BC CARMA CHIWOS COLLABORATION

British Columbia CARMA CHIWOS Collaboration (BCC3): Peer Research Associate Training Manual

REMOTE LEARNING TRAINING MANUAL

JULY - NOVEMBER 2020

British Columbia CARMA CHIWOS Collaboration (BCC3)

PEER RESEARCH ASSOCIATE TRAINING MANUAL

Acknowledgement

We are grateful for the work and advice from the CHIWOS PRA Training team, who kindly shared their work and experience with us. This training manual and guide was adapted from the CHIWOS PRA Training Manual:

CHIWOS PRA Training Working Group (2013). *CHIWOS Peer Research Associate Training Manual: English Quebec Version*. Canadian HIV Women's Sexual and Reproductive Health Cohort Study (CHIWOS): Toronto, Canada. Available online: www.chiwos.ca. Date: June 26, 2020

Manual Use and Citation Request

We are sharing the entirety of the BCC3 Training Manual, take-home modules, and resources so that others may benefit from this work. We ask that you cite this manual using the suggested citation below. We also have a publication about our training forthcoming. Please get in touch with a BCC3 team member for details.

BCC3 PRA Training Collaborative (2020). *BCC3 Peer Research Associate Remote Training Manual.* British Columbia CARMA CHIWOS Collaboration (BCC3): Vancouver, British Columbia. Available online: www.hivhearme.ca. Date accessed:

Potential users of this training manual are encouraged to involve BCC3 PRAs in the planning and/or delivering of their training. Please contact a BCC3 team member so we can be of further assistance.

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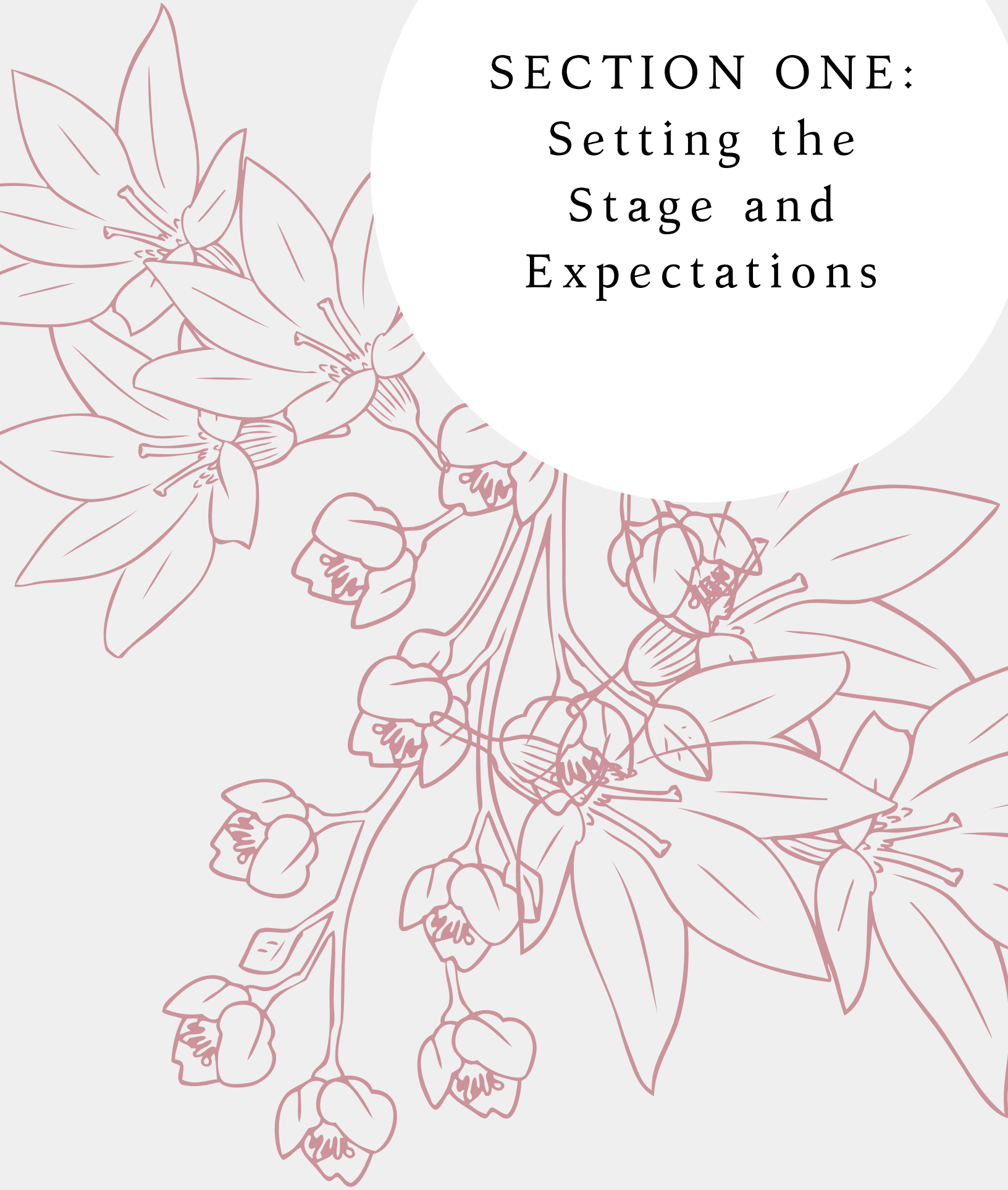
SECTION ONE: Setting the Stage and Expectations



1.1: Training Objectives

Working Group notes:

The BCC3 PRA Working Group Training objectives included specific objectives to survey administration as well as goals related to the personal development goals of each PRA. Thus, the provided Learning Outcomes handout below is considered working document.

We outline the specific training objectives and learning outcomes, as well as what we hope each PRA will be able to achieve during the course of the training, and throughout their role as a PRA.

One specific objective that was incorporated throughout the training was to highlight the expertise that each PRA is bringing to the training session. Prior to training, each PRA was asked what expertise they would be bringing to the training session and were asked to co-facilitate either a full training module, lead a specific discussion, or to lead an activity.

PRAs will continue to lead refresher training sessions throughout their role as a PRA.

LEARNING OUTCOMES FOR BCC3 PRA TRAINING SESSION

As we prepare to launch the BCC3 Survey and transition to interview administration, we expect Peer Research Associates to:

- Effectively represent and speak for BCC3 in the community
- Demonstrate familiarity with the project, background, context, and team, including information specific to study goals and objectives
- Administer the BCC3 survey in a confident, independent, and professional manner
- Practice successful survey techniques to ensure data quality
- Commit to protocols for contacting and recruiting participants to participate in the BCC3 Study
- Apply ethics, principles, and teamwork in practice
- Ensure privacy, confidentiality, and informed consent of participants
- Communicate constructively with survey participants and with the BCC3 team
- Practice self-care, communication, debriefing, and safety precautions
- Make informed and supported decisions about the impact on yourself of doing the research, including signs of burnout and experiences of grief and bereavement
- Contribute to Knowledge, Translation, and Exchange (KTE) initiatives to disseminate study findings in the community

We hope that your position as a Peer Research Associate with BCC3 will be a place where you can:

- Empower yourself and act in a community leadership role
- Build capacity and translate what is learned through BCC3 to other contexts
- Vision personal goals and opportunities for growth that can be supported by the BCC3 team
- Participate in BCC3 team meetings, to guide study procedures, and support and build team connections

1.2: Icebreaker Activities

Working Group notes:

Building trusting relationships amongst team members is critical for community-based research. As all training was done remotely, it was important for the research team to methodically build ways into each online meeting to 'break the ice' and learn more about each other. These 'icebreaker' activities not only allowed for us to get to know each other and laugh together; but it also served as an opportunity for the team to practice muting and unmuting themselves, and to practice speaking up in the meetings.

Each meeting opened with an ice-breaker, including some of the following:

- What animal are you feeling like today, and why?
- What is your favourite type of breakfast?
- What is your secret skill?
- Show & Tell: find one item nearby, and share it with the group.
- What is your favourite smell?
- Is cereal soup? Explain why.
- If you could eliminate one thing from your morning routine, what would it be?
- Share how you are feeling today in one word, that starts with the first letter of your first name.

1.3: Layout of Modules and Study Activities

Working Group notes:

The training schedule was linked to the learning outcomes and proposed activities and was updated where necessary to accommodate delays in material review and coverage (ie. where one topic might need extra review).

The final version is presented below.

MODULES BCC3 PRA TRAINING SESSION

Week	Main Topic(s)	Learning Outcomes	Activities
1.	Intro Meeting	Meet the team: Who's Who	- Introductions (secret skill) - Welcome to the Team! - What is a bio?
2.	Study background	- BCC3 goals, objectives, rationale - Research update on HIV, Equity, & Aging Research - Community based research (CBR)	- Review and reflection questions - Team to create their own personal bios
3.	Methods Science Concepts	- BCC3 CBR model - Research update on cellular aging	- Review and reflection questions
4.	Social determinants of Health Ethics	- Ethics, privacy & confidentiality - Rights of research participants	- UWW Online Video - Review and reflection questions - Online modules
5.	Ethics cont. Abstract review	- Informed, ongoing consent - Data linkage between studies and other databases - What is an abstract / KTE / providing feedback	- Review and reflection questions - Bio feedback - Abstract review & feedback
6.	Data Quality PRA logistics	- Data quality and administering successful surveys - PRA roles and responsibilities - Getting paid for interviews - Administering participant honoraria	- Review and reflection questions - Problem solve case studies - Work through question sets
7.	REDCap Survey Basics of a Good Interview	- Building consent scripts to open/close surveys, answer questions - Familiarize with the REDCap database and survey platform - Tips for administering a good interview	- Practice opening / closing survey - Review REDCap database, and navigating the different survey sections - Present Elevator Pitch

8.	Recruitment Booking an interview Survey Practice	- Interview and connect with participants in confident, independent, professional manner - Administering successful surveys	- Debrief survey administration - Role play scenarios - Model opening/closing survey - Practice giving constructive feedback
9.	Safety and Wellbeing Challenging interviews	- Cultural competency - Practice self-care, communication, debriefing, safety precautions - Make informed decisions about the impact on themselves of doing the research - Community resources	- Role play scenarios - Setting boundaries - Navigating shifting roles - Support participants and refer to resources - Practice self-care with the support of team - Demonstrate inter-cultural competency and empathy for others
10.	Self-Care Review & Wrap Up	- Build capacity and translate what is learned through BCC3 to other contexts	- Jeopardy
11.	Graduation and Training Completion Ceremony/Celebration	- Vision and set goals for ongoing learning	- Present certificates of achievements - PRAs to share their vision for their role as a BCC3 PRA

Other Training activities included as homework:

- Partnered scavenger hunt to gain familiarity with the BCC3 study team, materials, and processes
- Individual review of the BCC3 Survey
- Individual review of the REDCap platform
- Partnered interview administration and role-playing (x3)
- UBC Bullying & Harassment Online Course
- PHSA Privacy & Confidentiality Online Course
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCSP Core 2) Online Course
- Practice opening and closing Zoom

Additional Modules for Ongoing Training

- Knowledge Translation & Exchange
- CV / Resume Building
- Intro to statistics and data analysis
- Refresher for delivering in-person interviews, when public health advisories allow

1.4: Introductory Meeting

Working Group notes:

An introductory meeting with all team members started off the BCC3 Training, so that everyone had a chance to meet each other remotely, present their roles on the study, and start to learn more about each other.

A Who's Who document was circulated for reference for the PRAs and for the team.

The BCC3 Family

THE BRITISH COLUMBIA CARMA-CHIWOS COLLABORATION (BCC3) STUDY

DR HÉLÈNE CÔTÉ

Principal Investigator (PI);
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Dr. Hélène Côté is a professor of Pathology and Laboratory Medicine at the University f British Columbia (UBC), as well as an associate member at the Women's Health Research Institute (WHRI). She has many concurrent projects in her lab examining aging and mitochondrial toxicity in relation to viral infections and antiretroviral therapies. She has led the CARMA cohort for the past 12 years. As a principal investigator, she will be guiding and managing BCC3 study activities, ensuring that we are meeting our research goals, and doing research in a good way.

DR. ANGELA KAIDA

Principal Investigator (PI); kangela@sfu.ca

Dr. Angela Kaida is an associate professor and global health epidemiologist in the Faculty of Health Sciences at Simon Fraser University (SFU). She works closely with community leaders and decision-makers to integrate research evidence into health policy and programming, attending to social and gender equity. Her many research studies focus on access to HIV treatment and prevention services, and their impacts on sexual and reproductive intentions, behaviours, and outcomes of HIV-affected individuals.

DR. MELANIE MURRAY

Principal Investigator (PI);
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Dr. Melanie Murray is a clinical associate professor in the Department of Medicine at the University of British Columbia (UBC). She is an infectious disease specialist in HIV care at BC Women's Oak Tree Clinic. Her research interests include HIV and women, HIV and aging, and engaging persons in care for their HIV. As one of the principal investigators, she will be leading investigation into the impacts of HIV infection, psychosocial and structural factors on hormonal dysregulation in BCC3 cohort participants.

The BCC3 Family

THE BRITISH COLUMBIA CARMA-CHIWOS COLLABORATION (BCC3) STUDY

ELDER SHEILA NYMAN

Elder; bearrockconsulting@gmail.com;

Elder Sheila is a Syilx Metis woman from the Lower Similkameen in the Okanagan Valley, who began her work with women living with HIV/AIDS at Oak Tree Clinic as the former Executive Director of New Dawn, New Day and New Way Recovery homes during the mid-90s. She continues to use her skills as an Elder with traditional healing training and also as a Master level Clinical Social Worker, providing support to women living with HIV. She integrates western and Indigenous models of healing strategies and the wisdom she has learned over the many years of working with women, Indigenous people and AIDS research projects.

ELDER VALERIE NICHOLSON

Co-Investigator (Co-I); vjnicholson@live.ca;

Elder Valerie Nicholson is a Spirited Indigenous Warrior Woman who is an Indigenous Peer Navigator with the Positive Living Society of British Columbia, and was a past Chair of the Board of the Canadian Aboriginal AIDS Network. She also works in community-based research, and mentors HIV+ youth as a trainer for the Positive Leadership Development Institute. As a co-investigator, Elder Valerie also ensures that the research is being done doing in a good way.

EVELYN MAAN

Research Manager; emaan@cw.bc.ca

Evelyn is a research nurse at BC Women's Hospital, and research manager at Oak Tree Clinic, where she oversees multiple research projects that focus on the needs of women and children living with HIV.

The BCC3 Family

THE BRITISH COLUMBIA CARMA-CHIWOS COLLABORATION (BCC3) STUDY

AMBER CAMPBELL

Research Coordinator;
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Amber is a research coordinator at Oak Tree Clinic. She has worked on the CARMA study, investigating comorbidities and polypharmacy among women living with HIV. On the BCC3 study, she will be your contact for any questions related to study methods, consenting, survey conduction, PRA roles and responsibilities and our database, REDCap.

REBECCA (BECKY) GORMLEY

BC Research Coordinator;
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604-558-6686

Becky is the provincial research coordinator on 2 national studies (CHIWOS and WATCH). Highly committed to community-based research, her research interests include women's sexual and reproductive health, and HIV. On the BCC3 study, Becky will be your contact for any questions or concerns related to PRA roles and responsibilities, as well as all finance and payroll.

