be password protected. Tapes, transcripts, questionnaires and field notes will be maintained in a secure environment until they are destroyed. This period will be for a minimum of 5 years after the study findings are published. Only CLSA Principal Investigators and CLSA staff will have access to these tapes and transcripts. The summaries of the focus group will be circulated to key individuals including the principal investigators, co-investigators, moderators hired by the CLSA, and CLSA staff members directly working in this project.

Any summary of the results or published reports will not identify you by name, nor will any information be included that could be used to identify you. Although we will emphasize to all focus group participants the extreme importance of keeping information discussed during the focus group private, we cannot guarantee that all people involved in the focus group will do so. In an effort to protect your identity, we will only use first names during the focus group.

12. Questions

If you have questions about this study, you may contact any of the following:

Project Coordinator, Geoff Stropole – 1-866-515-5252, geoff.stropole@dal.ca
Lead Principal Investigator, Susan Kirkland, Ph.D. – 902-494-1235 susan.kirkland@dal.ca

13. Summary

The research you are being asked to take part in has as its goal to better understand people's views on participating in a long-term study of health and aging, such as the proposed Canadian Longitudinal Study on Aging. We are generally interested in finding out whether this type of research is supported by Canadians and what factors would influence their participation in such a study. If you choose, you may provide your name and address after this focus group has ended and a summary of the research results of the focus groups related to the study you participated in will be mailed to you after the entire study is completed.

15. Problems or Concerns

In the event that you have any difficulties with, or wish to voice concern about, any aspect of your participation in this study, you may contact Patricia Lindley, Director of Dalhousie University's Office of Human Research Ethics Administration, for assistance (902) 494-1462, patricia.lindley@dal.ca.

Title of the Research Project:

Exploring the acceptability and feasibility of conducting a large longitudinal population-based study in Canada

PARTICIPANT CONSENT: I have read or had read to me this information and consent form and have had the chance to ask questions which have been answered to my satisfaction before signing my name. I understand the nature of the study and I understand the potential risks. I understand that I have the right to withdraw from the study at any time. I have received a copy of the information and Consent Form for future reference. I freely agree to participate in this research.

Name of participant: (print) _____

Participant Signature: _____

Date: _____ / _____ / _____
Month / Day / Year

I understand and agree to the fact that this session will be audio-taped.

Participant Signature: _____

I hereby give consent to the use of my exact words (quotations) for any publication that may come out of this research study. I understand that no identifying information will be included in any reports.

Participant Signature: _____

STATEMENT BY PERSON OBTAINING CONSENT: I have explained the nature of the consent process to the participant to ensure that they understand that participation is voluntary and that they may withdraw at any time from participating.

Name: (print) _____

Signature: _____ Position: _____

Date: _____ / _____ / _____
Month / Day / Year

Appendix C

Focus Group Participant Questionnaire

Canadian Longitudinal Study on Aging

Feasibility Study 1

May 2005

Please tell us a little bit about yourself by answering the following questions. The information you provide is completely confidential and will only be used for the purposes of interpreting the results of this focus group. If you would prefer not to answer a question you may leave it blank.

1. How old were you on your last birthday?

___ Years old

2. Are you male or female?

- Male
- Female

3. What is the highest level of education you have completed?

- Less than high school
- Some high school
- Completed high school
- Vocational training or community college
- Some university
- University graduate
- Post-graduate degree or diploma

4. In what country were you born?

- Canada
- Outside Canada (please specify) _____

5. While most people in Canada view themselves as Canadians, this question refers to the origins of your ancestors. To which ethnic or cultural group did your ancestors belong? (Check all that apply)

- British Isles origins
- French origins
- Aboriginal origins
- North American origins
- Caribbean origins
- Latin, Central and South American origins
- European origins
- African origins
- Arab origins
- West Asian origins
- South Asian origins
- East and Southeast Asian origins
- Other... please specify _____

6. What is your current marital status?

- Single
- Married, including common law
- Divorced or separated
- Widowed

7. Do you have any children living at home?

No Go to Question 9

Yes
↓

8. What are their ages?

___ Child 1

___ Child 2

___ Child 3

___ Child 4

9. What is your current employment status?

- Working full-time
- Working part-time
- Unemployed
- Homemaker
- Student
- Retired

10. What is/was your occupation?

11. What is your household income?

- Less than \$25,000
- \$25,000 - \$49,999
- \$50,000 - \$74,999
- \$75,000 and over

12. What is your postal code?

_____ Postal Code

Thank you for completing this questionnaire.