YEVON LEE

Research Assistant; yevon.lee@cw.bc.ca

Yevon is a research assistant at Oak Tree Clinic. She primarily works on the CARMA-1-Preg study, investigating factors related to pre-term deliveries among women living with HIV. For the BCC3 Study, Yevon has built the REDCap database and has also been involved in the making of the BCC3 survey.

The BCC3 Family

THE BRITISH COLUMBIA CARMA-CHIWOS COLLABORATION (BCC3) STUDY

SHAYDA SWANN

Student researcher;
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Shayda is a graduate student at the University of British Columbia in the combined Doctor of Medicine/Doctor of Philosophy (MD/PhD) program. Shayda has experience working in HIV cure research at Simon Fraser University and at the BC Centre for Excellence in HIV/AIDS. She has a keen interest in HIV, women's health, and endocrinology and will be exploring the impacts of HIV infection and social factors on hormonal dysregulation in BCC3 cohort.

TSION GEBREMEDHEN

Student researcher; tgebreme@sfu.ca;

Tsion is a graduate student at Simon Fraser University in the Master of Public Health program. As a student researcher, she has mainly been involved in assisting development of training materials for the Peer Research Associates on the BCC3 study.

TETIANA POVSHEDNA

Student researcher;
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Tetiana is a graduate student at the University of British Columbia (UBC) completing her Master of Science (MSC) in the Pathology and Laboratory Medicine program.

The BCC3 Family

THE BRITISH COLUMBIA CARMA-CHIWOS COLLABORATION (BCC3) STUDY

CO-INVESTIGATORS

- Jason Brophy (MD, MSc)
- Allison Carter (PhD, MPH)
- Chelsea Elwood (MD)
- Elizabeth King (MD)
- Neora Pick (MD)
- Jerilynn Prior (MD)
- Kate Salters (PhD, MPH)
- Joel Singer (PhD)

KNOWLEDGE USERS

- Sarah Chown, Program Director at YouthCo
- Patience Magagula, Executive Director at Afro-Canadian Positive Network (ACPNet)

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- Joel Singer (PhD)
- Elder Valerie Johnson

KNOWLEDGE USERS

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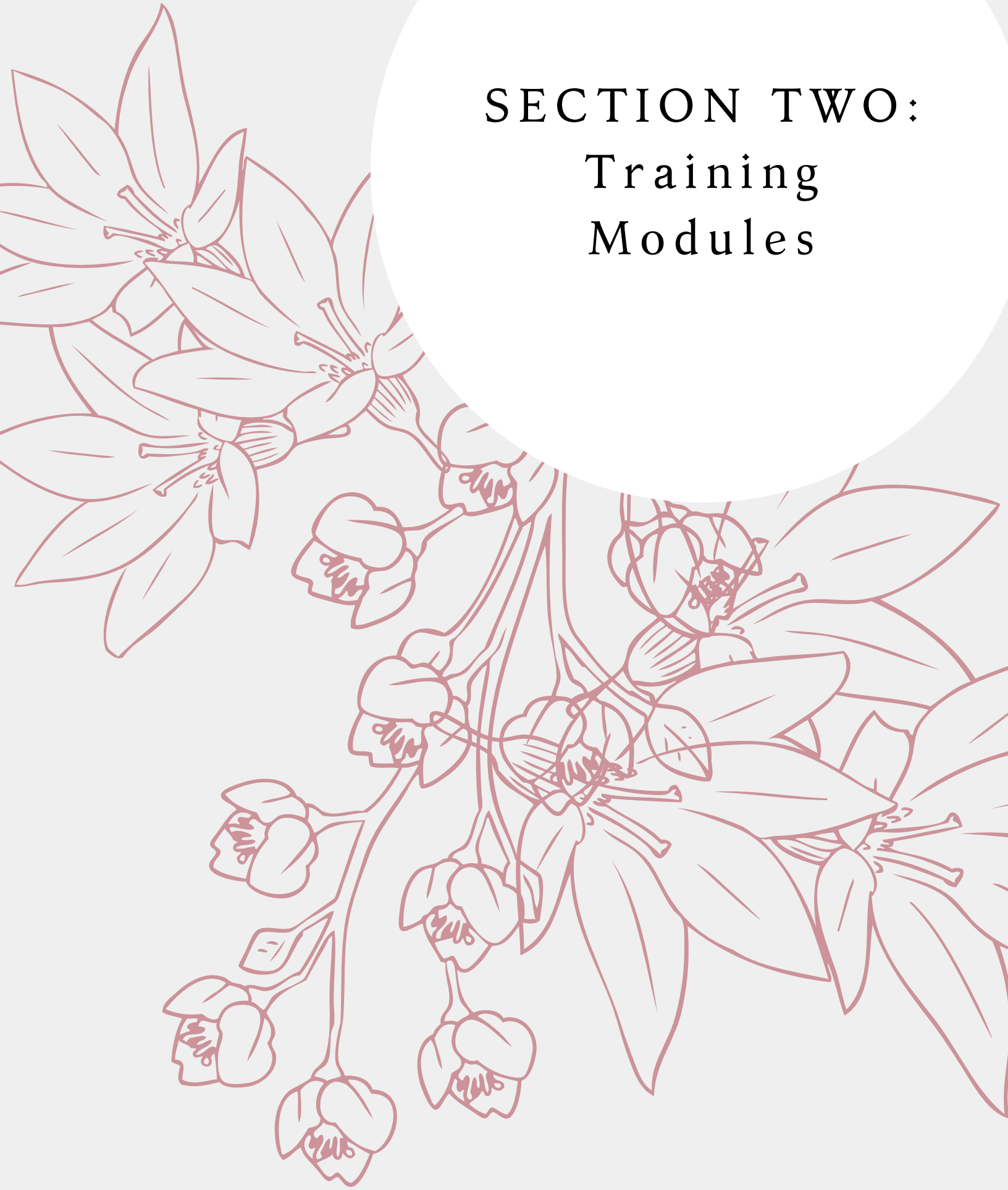
SECTION TWO:
Training Modules



Working Group notes:

The following section outlines the specific training modules that were covered over the course of the BCC3 PRA Training.

Each training session was 1.5 – 2 hours long, with a break included. Prior to each meeting, PRAs were asked to complete various activities, reflect on questions, and review material (approximately 1 hour worth of work).

Following each training session, PRAs were asked to fill out an anonymous evaluation on Google Scholar to provide feedback and suggestions to continue improving future training sessions (see Appendix).

2.1: BCC3 Study Background

BCC3 PRA Training Material

BCC3 Study Background Information

Hello Peer Research Associates! The purpose of this document is to provide background information on the science behind BCC3, the project goals, and study methods. Some of the concepts, especially the science concepts, may be brand new and difficult to understand. Please don't worry, as we will go through them together and only a basic understanding is needed! Please let us know if there is anything in particular that you would like to spend more time reviewing together. Thank you!

PEER RESEARCH ASSOCIATE ROLES & RESPONSIBILITIES

Roles & Responsibilities

We will go over your roles more specifically in another module, but briefly, your roles and responsibilities as a PRA are as follows:

- Engage in training sessions:
  - Attend all training sessions.
  - Engage in self-directed learning before and after these sessions.
  - Review and be familiar with training materials.
  - Pilot survey (practice administering the survey).

- Facilitate community study visit
  - Assist with setting up interviews for participants.
  - Confirm ongoing consent with participants.
  - Administer the BCC3 survey using a computer.
  - Administer the participant honorarium and complete necessary paperwork.

- Assist with knowledge translation and exchange
  - Participate in regular team meetings to discuss interview strategies.
  - Guide study methods, and assure that questions and topics covered are both safe and acceptable for WLWH.
  - Connect with your coordinator as needed.
  - Act as BCC3 representative within your region.
  - Assist in presenting findings to community.

Reflection Activity: mind map – where could this work as a PRA go? (I.e. traveling to conferences, representing/advocating for community, empowering yourself and others)

BCC3 OVERVIEW AND PURPOSE

The steps of a research project include community collaboration from the beginning to end, starting with designing the study, through to knowledge translation and exchange. In this document we will provide background information on the study design, including the guiding principles and goals, then we will discuss methods including how we are collaborating with the community, data collection, data analysis, and KTE. Then we will provide background information on the science-concepts that we are studying.

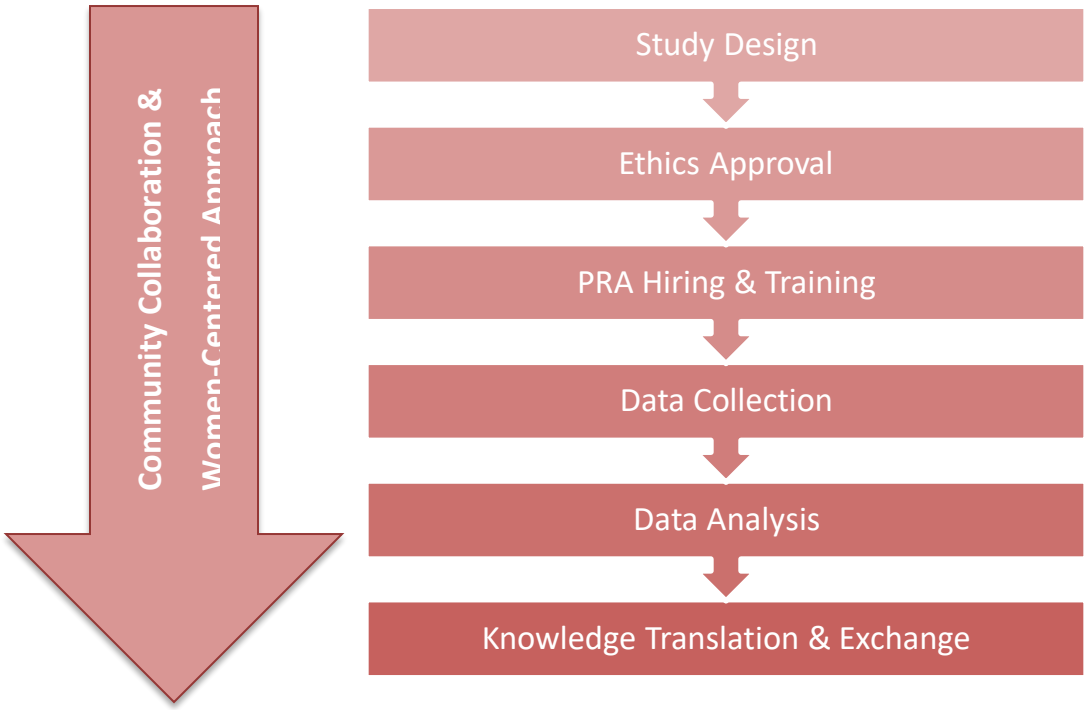


Figure 1. Steps of BCC3 project with community collaboration and women's centered approach throughout each aspect.

Overview of BCC3 Study

With health advances from combination antiretroviral therapy (cART), healthy aging with HIV is a research priority. Globally, women represent more than 50% of the 37 million persons living with HIV, yet remain understudied, particularly in areas related to reproductive health and age-related health diagnoses. Such research is especially important given that women living with HIV face increased morbidity (illness/diagnoses) and earlier mortality (death) compared to men living with HIV. In fact, women living with HIV have a life expectancy 5-10 years shorter than HIV-negative women, and 7 years shorter than men living with HIV. The research that has been done so far hasn't been able to clearly explain why this is.

Research has taught us that exposure to trauma, violence, poverty, substance use, and experiences of depression, anxiety, and post-traumatic stress disorder can impact stress in the body. In turn, this may affect women's biology, hormonal regulation, and lifespan. Though we know that people living with HIV experience faster aging in the cells in the body (cellular aging) compared to HIV-negative peers, we

also know that women living with HIV have more immune activation/inflammation in the body (see page 3 for explanation), which affect cellular aging and comorbidities. In order to promote healthy aging and guide strategies to prevent comorbidities, we must better understand cellular aging, as well as the factors and pathways that regulate aging in women living with HIV.

Overall: Healthy aging of women living with HIV is influenced by cellular, clinical, and social factors, which also interact with one another. A better understanding of the relationship between these factors and how they influence aging in women living with HIV is needed.

PURPOSE: We are taking a wholistic research approach to better understand the complexities of aging with HIV, as well as the physical, mental, and reproductive health of women living with HIV. We have created the **British Columbia CARMA-CHIWOS Collaboration (BCC3)**, bringing together two expert Canadian teams:

- Children and Women: AntiRetroviral therapy and Markers of Aging (CARMA)
- Canadian HIV Women's Sexual and Reproductive Health Cohort Study (CHIWOS) (BC)

The BCC3 team combines the expertise, experience, and infrastructure of two established research groups and their large cohorts of women living with HIV. Our team integrates CARMA's biomedical research approach and group of participants not living with HIV, with CHIWOS' community-based research approach and emphasis on social determinants of health. By collaborating together, we hope to be able to better understand how the lived experiences of the diverse community of women living with HIV in the lower mainland intersect with clinical and cellular markers of aging.

Overarching Research Question: How is cellular aging in immune cells influenced by chronic/latent viruses, and how might it be associated with comorbidities, hormones, and social determinants of health in women living with HIV?

GUIDING PRINCIPLES

Our guiding principles follow Community Based Research and a Women-Centered Approach to allow for a holistic analysis of the health and wellbeing of WLWH from cell to society.

Community Based Research

BCC3 follows the following community based research principles:

1) Greater Involvement of People Living with HIV/AIDS (**GIPA**)
2) Meaningful Involvement of Women Living with HIV/AIDS (**MIWA**)
3) Ownership, Control, Access and Possession of data collection processes in Indigenous communities (**OCAP**) – enacting the Truth and Reconciliation Commission

The key to successful and meaningful research is community collaboration. Studies that utilize a community based research approach create results that can properly address the needs of the community. In doing so, researchers collaborate with the community along every step of the research journey, including: designing the research questions and protocol, conducting the study, interpreting results, and translating knowledge. It is vital to foster lasting and genuine connections between researchers and the community, to ask what the community needs and let this guide the research, and

to come to research questions and study design together. This allows for a client-centered approach that can best improve care and access to health services. In regards to BCC3, this means ensuring that WLWH are included in each step of the research process and following the GIPA, MIWA and OCAP principles. In turn, community based research can create more meaningful findings and work to empower women living with HIV.

Women-Centered Approach

BCC3 follows a women's centered approach, which includes research that: purposely involves the perspectives of women; sees women as leaders and active participants in the research process; shares generated knowledge from research with the community to influence systemic and structural change. Some of the many different aspects of the lives of women living with HIV are shown in Figure 2.

Cell-to-Society Framework - Addressing Social, Clinical, and Cellular Science

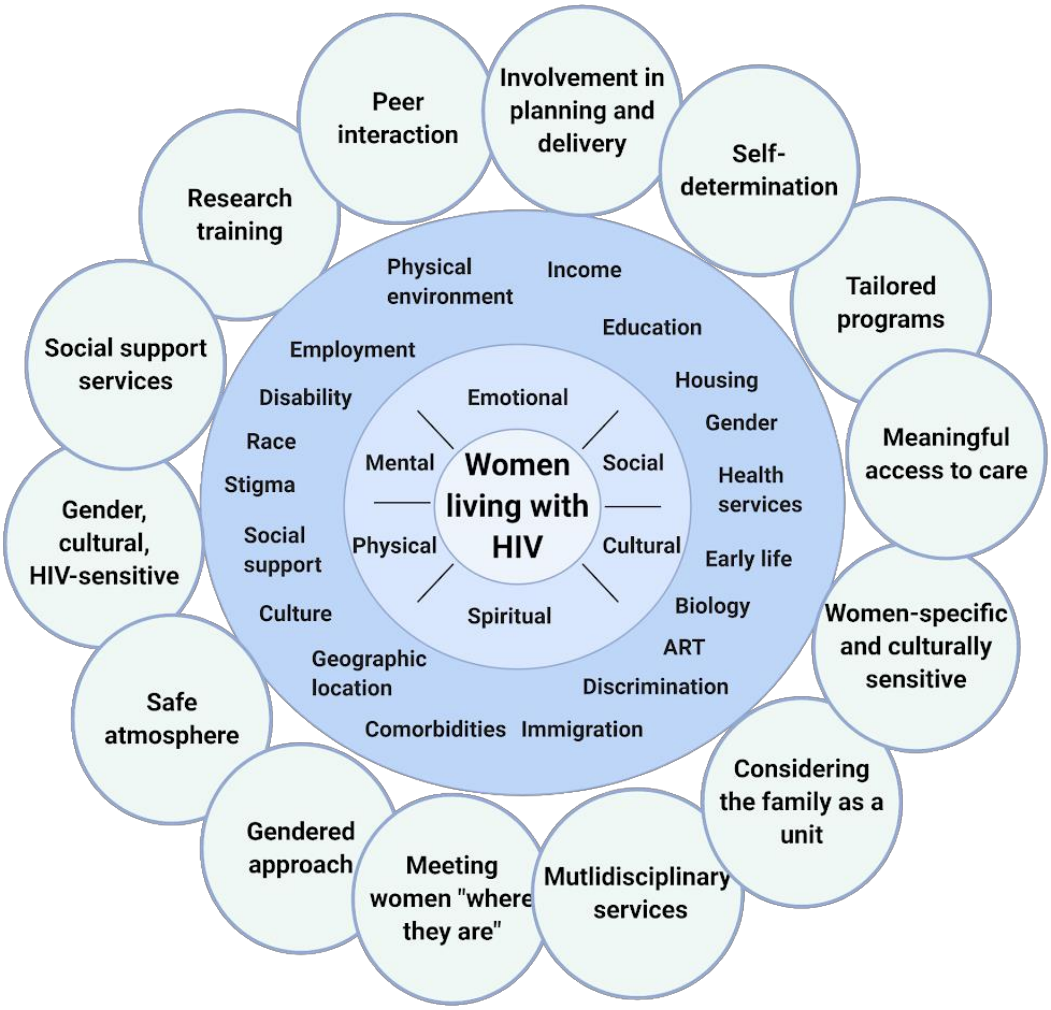


Figure 2. Components of a women-centered approach to research to support the holistic health and wellbeing of women living with HIV. Adapted from Carter et al 2013: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3545274/

To understand healthy aging of women living with HIV, we need to study the various cellular, clinical, and social factors, that interact with one another and influence aging (Figure 3).

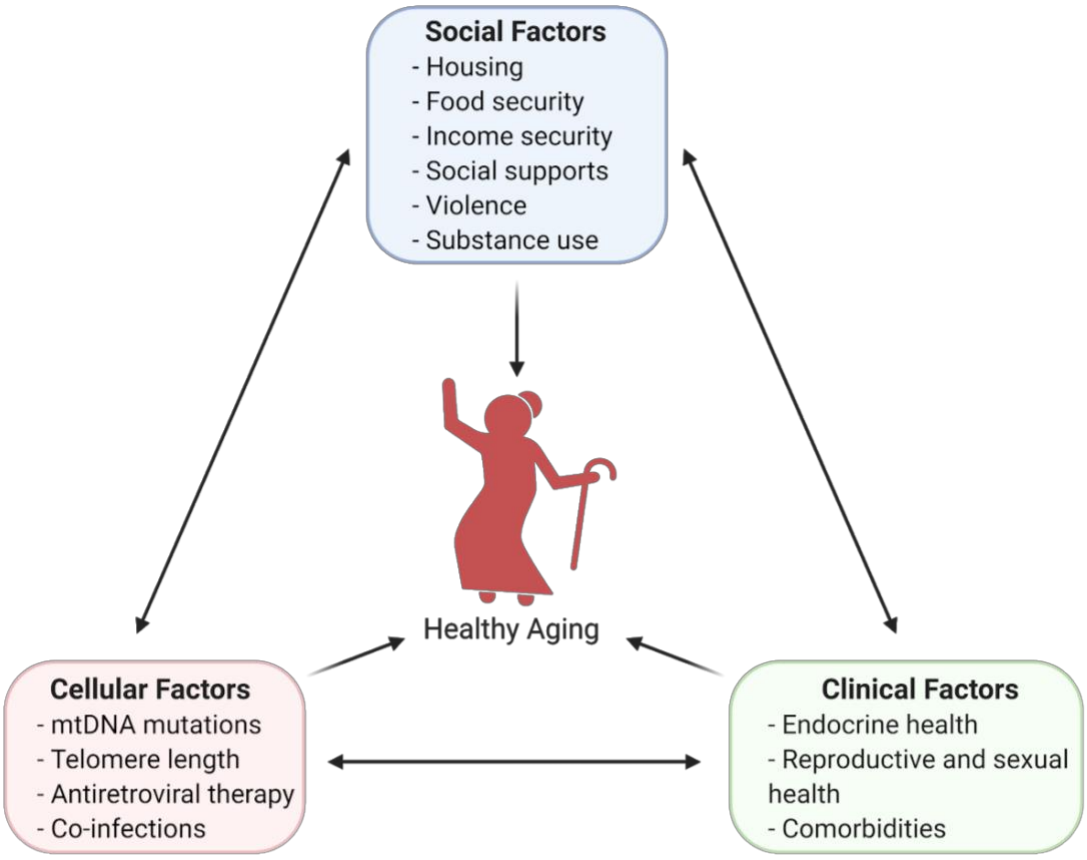


Figure 3. Pathways of cellular, clinical, and social factors affecting each other and the healthy aging of women

Please note: We will learn about these science concepts together and only a basic understanding is needed. We have provided more detail of these concepts at the end of the document, but the most important parts are as follows:

In regards to the *clinical factors*, women living with HIV are more likely to have more medical diagnoses (**comorbidities**) related to age than their HIV-negative peers, and the reasons for this are unclear. The hormones in a women's body are important for women's health. When levels of these hormones are not regular (**hormone dysregulation**), it could potentially lead to certain health diagnoses. Women living with HIV may experience more hormone dysregulation, leading to more health diagnoses and menopause at an earlier age. This has not been studied much, and we want to research it.

For the *cellular factors,* there are two markers of aging in the cells in the body that we can test to determine a person's "cellular age". *We will review these together and in more detail at the end of the document, but here are the basics:*

1) **Telomere length** – Telomeres are protective caps at the end of DNA that shorten with age. Telomere length can tell us about someone's cellular age. Shorter telomere length = older age.
2) **Mitochondrial DNA –** Mitochondria are the energy producing part of cells, and they have their own DNA called "mitochondrial DNA"

People living with HIV sometimes have shorter telomeres and more mitochondrial DNA damage than their HIV-negative peers, meaning their cells may be aging faster. The reasons for this are unclear, but it may be related to many factors, such as inflammation, stopping and starting cART, comorbidities, hormones, stress, and some social determinants of health. We want to understand this better.

Social factors include the social determinants of health, in which are the conditions we are born, grow up, live, and work, such as: age, income, education, food security, housing security, employment, social support, incarceration, experience with violence, etc. These determinants affect the health and wellbeing of individuals through their ability to access services, healthcare, etc. For WLWH, specific social determinants of health include sexual and reproductive rights, traditional gender roles, poverty and unstable housing, risk of violence, lack of access to care, and an underrepresentation in health research (Figure 4). In order to evaluate the role of HIV in health, it is crucial to also study women not living with HIV but with similar social determinants of health. The proposed BCC3 study will be uniquely positioned to do so given that controls will share many risk factors for comorbidities with WLWH.

Figure 4. Social determinants that affect the health of women living with HIV.

Thus, among WLWH, an important knowledge gap is understanding how aging is influenced by disturbances in levels of hormones, comorbid illnesses, and social determinants of health, as well as how these factors interact with each other. There are currently no studies investigating these issues from a wholistic cell-to-society framework. We need this information to identify the extent to which sex hormone changes impact the health and quality of life of WLWH, to highlight the need for HIV care that encompasses reproductive health, and to inform guidelines for comprehensive women-centered HIV care. With its mix of community leaders, basic scientists, clinicians, and psychosocial investigators, the BCC3 team is uniquely positioned to conduct this research.

AIMS AND HYPOTHESES

This section talks about the aims and hypotheses of the BCC3 study.

*What are **aims**? → the goals that a research team wants to address in their study*

*What is a **hypothesis**? → the guess to what the study will find*

Below are the exact aims and hypotheses written in the grant proposals, so they are technical, but we will go through them together! After this section, we will talk about the BCC3 study methods that we are doing to address these aims and test our hypotheses.

AIM1: To characterize and compare: a) chronic/latent viral infections, b) selected markers of cellular aging and c) comorbidities in BCC3 WLWH and controls.

Hypothesis: WLWH have i) a larger number of chronic/latent viruses than their negative peers; ii) greater aging in immune cell subset(s); and iii) more comorbidities than their HIV-negative peers.

AIM 2: To characterize longitudinal changes in markers of cellular aging and determine their association(s) with chronic/latent infections.

Hypothesis: Chronic/latent viral infections are associated with i) a higher rate of change in markers of cellular aging over time; and ii) an increased risk of comorbidities.

AIM 3: To characterize the modulating effect of a) ART interruptions over the HIV lifetime, b) HCV clearance, and c) change from types of cART (NNRTI or PI to INSTI-based cART), on markers of cellular aging.

Hypothesis: cART interruptions over the HIV lifetime are associated with increased mtDNA mutations and/or heteroplasmy.

AIM 4: To cross-sectionally determine and compare the prevalence of reproductive hormonal dysregulation between WLWH and HIV-negative women in the BCC3 Cohort.

Hypotheses:

1. WLWH will be more likely to have a history of prolonged secondary amenorrhea (historical hormonal dysregulation) than HIV-negative women.
2. WLWH will have lower levels of E2 or E1 (primary outcomes), P4, T, (secondary outcomes) than HIV-negative women.

AIM 5: To examine the associations between reproductive hormonal dysregulation, comorbidities, and determinants of health for WLWH and HIV-negative women.

Hypotheses:

3. Historical and current hormonal dysregulation will both be associated with a greater number of comorbidities.
4. The above associations will be moderated by socio-behavioural factors (e.g., opioid use, smoking), and psychosocio-structural factors (e.g. violence, PTSD, income, gender inequity).

Overarching AIM: We aim to develop greater and meaningful involvement of community in our research, and we will integrate community-based research (CBR) methods through all facets of the BCC3 study and build capacity in CBR through the training and support of PRAs and trainees.

METHODS

Community Collaboration

We have, and will continue to, prioritize community voices at every stage of the research process. Women representing Indigenous, African/Caribbean/Black (ACB), youth, mature women, and others have shared their lived and living experiences and expertise to this project and will continue to do so through to knowledge translation. Women living with HIV will lead our Community Advisory Board (CAB) and will meet regularly to discuss various aspects of the study and guide study procedures. As Peer Research Associates (PRAs), you will be leading data collection and other aspects of the study.

Community leaders, clinicians, and academics worked together to create the survey questions, and are continuing to review and discuss the questions through a piloting of the survey. In late January, the BCC3 survey was piloted and workshopped by women living with HIV with research experience. We will be asking you to pilot the survey and give feedback as well!

CAB members and PRAs (you!) will play integral roles in assuring that questions and topics covered are both safe and acceptable for WLWH, while capturing the information required in order to answer scientific questions related to community priorities. You will be paid for your time in two different ways: per survey ($80), and for other activities per hour ($25/hr). Training will be a set payment amount.

As a PRA, you will assist with participant recruitment, will administer the surveys in study visit part 2 with participants (described further below), and support ongoing integrated knowledge translation and exchange activities, which means sharing study findings with the community, academics, healthcare providers, etc. and receiving feedback from those we share our findings with (described further below).

Reflection Activity: Why do we have community advisory boards? What is the importance?

Data Collection Methods

This study is taking place in the Vancouver area, and will enroll **350** women living with HIV and **350** women who are not living with HIV; **700** women in total.

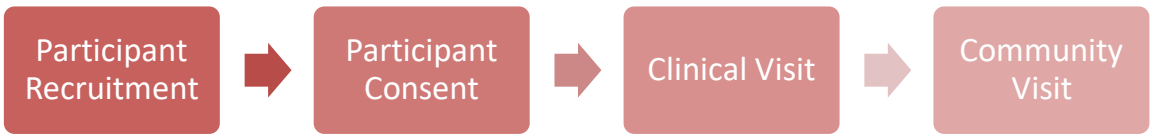


Figure 5. Steps to participation in BCC3 study.

Who can participate in the study?
Women are eligible to participate if they meet the following inclusion criteria:

a. Identify as a cis-gender woman (born and currently identify as female)
b. Able to attend a study visit at Oak Tree Clinic (no need to be a clinic client)
c. Living with HIV (up to 350 participants)
d. Not living with HIV (up to 350 participants)
e. Not currently pregnant or breastfeeding
f. Able to provide written informed consent in English and to attend the clinic visit.
g. 16 years of age or older.

NOTE – Women who are <45 years of age will be asked to take a urine pregnancy test (like a home test) after she has consented to participate in the study, but before any other activities. This is because the hormones in the body are very different during pregnancy. If the test is positive, they will be advised of this, and the visit cannot proceed at that time. We would be very happy to welcome them back for a study visit after they are no longer pregnant or breastfeeding, if applicable, and their menstrual cycle has returned to normal.

Participant Recruitment
We will reach out to women currently enrolled in CARMA and in CHIWOS BC to see if they would like to participate in BCC3. We will also recruit women who did not previously participate in either CARMA or CHIWOS. A significant portion of recruitment for women living with HIV will occur at the Oak Tree Clinic in BC Women's Hospital and Health Centre. Posters will also be put up in the community in locations where women living with HIV gather with the contact info of the study team; locations to be determined following community consultation. We also expect some recruitment to be "word of mouth" – that means women learn about the study through friends, healthcare providers, or other service providers (or maybe from you!). For poster and potential word of mouth recruitment, when interested participants contact the study team, if they self identify as meeting the inclusion criteria, they will be invited to participate.

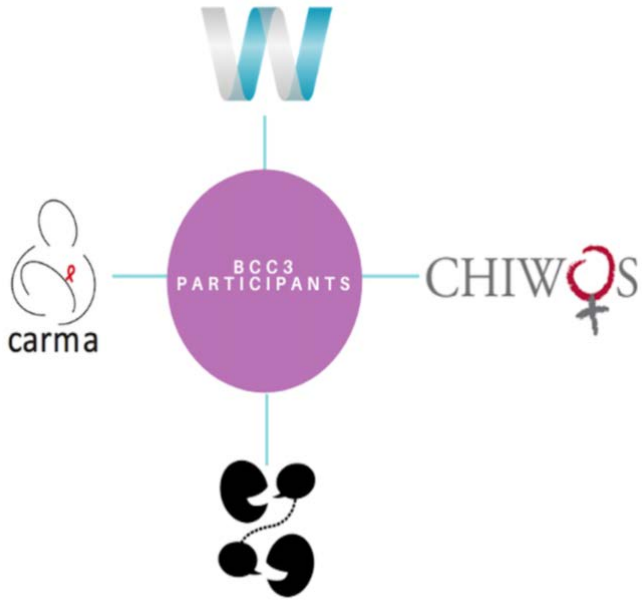


Figure 6. BCC3 participant recruitment will include women from CARMA and CHIWOS studies, Oak Tree Clinic at BC Women's Hospital, and by "word of mouth".

Participant Consent
All interested and eligible women will be asked to provide **informed consent** before participating in the BCC3 study. Participation in this research is entirely voluntary and participants are under no obligation

to participate in this study. That means they may withdraw from this study at any time, without giving reasons. The participant has the right to request the withdrawal of their information collected during the study, too. Please note, however, that there may be exceptions where the data will not be able to be withdrawn, for example where the data is no longer identifiable (meaning it cannot be linked in any way back to their identity) or where the data has been merged with other data. **We will be going over informed consent and ethics in an upcoming module.**

Consenting to the BCC3 study includes survey data collection, specimen collection (blood and hair) and biobanking, data sharing between CARMA and CHIWOS, data linkage to Population Data BC, access to medical charts (for women living with HIV only), testing for co-infections, hormones, and markers of cellular aging, and permission to be contacted in future. For participants who have previously participated in either the CARMA or CHIWOS studies, data collected as part of their previous participation in the CARMA or CHIWOS studies will be accessed and included in the BCC3 study.

What does the study involve?

If women agree to take part in this study, the visit and sample collection schedule they can expect are outlined below. There will be one visit made up of two parts:

1) **Clinical Visit** – Includes bloodwork and first part of survey – at Oak Tree Clinic

2) **Community Visit** – Includes second part of survey with PRA – in community

The two parts of the study can happen on the same day, but have to occur within 1 month of each other. The **Clinical Visit** is expected to take between 1-1.5 hours and the **Community Visit** is expected to take between 1-2 hours. See Figure 7 below.

Women who are not using a hormonal contraceptive and have had a period in the past 3 months, will also be asked to participate in 1 or 2 extra visit(s) for timed bloodwork. The additional timed bloodwork visit(s) would take between 15-30 minutes each.

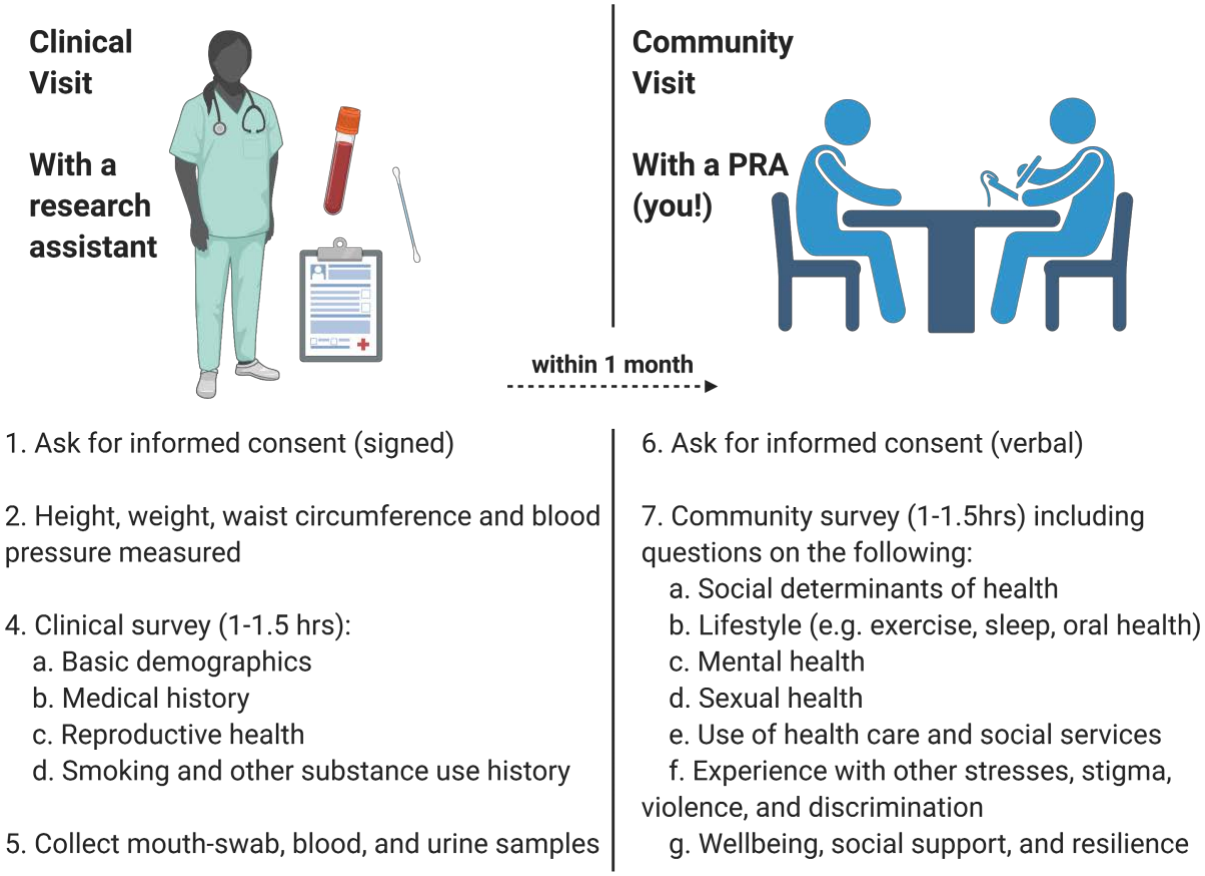


Figure 7. BCC3 study visit split into clinical visit (part 1) vs community visit (part 2).

CLINICAL VISIT – Study Visit Part 1 (1.5-2 hours)
This portion of the visit must occur first and will take place at Oak Tree Clinic in BC Women's.

1. One of the Oak Tree research staff will meet with the participant and review the consent form, answer any questions the participant may have, and obtain informed, signed consent.
2. A urine pregnancy test will be done to determine if the participant is pregnant (only for women <45 years of age).
3. Height, weight, waist circumference and blood pressure will be measured
4. A survey (1-1.5 hrs) with a trained interviewer including questions on the following:
    a. Basic demographics (e.g. age, gender, income, education, housing)
    b. Medical history (e.g. diagnoses, medication use, vaccinations, HIV history)
    c. Reproductive health (e.g. menstrual cycle, menopausal status, pregnancies, contraception use)
    d. Smoking and other substance use history
5. A mouth-swab will be collected
6. A blood sample will be collected
7. A urine sample will be collected for tests in addition to the pregnancy test

Blood that will be collected as part of this study and will be tested for the following (Figure 8):

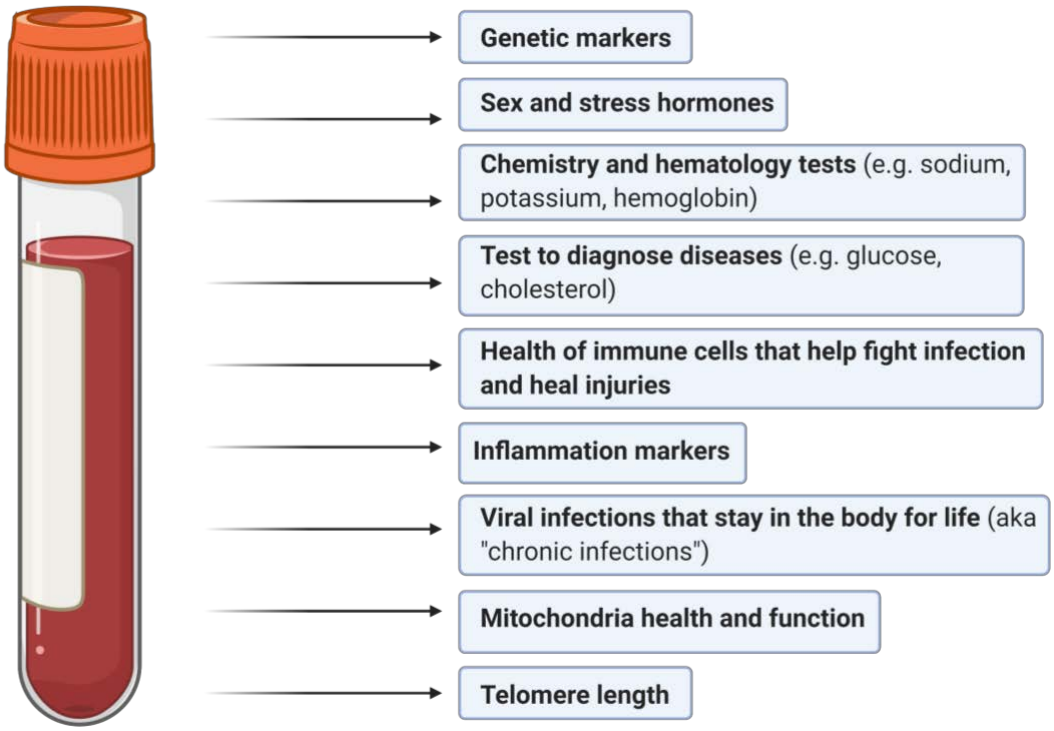


Figure 8. Tests that will be performed with the blood draw. Some are non-diagnostic.

NOTE: Some of the tests for the study are being done using non-diagnostic methods of testing (for research use only), and as such, we will not be able to give these testing results to participants or their doctor.

Hormonal bloodwork: If a woman has menstrual periods and is not using a hormonal contraceptive, included in the above amount of bloodwork will be testing for hormones that require blood drawn to be timed to their menstrual cycle at two different times. One is during the early follicular phase of their cycle (2-5 days after starting flow) and the other is mid-luteal phase (cycle day 21-23 after menses, or 7 days before next flow). We will do our best to time one of these at the same time as their clinical visit. For the other test, a separate visit just for the bloodwork will be required again at Oak Tree Clinic in BC Women's Hospital and Health Centre. She will be reimbursed for this additional visit and it will take 15-30 minutes of her time.

COMMUNITY VISIT – Study Visit Part 2 (1-2 hours)
This portion of the visit must occur after Part 1, can take place 0-31 days (1 month) afterward and can take place at a community or clinical location. This visit will be facilitated by you as a PRA.

8. You will ask for informed, ongoing consent to participation – without requiring a signature

9. You will administer a survey (1-1.5hrs) including questions on the following:
    a. Social determinants of health (eg. food security, incarceration, etc.)
    b. Lifestyle (e.g. exercise, sleep, oral health)
    c. Mental health
    d. Sexual health
    e. Use of health care and social services
    f. Experience with other stresses, stigma, violence, and discrimination
    g. Wellbeing, social support, and resilience

The interview will take place in a quiet, confidential space at a local clinic, community organization, in the participant's home, or via telephone or Skype for those living in more remote areas.

Survey Details
As described above, the survey is split into the clinical visit and the community visit. Each part of the survey includes various sections that will take 1-1.5 hours to complete. The survey will be completed on a computer, through a secure online database called REDCap. The information will be saved on REDCap. Participant's name, contact information and other personal information that can identify them will be kept separate from their answers to the survey. **Therefore, it is not possible to connect them to the answers they have shared.**

A link for each participant will be provided to the PRA, and upon clicking the link and following the log-in steps, the survey will open. We will teach you how to do this. For the community visit, the PRA does not need to receive informed consent, but will need to review the participant's rights in an ongoing consent process. This means receiving verbal consent to continue with the study.

Participant Reimbursement
At the Clinic Visit – the participant will be paid $30 to assist with the cost of parking and transportation, and as a thank-you for their time.

If the participant is a menstruating woman and not on hormonal contraception, they will have 1-2 additional visits to complete the timed hormonal bloodwork, and will be paid $25 for each additional visit to assist with the cost of parking and transportation.

At the Community Visit – the participant will be paid $50 to assist with the cost of parking and transportation (receipts are not required), and as a thank-you for their time.

Participants will be paid at the time of each visit. You will be in charge of giving the honoraria to the woman after she has completed the survey, and making sure she signs the appropriate document. You will be submitting these documents to the research coordinator (Becky).

Data Analysis
After we recruit 700 participants, we will analyze the data we collected with statistical tests. These tests will be performed by a statistician. Then the results from these tests will be written up for knowledge translation and exchange purposes. We would like your input on interpretation of these findings, and how to best present them!

Knowledge Translation and Exchange

New knowledge gained from this study will inform approaches to health care that will promote healthy aging for women living with HIV. As results become available, Community Leaders and Knowledge Users will work together to lead all facets of our Knowledge Translation and Exchange (KTE) strategy – ensuring KTE outputs are grounded in and responsive to the priorities of the communities with which we work.

We hope that you and other Community Leaders will be active in presenting study findings with conference presentations, abstracts, peer-reviewed publications, and in other settings. So, as to ensure KTE back to affected communities, PRAs and other team members will communicate findings with and receive feedback from WLWH attending local HIV/AIDS Service organizations and groups, such as YouthCo, the Afro-Canadian Positive Network of BC (ACPNet), and the Canadian Aboriginal AIDS Network (CAAN). Additional KTE will occur through presentations in the form of a community forum and a Sharing Circle for community, and a care provider education event. KTE will be shared through CHIWOS and BCC3's partners' (Women's Hospital Research Institute (WHRI), UBC, BC CfE, etc.) websites, Twitter feeds, Facebook pages, community websites, listservs, newsletters, presentations and forums to reach a broad audience of community members and care providers. Clinical leaders will lead translation of findings to local and national guideline committees to facilitate the rapid translation of findings to clinical care.

Reflection Activity: Why do you think knowledge translation/exchange might be important?

Reflection Activity: What would be your "elevator pitch" to describe what the BCC3 study is about to someone? (Please note: we will go over this together and practice together, so don't worry – this is just something to get you thinking!☺)

Thank you for reviewing this training module! We will work through these concepts together, so don't worry if there is anything you're unsure of. Feel free to ask us ANY questions!

2.2: BCC3 Methods, Science Concepts, Social Determinants of Health

BACKGROUND INFORMATION ON THE SCIENCE BEHIND THE PROJECT

Here we provide detailed background information on the cellular, clinical, and social factors that we are studying to capture a wholistic look into the health of women living with HIV.

Cellular Factors

***Please note: this is a very scientific section! We've provided a lot of detail, but only a basic understanding is needed and we will go through it together and learn together. The most important things you need to know are that:*

- *There are two markers of aging in the cells in the body that we can test to determine someone's "cellular age".*
    1) ***Telomere length** – Telomeres are protective caps at the end of DNA that shorten with age. Telomere length can tell us about someone's cellular age. Shorter telomere length = older age.*
    2) ***Mitochondrial DNA –** Mitochondria are the energy producing part of cells, and they have their own DNA called "mitochondrial DNA"*
- *People living with HIV sometimes have shorter telomeres and more mitochondrial DNA damage than their HIV-negative peers, meaning their cells may be aging faster. The reasons for this are unclear, but it may be related to many factors, such as inflammation, stopping and starting cART, comorbidities, hormones, stress, and some social determinants of health. We want to understand this better.*

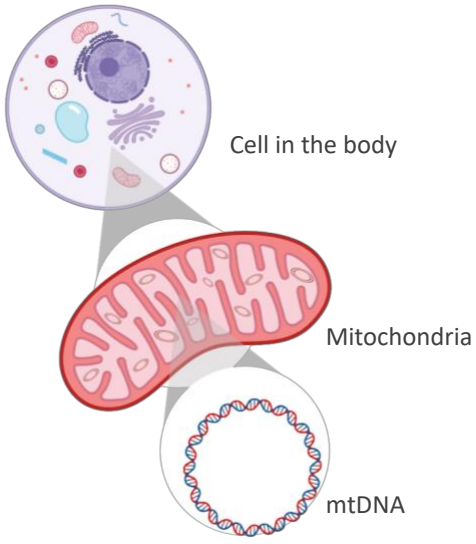


Figure 9. Mitochondria and mtDNA

The immune system is a complex system of defense mechanisms in the body that evolved to protect us from disease. Part of this defense system is inflammation, which occurs to help fight against things that may harm the body. Sometimes when the immune system is "turned on" all the time and not able to rest, it can lead to chronic inflammation in the body and oxidative stress (cellular toxicity), both of which can cause damage to DNA and influence early aging of the cells in our body. "Cellular age" is not the same as chronological age. For example, two people may be 50 years old (chronological age), but their cells may function very differently (cellular age). Having healthy cells is a more important predictor of overall health and aging than chronological age.

HIV and other viruses such as hepatitis C virus (Hep C) and herpes simplex virus (HSV) that can stay with you for life (they are called chronic or latent viruses) can cause chronic activation of the immune system (the immune system remains 'turned on' and is not able to rest). In addition, social stresses such as stigma, violence, and food insecurity also contribute to stress and inflammation in the body. This stress and inflammation could cause hormonal dysregulation in women living with HIV, which may lead to an increase in number of diseases and a decrease in lifespan. Factors such as substance use, HIV medications, amount of HIV virus and CD4 cell count, do not entirely explain differences in markers of aging for women living with HIV. One of these markers is **mitochondrial DNA** (mtDNA) (energy producing part of all the cells in our body) and the other is the **telomere length** (the length of DNA at the end of chromosomes). The use of different kinds of HIV medications, as well as being on and off them over time may also have an impact.

Mitochondrial DNA as a marker of cellular aging and DNA damage:
Mitochondria are little organs in cells involved in energy production, calcium balance in the body, cell signalling, regulation of cell death, and hormone creation. They contain their own DNA (mtDNA), which is maternally inherited and codes for important proteins involved in creating energy for cells. mtDNA is particularly susceptible to mutations, which are changes to the genetic code. When many mtDNA mutations accumulate, they can lead to human aging and age-related diseases. mtDNA mutations are central to biological aging, but challenging to detect and quantify.

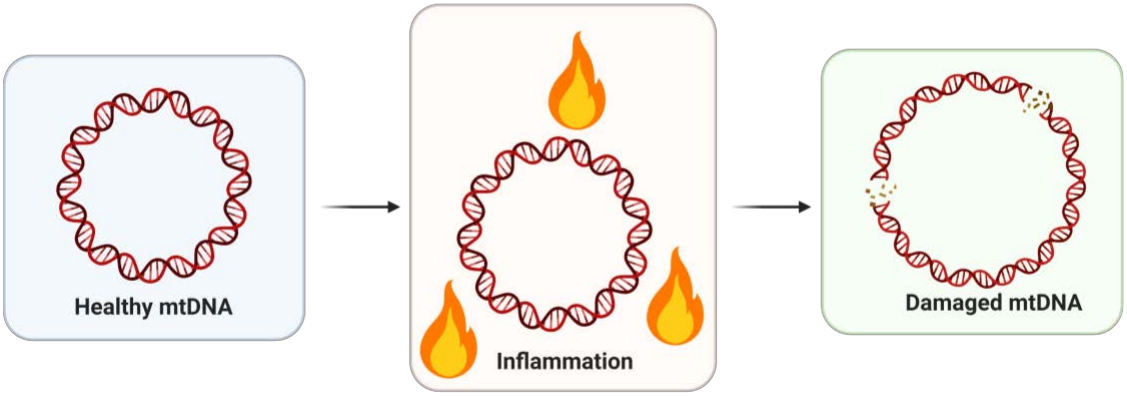


Figure 10. Chronic inflammation occurs when the immune system is over-activated, or "turned on" for too long and not able to rest, and it can cause damage to mitochondrial

In people living with HIV, there is evidence that HIV itself affects mitochondria and energy metabolism. In addition, many HIV medications are known to affect mitochondria directly or indirectly, and contribute to mitochondrial dysfunction. For example, a type of ARVs called nucleoside reverse transcriptase inhibitors (NRTIs) can block mtDNA replication and lead to mutations and dysfunction. So, cART could affect cellular aging and comorbidities through alteration of mtDNA and mitochondrial function.

Telomere length as a marker of cellular aging:

Telomeres are caps that protect the ends of chromosomes (compact DNA) to keep the genetic information protected. Telomere length naturally shortens as we age, due to the cells dividing. You can think of telomeres as the little plastic caps at the ends of shoelaces. If they become damaged, the shoelaces will fray. Similarly, cells become less healthy when telomeres become too short, as the DNA (shoelaces) can become damaged. Telomere shortening can also occur as a consequence of inflammation and DNA damage, but there are many things we can do to prevent this, which we want to study! *What are some things you do to live a healthy lifestyle?*

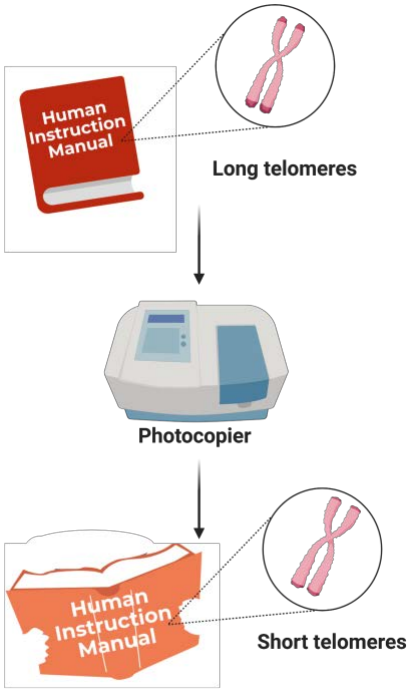


Figure 11. Chromosome with telomeres shown with manual and

Another way to think of telomeres and DNA is in relation to books: DNA is like a manual for how the body functions and telomeres are the hardcovers of the manual. Each time the manual is photocopied, the cover gets more damaged. Overtime, if the cover is too tattered, the whole manual can start to fall apart (Figure 11)! So, once telomeres reach a critically short length, the cell dies or causes inflammation, cellular stress, and DNA damage to other cells. Thus, telomere length is a marker of cellular aging and damage, and predicts mortality (death) among older individuals. It is also established that short telomere length is a strong predictor of cardiovascular disease in the general population.

shorter telomere length = greater cellular age

However, it is unclear what is taking place at the cellular level when telomeres get shorter. In regards to HIV, research has shown that PLWH have shorter telomere lengths than their HIV-negative peers; thus, PLWH may experience increased cellular aging. HIV infection clearly regulates telomere length somehow, likely through immune activation and inflammation. The telomere length in untreated PLWH is shorter, so taking cART may be associated with longer telomere length. However, few studies have investigated telomere length in the immune cells of PLWH treated with cART. This is something that BCC3 is studying.

Thus, chronic/latent viruses may contribute to accelerated aging and the risk of comorbidities among PLWH. It remains unknown whether mitochondrial aging within immune cells may be exacerbated by chronic/latent viral infections and how if this may affect comorbidity risk.

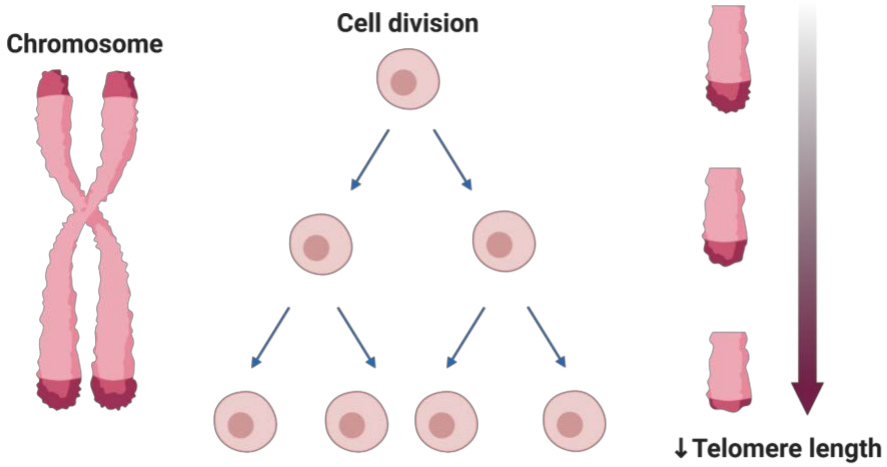


Figure 12. Chromosome with telomeres shown on the tips. Telomere length shortens as cells divide.

Clinical Factors

*** Please Note: This is another scientific section. We will go through it together and learn together. The most important things you need to know are that:*

- *Women living with HIV are more likely to have more medical diagnoses (**comorbidities**) related to age than their HIV-negative peers, and the reasons for this are unclear.*
- *The hormones in a women's body are important for women's health. When levels of these hormones are not regular (**hormone dysregulation**), it could potentially lead to certain health diagnoses.*
- *Women living with HIV may experience more hormone dysregulation, leading to more health diagnoses and menopause at an earlier age. There is very little research done on this, so we are leading the way to learn more about the health of women living with HIV!*

Clinical factors associated with healthy aging of women include comorbidities, hormones, and reproductive and sexual health. Compared to the general population, WLWH are at higher risk of having comorbidities such as kidney, liver, bone, neurocognitive, and cardiovascular diseases, depression, anxiety, and some virus-related cancers (such as HPV-related cancers), even among young individuals. The reasons for this are unclear, however one influential factor may be hormone health, in that hormone dysregulation may lead to an increased number of diagnoses.

The three major estrogens in women are estrone (E1), estradiol (E2), and estriol (E3):

- E1 is the main estrogen present **after menopause**
- E2 is the main circulating estrogen **in menstruating women**
- E3 is present mainly **during pregnancy.**

In addition, there is progesterone (P4) and testosterone (T) (see Table 1 for a list of the hormones and their functions). Estrogens and progesterone are responsible for the development and maintenance of reproductive tissues including breasts, ovaries, the uterus and the vagina. Abnormal E2 and P4 levels are linked to abnormal uterine bleeding and irregular menses (not regular menstrual periods).

For women in general, both menopause (starting >1y after final flow) and amenorrhea (no menstrual periods for >3, 6, or 12 months, depending on the study) are associated with decreased levels of E2 and P4. As well, dropping E2 and P4 levels are associated with an increase of many age-associated diseases. Compared with HIV-negative women, WLWH are much more likely to have a history of amenorrhea and reach menopause at an earlier age. This strongly suggests low sex hormone levels occur earlier in the lives of WLWH. Given the known protective role of hormones in health, this low hormone state may result in earlier and increased risk for comorbidities.

Beyond their role in reproductive health, sex hormones are important in the health of multiple organ systems. With menopause, low E2 levels results in increased risks of health issues related to the heart, liver, and kidneys. In addition, E2 can lead to reducing inflammation. So, these sex hormones are important in regulating health and preventing many comorbidities.

Table 1. List of female sex hormones, where they are produced, their main functions in the body, and what dysfunction of that hormone may look like.

Hormone	Production	Main Functions	Dysfunction
Estrogen (E1, E2, E3)	E1 – post-menopause (fat tissue) E2 – menstruating (ovaries) E3 – pregnancy (placenta)	• Reproductive health • Bone health • Kidney function • Liver health • Protects against heart disease, diabetes *E2 can reduce inflammation	Decreased E1: • Increase in menopausal symptoms • Greater mortality Decreased E2: • Amenorrhea • Age-associated diseases • Increased health risks for heart, liver, kidneys
Progesterone (P4)	Produced by ovaries	• Normal menstrual periods • Liver health	Decreased P4: • Age-associated diseases • Amenorrhea
Testosterone (T)	Produced by ovaries, and adrenal gonads	• Sexual function • Bone health • Muscle Growth	Changes in: • Body weight • Skin quality • Perimenopausal symptoms • Sexual desire, mood • Mental health
Follicle Stimulating Hormone (FSH)	Produced by pituitary gland (brain)	• Ovary function and reproduction	• Menstrual difficulties • Infertility
Luteinizing hormone (LH)	Produced by pituitary gland (brain)	• Tells ovaries to make estrogen, progesterone, testosterone	• Menstrual difficulties • Infertility

Another factor influencing hormone dysregulation is opioid use, which can result in a reduction of female sex hormones, including follicle stimulating hormone (FSH), luteinizing hormone (LH), estrogens, and progesterone. These changes can result in a state of hormone deficiency, which can lead to abnormal uterine bleeding, amenorrhea, and infertility; however, women can recover from this state.

Other factors such as very low body fat, severe physical or psychosocial stress, nutritional deficiency, and chronic illness can also affect women's hormone levels.

Hormones and biological aging: Mitochondria produce energy, regulate metabolism, and are involved in hormone synthesis. When aging is considered at the cellular level, E2 appears to improve overall mitochondrial function and preserve normal mitochondrial function in tissues such as heart, muscle and brain. The protective effect of pre-menopausal E2 and P4 lasts beyond the reproductive years. Among menopausal women, low levels of E1 are associated with increase in menopausal symptoms (i.e. hot flushes, vaginal dryness) and greater mortality.

Hormones with HIV and cART: Levels of hormones are influenced by many factors. Among these factors, HIV and cART can both influence hormone use/breakdown and lead to hormone

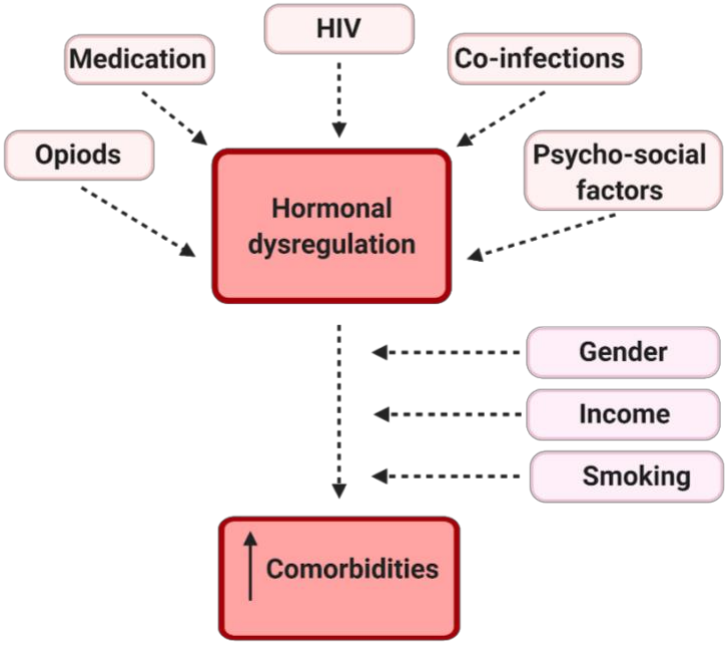


Figure 13. Pathways to increased comorbidities in women through hormone dysregulation and other factors.

dysregulation. Alongside a high risk of comorbidities, CHIWOS and CARMA data indicate high rates of adverse reproductive health outcomes among WLWH, including a frequent history of amenorrhea (lack of menstrual period for many months), abnormal menstrual bleeding, and earlier menopause compared to the general population. Whether and how HIV is associated with hormone dysregulation remains unclear, especially given the likely intersection with stress-inducing social determinants of health such as trauma, violence, poverty, substance use, mental health/resilience and gender inequity.

Hormone dysregulation can affect a woman's life through several avenues. For instance, altered E2, P4

and/or T levels can affect body weight, skin quality, perimenopausal symptoms, as well as sexual desire, mood and mental health (Table 1). Many of these effects may be amplified by HIV associated inflammation. In addition, little is known on how hormonal therapy, hormonal changes and comorbidities may intersect with socio-structural factors to influence the healthy aging of WLWH (Figure 13).

Social Factors

Activity: before reading, what are some of the social determinants of health that you know?

Social factors include the social determinants of health, which are the conditions we are born, grow up, live, and work in, such as: age, income, education, food security, housing security, employment, social support, incarceration, experience with violence, etc. These determinants affect the health and wellbeing of individuals through their ability to access services, healthcare, etc. For WLWH, specific social determinants of health include sexual and reproductive rights, traditional gender roles, poverty and unstable housing, risk of violence, lack of access to care, and an underrepresentation in health research. CHIWOS showed that non-HIV determinants of health are over-represented among WLWH in Canada and play an important role in their health.

Health care provider practice and knowledge: Access to appropriate and holistic care is an important determinant of health. WLWH most often receive health care from infectious disease specialists or family physicians. Neither group of health care providers has specific expertise in identifying menstrual cycle disturbances that may indicate hormonal dysregulation. From community members involved in this study, and CHIWOS data, WLWH report that health care providers seldom even ask them about menstrual cycles. Research from CHIWOS reveals that HIV care providers rarely discuss reproductive health issues with their patients. Obtaining this history is essential for providing best care in the health of WLWH.

Reflection Activity: Now that we've gotten a little bit of training under out belts, was there anything that spoke to you a little more than something else? Work as a PRA can go in many directions beyond facilitating surveys to analyzing data, presenting results to community, writing papers, presenting at conferences, etc.! Where would you like your PRA journey to take you?

Thank you for reviewing this training module! We will work through these concepts together, so don't worry if there is anything you're unsure of. Feel free to ask us ANY questions!

BC CARMA CHIWOS COLLABORATION

BCC3 Training Part 3

July 24th, 2020

1

Land Acknowledgment

- We respectfully acknowledge that the land we work, live, collaborate, and play on is the unceded, ancestral, traditional territory of the Coast Salish Peoples, and the traditional territories of the xʷməθkʷəy̓əm (Musqueam), Sḵwx̱wú7mesh Úxwumixw (Squamish), səl̓ilwətaʔɬ (Tsleil-Waututh), kʷikʷəƛəm (Kwikwetlem) and Katzie Nations.

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Agenda

Intro to Immune system	
Cellular Factors	• Markers of cellular age: telomere length & mitochondrial DNA
Clinical Factors	• Hormonal dysregulation, comorbidities
Social Factors	• Social determinants of health

3

Quick Recap

- Remember that health is influenced by the interplay between social, cellular, and clinical factors!

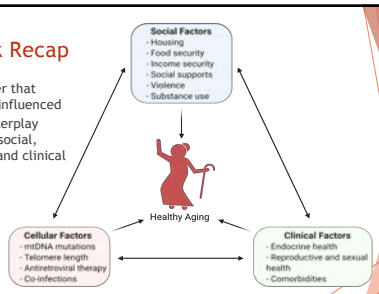

Figure 1. Pathways of cellular, clinical, and social factors affecting each other and the healthy aging of women

4

Section 1

Intro to Immune system

5

What Is DNA?

- DNA is our genetic information
- It determines the makeup of our bodies

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The Immune System – What Is It & How Does It Work?

- A complex system of defense mechanisms in the body that evolved to protect us from disease
- Part of this defense system is **inflammation**
- Chronic inflammation, or long-lasting inflammation, means the immune system is turned on all the time, and the body can't rest

Chronic inflammation + damage to cells (oxidative stress)

⬇

DNA damage + early cellular aging

7

Section 2

Cellular Factors

- Markers of cellular age: telomere length & mitochondrial DNA

8

Telomeres as a Marker of Cellular Age

- Telomere length
- What is a telomere?
  - Protective cap on DNA (genetic information), sort of like the plastic bit (aglet) on a shoelace!

Image retrieved from:

9

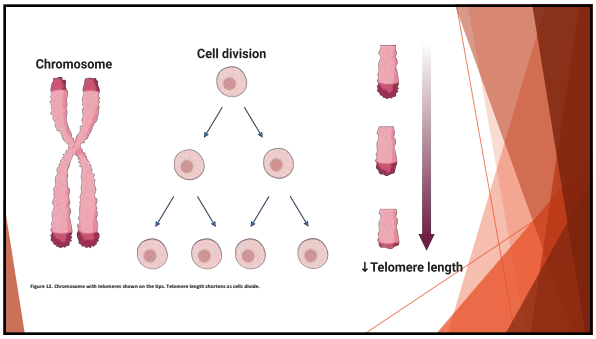


Figure 12. Chromosome with telomeres shown on the tips. Telomere length shortens as cells divide.

10

Why Do Telomeres Get Shorter?

Chronic inflammation + damage to cells (oxidative stress)

↓

DNA damage + early cellular aging

- Cell division
  - Happens in all our cells
- Inflammation
  - Chronic viruses lead to inflammation, so they might contribute to cellular aging, eg: HIV, Hepatitis C
- DNA damage
  - Can be caused by immune system being turned on all the time, eg: in response to chronic viruses

11

Telomere Length

Longer telomere length	Shorter telomere length
HIV-negative peers	People Living with HIV
People Living with HIV taking cART	People Living with HIV not taking cART

*BCC3 is studying telomere length in the immune cells of people living with HIV treated with cART to understand these differences among People Living with HIV !

12

QUICK POLL!

13

Mitochondrial DNA as a Marker of Cellular Age

- Mitochondrial DNA, AKA mtDNA
- What are mitochondria?
  - Mitochondria are the energy producing part of cells, and more!

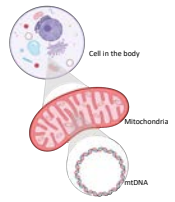


Figure 9. Mitochondria and mtDNA

14

Mitochondrial DNA (mtDNA)

- What is mitochondrial DNA?
  - Mitochondria have their own DNA, called "mitochondrial DNA" that codes for anything specific to the mitochondria. Eg: proteins for creating energy
- mtDNA is particularly susceptible to mutations (changes to the genetic code). Many mutations can add up and lead to aging, & age-related diseases

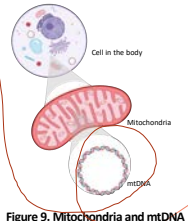


Figure 9. Mitochondria and mtDNA

15

What Causes mtDNA Mutations?

- Inflammation
- Viruses, eg: HIV
- HIV medications, eg: NRTI ARVs

mtDNA mutations can lead to cellular aging, and age-related diseases!

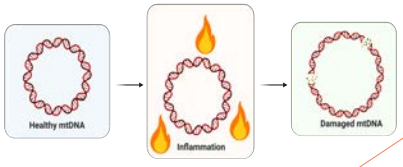


Figure 10. Chronic inflammation occurs when the immune system is over-activated, or "turned on" for too long and not able to rest, and it can cause damage to mitochondrial DNA (mtDNA), a marker of cellular aging.

16

Cellular Factors: Take Home Messages

- 2 markers for cellular age: **telomere length** and **mtDNA damage**
  - Shorter telomere length = older/greater cellular age
  - More mtDNA damage = older/greater cellular age
- People living with HIV sometimes have shorter telomeres and more mtDNA damage than their HIV-negative peers, which could be due to many factors, such as:
  - Inflammation
  - Stopping and starting cART
  - Comorbidities
  - Hormonal Dysregulation
  - Social stressors
  - Some social determinants of health
- **However, there are many things we can do to prevent this!**

17

What are some things you do to live a healthy lifestyle?

18

Section 3

Clinical Factors • Hormonal dysregulation, comorbidities

19

What Are Hormones?

- Hormones are chemicals in our body that travel through our bloodstream to deliver important messages to other parts of our body
- Hormones influence our mind and body
- Some examples include estrogen and testosterone

20

Clinical Factors - What are they?

- Imbalance in hormones (or **hormonal dysregulation**)
- Multiple health diagnoses (or **comorbidities**)
- Reproductive and sexual health

21

What Causes Hormonal Dysregulation?

- Stress
- Inflammation
- Opioid use
  - Women can recover from this state

Image retrieved from:

22

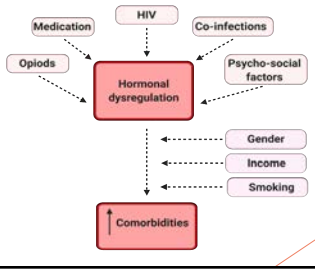
Clinical Factors in Women Living with HIV

- **Hormonal dysregulation** could lead to certain health diagnoses
- Women living with HIV may experience **more hormonal dysregulation** than HIV-negative peers, which **leads to certain health diagnoses**
- Women living with HIV are more likely to have **comorbidities** than their HIV-negative peers
  - Eg: comorbidities related to kidney, bone, & liver health

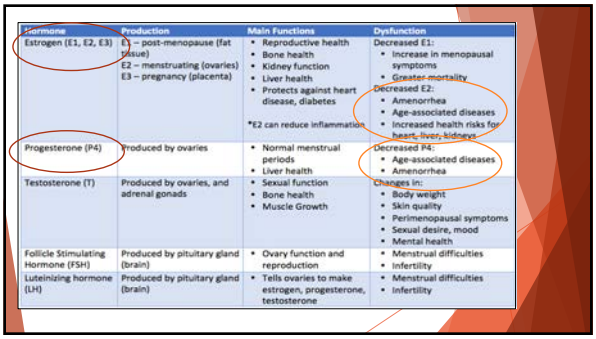
***BCC3 is investigating this, and how it happens!**

23

How does this happen?



24



Hormone	Production	Main Functions	Dysfunction
Estrogen (E1, E2, E3)	E1 – post-menopause (fat tissue) E2 – menstruating (ovaries) E3 – pregnancy (placenta)	• Reproductive health • Bone health • Kidney function • Liver health • Protects against heart disease, diabetes *E2 can reduce inflammation	Decreased E1: • Increase in menopausal symptoms • Greater mortality Decreased E2: • Amenorrhea • Age-associated diseases • Increased health risks for heart, liver, kidneys
Progesterone (P4)	Produced by ovaries	• Normal menstrual periods • Liver health	Decreased P4: • Age-associated diseases • Amenorrhea
Testosterone (T)	Produced by ovaries, and adrenal gonads	• Sexual function • Bone health • Muscle Growth	Changes in: • Body weight • Skin quality • Perimenopausal symptoms • Sexual desire, mood • Mental health
Follicle Stimulating Hormone (FSH)	Produced by pituitary gland (brain)	• Ovary function and reproduction	• Menstrual difficulties • Infertility
Luteinizing hormone (LH)	Produced by pituitary gland (brain)	• Tells ovaries to make estrogen, progesterone, testosterone	• Menstrual difficulties • Infertility

25

Why Are Sex Hormones Important?

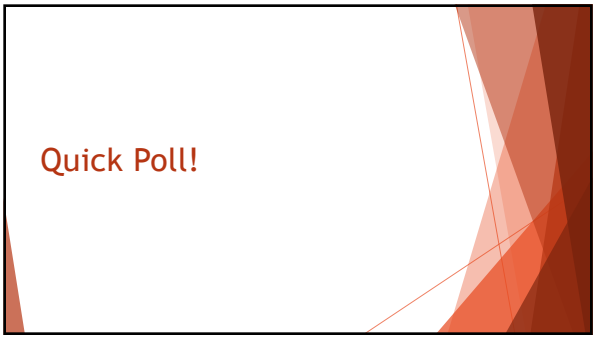
- Sex hormones are important for our health and in preventing many comorbidities (multiple diagnoses).
- Low sex hormone levels could increase risk for comorbidities
- Women living with HIV are more likely to have a history of amenorrhea (lack of a menstrual cycle), and reach menopause at an earlier age than their HIV-negative peers
  - Women living with HIV have low sex hormone levels earlier in their lives (Eg: E2, P4)

26

Clinical Factors: Take Home Messages

- **Hormonal dysregulation** can lead to multiple health diagnoses
- Many factors lead to **hormonal dysregulation**
- Sex hormones play a protective role against **comorbidities** (multiple health diagnoses)
- Women living with HIV have different levels of sex hormones than their HIV-negative peers. This is associated with early menopause and amenorrhea

27


Quick Poll!

Section 4

Social Factors

- Social determinants of health

1

What do you think of when we talk about “health”?

What do you think of when I say “social determinants of health”?

2

Social determinants of Health

Health: A complete state of body (physical), mind (mental), spiritual, emotional, and social wellbeing- not just the absence of disease.

Determinant: The circumstances that influence a person's current state of health.

Social Determinants of Health (SDOH) are the conditions we are born, live, work, and age in; and the wider forces and systems **shaping the conditions of daily life (including accessing healthcare).**

- Positively or negatively impact one's health

3

Can you brainstorm some social determinants of health?

4

Social determinants of Health

- Age
- Income
- Racism
- Sexism
- Education
- Food security
- Social inclusion / exclusion
- Education
- Experience with violence
- Gender
- Poverty
- Incarceration
- Housing security

Paper: Shokoohi, M et al. Social determinants of health and self-rated health status: A comparison between women with HIV and women without HIV from the general population in Canada (2019).

5

* we will have a session specifically dedicated to race, ethnicity, and culture

6

How might housing influence daily life, and/or health?

7

Quick Recap

- Remember that health is influenced by the interplay between social, cellular, and clinical factors!

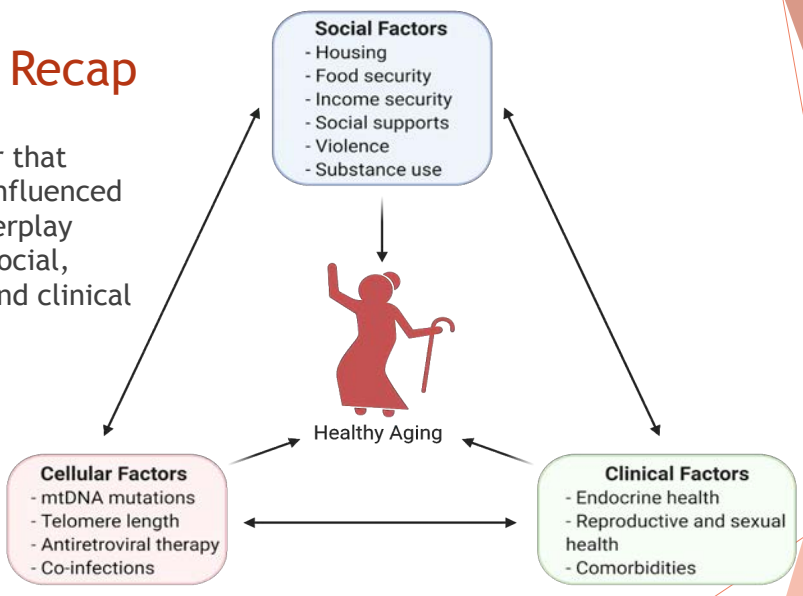


Figure 1. Pathways of cellular, clinical, and social factors affecting each other and the healthy aging of women

8

Access to appropriate and holistic care is an important determinant of health.

- What might impact someone's ability to access health care?
- Many women living with HIV access care from infectious disease specialists or family physicians.
- When we think of **holistic health,** what might be missing?

2.3: Ethics

ETHICS

This is an important module covering ethics of conducting research. We will be reviewing important processes and activities that you will be expected to participate in, to ensure the safety and rights of women interested in participating in the BCC3 study, and the BCC3 research team.

First, please watch a video that was made for the CHIWOS study, to strengthen your understanding of the ethical aspects of conducting research. This will cover two key questions:

1) Where do research ethics come from, and why are they so important?
2) What are the guiding ethical principles of research in Canada?

Listen to the presentation (20 minutes): https://youtu.be/b2HgM4oifYg

Informed Consent

Informed consent is an important term that you will hear over and over again. Informed consent is the process through which participants give their permission for the study to begin. It is an important way that the researchers show respect for the autonomy of the person interested in participating. We will also go to **Universities Without Walls** to watch a module called 'Informed Consent for Community based-research.' This will describe what informed consent is, the different details, and the process. This module also includes a video role-playing how to obtain informed consent.

Work through the presentation here (approximately 15 minutes):
http://www.universitieswithoutwalls.ca/emodules/cbr-101/informed-consent/

An important aspect of informed consent is that it is **ongoing**. Consent is more than getting a signature on a piece of paper. This means that for each question, and each stage of the research process, an individual has the right to continue their consent by deciding how they would like to participate; or knowing that they may withdraw their consent, and stop participating in the study at any time, and without providing any explanation.

In some cases, participants may decide after participating in a study (ie. after completing an interview) that they do not want us to use their data. As a study team, where possible, we will remove their answers from the data set. Where this is not possible this must be clearly stated in the consent process.

In BCC3 we collect biospecimen data as well as survey data. If a participant wishes to withdraw after completing the survey and biospecimen collection, they have a couple of options.

1. They can withdraw from the community (survey) portion, and leave the clinic survey and the biospecimen samples;
2. They can choose to have their clinic survey and biospecimen samples **anonymized**, which means we could keep their data and samples, but their name would be removed from our database, surveys, samples, so that we would not be able to link anything back to them.
3. We will also destroy their specimen and associated data if they ask us to do so.

Confidentiality and Privacy

We are asking women to share potentially sensitive and personal information with us. It is our responsibility to protect this information that is shared. **You will be completing an online course titled, TCPS 2 (Tri-Council Policy Statement) which covers this responsibility in detail.**

Privacy refers to the right of an individual to keep their health information private.

> "Privacy refers to an individual's right to be free from intrusion or interference by others. It is a fundamental right in a free and democratic society. Individuals have privacy interests in relation to their bodies, personal information, expressed thoughts and opinions, personal communications with others, and spaces they occupy. Research affects these various domains of privacy in different ways, depending on its objectives and methods. An important aspect of privacy is the right to control information about oneself. The concept of consent is related to the right to privacy. Privacy is respected if an individual has an opportunity to exercise control over personal information by consenting to, or withholding consent for, the collection, use and/or disclosure of information." (TCPS 2 – Chapter 5)

Confidentiality refers to the duty of anyone entrusted with health information to keep that information private. This means that participants do not have to share anything that they do not want to share; and that anything that is shared must be kept safe, private, and secure.

> "The ethical duty of confidentiality refers to the obligation of an individual or organization to safeguard entrusted information. The ethical duty of confidentiality includes obligations to protect information from unauthorized access, use, disclosure, modification, loss or theft. Fulfilling the ethical duty of confidentiality is essential to the trust relationship between researcher and participant, and to the integrity of the research project." (TCPS 2 – Chapter 5)

Informed and Ongoing Consent in BCC3

1 

Clinic Visit: BCC3 staff will go through the consent form with the study participant, outlining all their rights as a participant.

- Right to skip any question
- Right to know what the study is about, and what will be done with their data
- Right to stop at any time

2 

Community Visit: the PRA will have a blank copy of the consent form to review with the participant. You do not need to go line by line, but a good resource. Need to highlight important points:

- Right to skip any question
- Right to stop at any time
- Ensure understanding of what

3+ 

ONGOING CONSENT

- Continue to answer questions
- If a participant decides they no longer want to participate → report to coordinator
- Coordinator will review options with participant re: collected data; remove/destroy data and

BCC3 study processes to ensure privacy and confidentiality are as follows:

- All BCC3 team members will sign a confidentiality agreement to protect the identity and information shared by study candidates and participants.
- All data collected from participants will be stored in a secure system that is password protected. Survey data will be stored separately from personal identifying data.
- All biospecimens will be stored in a locked room and will not contain any personal identifying data
- Participants will be given a unique participant ID to ensure their name and contact information is protected.
- At the beginning of every survey PRAs will let the participant know they may be sensitive to and/or emotionally activated by some of the questions.
- Throughout the survey and especially when it has been completed, the PRA will check-in with the participant to make sure they are feeling emotionally okay and will provide referrals and resources when needed.
- When completing the questionnaire, participants always have the option to skip sections or refuse to answer any question(s) that makes them feel uncomfortable.
- PRAs will not disclose a person's HIV status to any member of the research team nor the public.
- PRAs will not disclose a participant's name, or any identifying information to anyone. What is shared during the survey – including any stories shared that may not be related to a specific question asked – is not to be shared with anyone. This also means we have to be careful how we are sharing and storing information.

- EXCEPTION: one of the ways that we support each other as a team is by debriefing. If you need to debrief a particular situation, you may need to share some details with the team. **Please consider what information is important to share, and what isn't.**

Pre-Meeting Activity

1. Please write down any questions that you would like to discuss together.

2. Please reflect on a time where you participated in a study and were asked to provide your consent to participate. Can you identify the different steps of informed consent in your own experience? What did you find helpful, and/or unhelpful, in the way your interviewer approached this conversation?

3. Please list some actions that you think need to be taken and considered in order to safekeep the privacy and confidentiality of BCC3 participants.

EXTRA: For more Information

If you are interested in learning more, **Universities Without Walls** has a module that describes the **ethics review** in community-based research. This is taught by academics and community experts about the ethics review process in more depth, and how to create a relationship with your ethics review board. If you have time, you may wish to look into this further using the link below:

http://www.universitieswithoutwalls.ca/emodules/cbr-101/ethics-review/

2.4: Data Quality

DATA QUALITY

This module is about **Data Quality** in the BCC3 Study. We will review what data quality means; why it's important; and how you can collect high quality data! We will be reviewing a lot of information to support you in collecting high quality data – but as always, do not expect you to memorize all of the information in this module. This will be a resource that you can continue to draw on! **We will be highlighting all of the key aspects of data quality when we come together.**

Data are facts or information used usually to calculate, analyze, or plan something; a set of values of qualitative or quantitative variables about one or more persons or objects.

First, it is important to understand the **types** of data.

Types of Data: Qualitative vs. Quantitative

Qualitative data:

"I am a 29 year-old woman. My parents are both of mixed ethnicity and I also consider myself "Mixed". Yeah, I'm on treatment and try to take my medication every day. Some days it's easy. Some days it just sucks, you know? I try to relax sometimes. A little red wine here and there never hurt anyone. You wanna know about my sex life? … What sex life! Ha! Ha! I don't have anyone keeping me satisfied just now, if you know what I mean? (laughs) But, you know, I'm okay. I'm okay with the way things are right now. I don't LOVE it. But I'm satisfied with my sex life."

Qualitative data uses words, sentences, even expressions to capture information. Here is an example of qualitative data given by a woman who could be an eligible BCC3 participant. You can see that her narrative is full of life and personality. There is a lot of nuance here. And her responses are fully in her own words. This is a strength of qualitative data.

Quantitative data:

ID	Province of residence	Gender	Age (yrs)	Ethnicity	Alcohol use in last yr	Sexually active	Sexual satisfaction
CH_BC-01	BC	Woman	29	Mixed Race	Yes	No	Somewhat satisfied

While qualitative data uses words, quantitative data uses numbers and categories. Instead of asking questions that participants can answer in their own words, the questions are highly structured with very few response

options. These are the types of questions that we ask in the BCC3 online questionnaire. If we were to ask survey questions to get at the information that she gave in her narrative, it would look something like this when you enter it into the survey.

You can see that by doing this, we lose some of the information that is provided in the narrative. But we sometimes sacrifice the nuance of the responses to be able to describe and compare features of large groups of participants.

While it can feel strange to look at complex narratives reduced to numbers, this is how we start to understand the structure of the data. By transforming the data into numbers, we can start describing our **BCC3 participants as a GROUP**. This is the value of quantitative data. It allows us to examine patterns and trends and associations between variables using data from groups of people.

BCC3 uses quantitative and biospecimen data.

What kinds of questions does quantitative data help us answer?

How many 'conditions' are in a certain population at a given time (also known as **prevalence**).

- e.g., What proportion of women living with HIV in Canada are living with mental illness?

Identify risks for developing a condition

- e.g., Are women living with HIV more likely to have early menopause compared with women not living with HIV?

Determine which groups are affected by a health state

- e.g., Are older women living with HIV more likely to be sexually dissatisfied?

Why are these data important?

- To produce scientific evidence about health, healthcare, and social priorities for women living with HIV.

- Advocate for improved policy, programming, and services for women living with HIV.

- Implementation of recommendations from the research can improve women's health, healthcare, lives, and well-being.

BUT in order to do this, data needs to be accurate (reflect the true answer/response), **reliable** (do not contradict another piece of information), **and complete** (answered fully). Otherwise, we can be led to findings that are inaccurate, unrepresentative, or low priority.

If the data are inaccurate or incomplete for some groups of women, then their priorities will be under-represented.

As PRAs, you are the first step in the entire process of producing evidence to improve women's health and lives.

When you are administering the survey, you will be entering the information into REDCAP by checking the right response options. And then we analyse those data.

Let's look at an example

In the survey, below (top of page 4) is how we ask the question about racial and/or ethnic background. ***Note: this example is taken from the CHIWOS survey – please know that in BCC3, we have updated our work to the appropriate terminology (ie. Aboriginal → Indigenous, and Caucasian → White). We will discuss during our training session.**

Why do we ask about racial and/or ethnic background? We are interested to know if we have recruited women who reflect the diversity of women affected by HIV in Canada. I will also want to see whether women of certain ethnic groups have better or worse health outcomes, including healthy sexuality. Let's look at a data sample a bit more closely.

S1-Q7. What do you consider to be your racial and/or ethnic background?
Select all that apply.

- ❑ Aboriginal person living in Canada (e.g., First Nations, Métis, and Inuit) → **S1-Q8a Eligible**
- ❑ Indigenous Person from a country outside of Canada
- ❑ Black African (e.g., Nigerian, Somali)
- ❑ Black Caribbean (e.g., Haitian)
- ❑ Black Other (e.g., Black Canadian)
- ❑ Caucasian/White
- ❑ Chinese or Taiwanese
- ❑ Filipino
- ❑ Japanese
- ❑ Korean
- ❑ Latin American (e.g., Chilean, Costa Rican, Mexican)
- ❑ South Asian (e.g., Indian, Bangladeshi, Pakistani, Punjabi, and Sri Lankan)
- ❑ Southeast Asian (e.g.,Cambodian, Laotian, Malaysian, Vietnamese)
- ❑ Arab (e.g., Egyptian, Kuwaiti, and Libyan)
- ❑ West Asian (e.g. Iraqi, Isreali, Lebanese, Afghani, Iranian)
- ❑ Central Asian (e.g., Kazakhstan, Krgyzstan, Tajikistan, Turkmenistan)
- ❑ Multiple races / Multiracial / "Mixed"
- ❑ Other, please specify: _____
- ❑ Don't know **[exclusive]→ Skip to question S1-Q9**
- ❑ Prefer not to answer **[exclusive] → Skip to question S1-Q9**

You can see here the instructions saying that if a participant reports being an "Indigenous person living in Canada", then the questions specific to Indigenous women are opened up. Otherwise, there are a lot of options of how to identify a participant's ethnicity.

From the table below, you can see here how diverse participants are in terms of ethnicity. A few categories are so small that we risk identifying participants. Usually if there are fewer than 5 participants in a particular category, we don't report that actual number. We just report "<5".

ETHNICITY	# of responses
Aboriginal person living in Canada (e.g., First Nations, Métis, and Inuit)	297
Black African (e.g., Nigerian, Somali)	302
Black Caribbean (e.g., Haitian)	64
Black Other (e.g., Black Canadian)	9
Caucasian/White	553
Chinese or Taiwanese	5
Filipino	< 5
Japanese	8
Korean	<5
Latin American (e.g., Chilean, Costa Rican, Mexican)	25
South Asian (e.g., Indian, Bangladeshi, Pakistani, Punjabi, and Sri Lankan)	15
Southeast Asian (e.g., Cambodian, Laotian, Malaysian, Vietnamese)	< 5
Arab (e.g., Egyptian, Kuwaiti, and Libyan)	5
West Asian (e.g. Iraqi, Isreali, Lebanese, Afghani, Iranian)	<5
Multiple races / Multiracial / "Mixed"	29
Other, please specify:	58

Also, participants can list more than one ethnicity in this list so the number of responses is bigger than the number of participants. But with so many categories, it is difficult to interpret these numbers.

The first data collection lesson that we want to highlight comes from the data on the high number of **"OTHER, specify"** responses. This option is included in the survey in case you and the participant can truly not fit the participant into one of the categories listed. Let's take a closer look at the "specified responses"…

African		NON STATUS METIS
Black African - Zimbabwe		PACIFIC ISLANDER
British Isles		PORTUGUESE
CANADIAN		Romainian
CARIBBEAN - SOUTH ASIAN DIASPORA		Romanian
Caribbean-South Asian diaspora		Russian
Congo		SCOTTISH
DIASPORIC INDIAN COMMUNITY		Thai
ENGLISH,JAMAICAN		Thailand
Ethiopia		WEST INDIAN CARIBBEAN
European		ZIMBABWE
French/Franco Canadian		black canadian
GERMAN		british
Greek		european canadian
HUNGARIAN		french canadian
ITALIAN AND UKRAINIAN		italian
Iranian/German		jamaican
Italien		latina
JEWISH		latino
Jewish Eastern European		polish
KENYAN		south america
Kurdish		

Activity: Before going to the next page, can you identify any of the 'other specify responses' that could have been coded into an existing category with the question above?

In order to use the ethnicity data for all of our participants, including those 58 where "Other" was reported, requires **re-coding**.

To do this, the analyst (often the research coordinator, PRA, or other collaborator) tries **a 'best guess' of what might be the best category to fit this participant into**. But the participant isn't there to advise whether that fit is good or not. So, it's better if the PRA and participant can choose the category, rather than leaving it to the analyst.

Missing sections / Prefer not to answer

We added the option of 'prefer not to answer' because we respect and honour that women may not want to answer questions – for any reason – and they have the right to skip any questions they don't want to answer.

However, these are not options to take lightly because this means that their priorities, needs, and voices concerning particular topics are missing from the survey. For example, if a woman decides not to answer a question about her age, that may exclude her from a range of analyses where age is a factor (like a reproductive question, or an analysis looking at experiences of youth).

We cannot force or coerce anyone to be completing any questions they don't want to, but we need to make sure that the section/question isn't being skipped for time concerns or other sorts of reasons.

Biospecimen and Clinical Samples

The BCC3 study also collects **biospecimen** data (physical samples taken, including spit (saliva), blood, hair, etc.) and **clinical** data (including measuring height, weight, blood pressure, etc.).

There are important steps to ensure data quality here as well, including making sure that machines are working properly (ie. the arm cuff is accurately measuring blood pressure readings), that the samples are collected in a similar manner across participants and according to the proper protocol (ie. making sure that all participants' heights are taken without their shoes on).

Team members collecting the clinical and specimen data will be properly trained in these methods to make sure that it is measured and stored properly.

Bias in research

There will always be some form of bias or error in research (we are all human!); so, it is important to understand the risks of **bias** that might be present, so that we can work to address possible sources ahead of time.

Bias: an error in the design or conduct of a study that leads to an erroneous (or incorrect) association.

First, let's review definitions and types of bias. There are many different types of biases, but we will focus on a few select types that are particularly important to us.

- **Recall bias**: when survey respondents are asked to answer questions about things that happened to them in the past, the researchers have to rely on the respondents' memories of the past. Sometimes different types of events are more likely to be remembered than others, causing respondents to report those types of experiences more readily.

- **Social desirability bias**: survey respondents answer questions based on what they think will be viewed "positively" or "favourably" by others.
- **Selection bias**: research samples can sometimes under-represent certain people or groups, and over–represent others. We need to be aware of who is more likely, and who might be less likely to be included in studies, programs, etc. so that we can make sure we have equal and appropriate representation and voices included.
    - Thoughtful recruitment and retention efforts (keeping participants in the study) are important here.
- **Interviewer bias**: the interviewer's expectations or opinions may interfere with their objectivity (their ability to be neutral), or interviewees may react differently to their personality or social background.

What BCC3 Can do to promote good Data Quality

There are many things that we can do as team members to make sure that we have good, respectful interviews with women while maintaining data quality.

1. **Have a well-designed survey!** This is why we pilot the surveys over and over again – to make sure that we are asking the right questions, in the right order, in a way that makes sense and do not **lead** the participant to answer in a particular way.

2. **Standardized questions**: you will hear us say that some of our questions or scales are "standardized" or "validated". That means that the way the question is asked, and the answers provided have been piloted and tested in other surveys and other studies; and we can be confident that the way the question has been used will measure what we want to measure.
    - That means that we MUST use the exact wording if we want to be able to compare the results with another study, or across different surveys within the same study.

3. **Control questions**: including questions in different parts of the survey that should theoretically "match"; or switching up questions in a **scale** question.

   Example from the CHIWOS Survey: In section 1, we asked participants:

S1-26. Do you make money from any of the following sources:
Select all that apply:

- ❑ Pension
- ❑ Sex work
- ❑ Selling drugs / drugs paraphernalia
- ❑ Pan-handling/ 'squeegeeing' / recycling
- ❑ Personal Savings
- ❑ Loan(s) / Student Loan(s)
- ❑ Parent / friend / relative / partner income

- ❑ Honoraria (workshops, trainings)
- ❑ Money from First Nations Band
- ❑ None of the above
- ❑ Don't know
- ❑ Prefer not to answer

And then in section 9, we asked participants:

S9-17a. These next questions are specific to sex partners from whom you have received money, drugs, shelter, goods, or services in exchange for sex. Remember that the information you are providing us is completely confidential.

Have you ever been provided with any of the following in exchange for sex?
Select all that apply.

- ❑ Money
- ❑ Drugs
- ❑ Shelter
- ❑ Food
- ❑ Gifts
- ❑ Clothes
- ❑ Services
- ❑ Other, please specify:
- ❑ No, I have never been provided with anything in exchange for sex
- ❑ Don't know
- ❑ Prefer not to answer

If in section 1, participants mentioned that they made money from sex work, then we would expect that they would also select "money" in section 9.

Additionally, in several included scales we will **reverse** some questions; so that, for example, it wouldn't make sense to just select "agree" for all of the responses.

Example from CHIWOS:

S4-02. Below is a list of the ways you might have felt or behaved **during the past week**. Please tell me how often you have felt this way **during the past week**.

Select one per line.

	Most or all of the time (5-7 days)	Occasionally or a moderate amount of time (3-4 days)	Some or a little of the time (1-2 days)	Rarely or none of the time (less than 1 day)	Don't Know	Prefer not to answer

a.	I was bothered by things that usually don't bother me.	❑	❑	❑	❑	❑	❑
b.	I had trouble keeping my mind on what I was doing.	❑	❑	❑	❑	❑	❑
c.	I felt depressed.	❑	❑	❑	❑	❑	❑
d.	I felt that everything I did was an effort.	❑	❑	❑	❑	❑	❑
e.	I felt hopeful about the future.	❑	❑	❑	❑	❑	❑
f.	I felt fearful.	❑	❑	❑	❑	❑	❑
g.	My sleep was restless.	❑	❑	❑	❑	❑	❑
h.	I was happy.	❑	❑	❑	❑	❑	❑
i.	I felt lonely.	❑	❑	❑	❑	❑	❑
j.	I could not get "going".	❑	❑	❑	❑	❑	❑

If a participant selected "most or all of the time" for all of the answers, it wouldn't make total sense – they would be saying that they felt depressed most or all of the time, AND happy most or all of the time.

4. Make sure that you know the survey well and can clearly understand what each question is asking and/or know who you can call or ask to clarify. We anticipate that as you start administering the survey, more questions about the survey will come up, and you might not have the answer right away. In that case, please make a note and we can discuss, share, and learn as a team. ☺

5. Don't rush participants – make sure that you book enough time to work through the survey.

6. Only use "Other/Specify" responses if there is truly no other option available.

7. We will also introduce and continue to grow a "Hot Tips" sheet that CHIWOS PRAs started, sharing tips and tricks as we go.

- Others? ***Please brainstorm some other "Hot Tips" that might help to have a successful survey! You can also look at the CHIWOS PRA Hot Tips sheet for some ideas.***

Pre-Meeting Reflection Activities

4. Please write down any questions that you would like to discuss together.

5. What are some other factors that might influence data quality?

6. Imagine that you are administering a survey to a woman. Mid-way through the survey, she starts fidgeting and seems to be giving conflicting answers. What might you do to try and uphold **data quality**?

7. Have you ever participated in an interview, survey, or other situation where you felt that the person administering the interview was trying to get you to answer in a certain way?

2.5: PRA Logistics

OVERVIEW OF THE JOB

BC CARMA CHIWOS COLLABORATION

1

KEY QUESTIONS

- What are my roles & responsibilities?
- What is expected of me?
- What can I expect from BCC3?
- What's the process for getting paid for surveys?

2

ROLES & RESPONSIBILITIES

During Recruitment

- Collaborate with your coordinator, PRA team, community organizations, partners and peer networks to recruit participants
- Assist with screening potential participants to confirm study eligibility

3

ROLES & RESPONSIBILITIES

During Surveys

- Assist with setting up interviews for participants
- Confirm ongoing consent with participants
- Administer the BCC3 survey using a computer (laptops will be provided)
- Administer the participant honorarium and complete necessary paperwork**

4

ROLES & RESPONSIBILITIES

Ongoing

- Participate in regular provincial team meetings to discuss interview-related issues and to support fellow PRAs
- Connect with the BCC3 coordinator and study team as needed
- Return all completed study materials to your coordinator
- Act as a BCC3 representative within your region

5

WHAT'S EXPECTED OF YOU

When working in your new job as a PRA

6

1) Steward and represent BCC3 proficiently in the community

2) Demonstrate familiarity with the project, background, context, and team

7

3) Survey and assist research in confident, independent, professional manner

4) Apply ethics, principles, and teamwork in practice

8

5) Communicate constructively with survey participants and the BCC3 team

6) Practice self-care, communication, debriefing, and safety precautions

7) Make informed decisions about then impact on yourself of doing the research

9

WHAT I CAN EXPECT

When working for BCC3

10

SURVEY PAYMENT

How much?	How often?	What does this include?
$80 per survey	Every 2-4 weeks, you'll submit an invoice for the # of surveys completed*	All time required to complete the interview and for other roles and responsibilities outlined previously

11

YOUR OWN TIME

It is expected that you fulfill the roles and responsibilities outlined previously.

This includes reviewing and getting familiar with the survey materials, sometimes on your own time.*

Please know that we welcome involvement in various study activities besides survey work (for example, the Community Advisory Board). However, due to limited funding, sometimes these extra activities might not be paid. These activities are voluntary.

12

TIMELINES

- Due to COVID-19, there have been research curtailments placed on research teams
- Aim to enroll participants over a 2-year period
- Initially contacting CHIWOS + CARMA participants to see if they are interested in participating, before general recruitment

Timelines may shift; please be prepared to be flexible.

13

DELAYS

It's important to expect delays and be patient.

There are often delays in these types of research projects, as we:

- Wait for Research Ethics Board approvals
- Finalize work with team members
- Build partnerships
- Public Health Advisories

14

IRREGULARITY IN WORK

THIS MEANS:

- Some months might be slow
- Other months might be busy
- Sometimes participants won't show up. You won't get paid when this happens.

Be prepared for varying numbers of surveys from one week to the next.

15

SUPPORT

YOU CAN EXPECT:

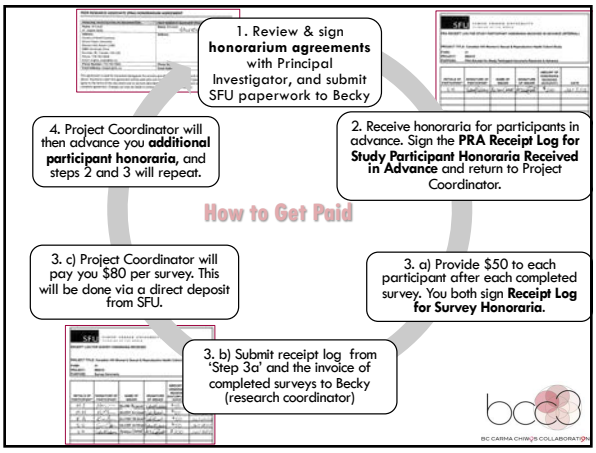
- Practical support
- Emotional support
- You can go to any member of the team for support
- Elder Sheila Nyman

16

HOW TO GET PAID

When working for BCC3

17



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QUESTIONS?

19

2.6: Basics of a Good Interview

BASICS OF A GOOD INTERVIEW

BC CARMA CHIWOS COLLABORATION

1

ROLE PLAY

2

S4-02. Below is a list of the ways you might have felt or behaved **during the past week**. Please tell me how often you have felt this way **during the past week**.

Select one per line.

		Most or all of the time (5-7 days)	Occasionally or a moderate amount of time (3-4 days)	Some or a little of the time (1-2 days)	Rarely or none of the time (less than 1 day)	Don't Know	Prefer not to answer
a.	I was bothered by things that usually don't bother me.	▫	▫	▫	▫	▫	▫
b.	I had trouble keeping my mind on what I was doing.	▫	▫	▫	▫	▫	▫
c.	I felt depressed.	▫	▫	▫	▫	▫	▫
d.	I felt that everything I did was an effort.	▫	▫	▫	▫	▫	▫
e.	I felt hopeful about the future.	▫	▫	▫	▫	▫	▫
f.	I felt fearful.	▫	▫	▫	▫	▫	▫
g.	My sleep was restless.	▫	▫	▫	▫	▫	▫
h.	I was happy.	▫	▫	▫	▫	▫	▫

3

BEFORE

- Choose an appropriate setting (for yourself and for the participant)
- Explain purpose of the interview
- Explain what to expect (ie. length of time, what will happen)
- Review all comforts (ie. can take a break at any time, if in person where bathrooms are, etc)
- Re-affirm confidentiality
- Are there any questions?

4

DURING

- Active listening!
- Stay neutral
- Take breaks when needed, don't rush through
- Help to answer any questions
- Share screen with the participant if possible, so you can go through the questions together

5

CLOSING THE INTERVIEW

- Once you are finished going through the questions, there will be a space to fill in any comments or thoughts that the participant has.
- Do a quick check-in after the survey with the participant about how they are doing, and any feedback about the survey
  - Ask the participant about their supports, and what they will do for self-care if it is appropriate

6

AFTER

- Thank and honour the participant for their time
- Confirm honoraria
  - If they would like a mailed cheque, please collect their address
  - If they would like an e-transfer, please confirm the appropriate email
- Hand out resources
- Let them know where to get in touch with any questions

7

2.7: Recruitment & Booking an Interview

BCC3 PRA Training

Recruitment & Booking Study Visits

BC CARMA CHIWOS COLLABORATION

1

Acknowledgement

- We respectfully acknowledge that the land we work, live, and collaborate on is the unceded, ancestral, traditional territory of the Coast Salish Peoples, including the territories of the Səl̓ílwətaʔ/Selilwitulh (Tsleil-Waututh), xʷməθkwəy̓əm (Musqueam), and Skwxwú7mesh (Squamish) Nations.

2

Overview

- Participant Recruitment
  - How are we recruiting for BCC3?
- Booking a Study Visit
  - How will you be assigned participants?
  - How will you book study visits?

3

Data Collection Methods

Participant Recruitment → Participant Consent → Clinical Visit → Community Visit

4

Participant Recruitment

- CHIWOS
- CARMA
- Posters
- Word of mouth

Figure 6. BCC3 participant recruitment will include women from CARMA and CHIWOS studies, Oak Tree Clinic at BC Women's Hospital, and by "word of mouth".

5

How will we make contact?

Email

Phone

In-person at Oak Tree Clinic with Research Staff

Word of Mouth

6

Participant Recruitment from CHIWOS & CARMA

- We want to merge **CARMA** and **CHIWOS** participants, so we will be contacting past participants through various means to ask if they'd like to participate in BCC3!
  - We will send an email to everyone who we have emails for to let them know about the BCC3 study.
  - If we only have a phone number for the participant, we can call them to let them know about the study and see if they would like to participate.
  - At Oak Tree we have access to the CARMA list, so we can reach out to past CARMA participants as they come in.

7

New Participant Recruitment

- For **new** participants (not from CHIWOS or CARMA):
  - We will recruit new participants from Oak Tree, posters at various clinics/centres, craigslist (women not living with HIV), email lists, and word of mouth.
  - Let us know if you know of good places to put up posters!
- When you are talking to people about the study, you will give them your contact info and/or Amber's contact info to get in touch for more information and to participate.
- We will create a little info card that you can hand out to people that you talk to about the study.

8

Consent Process

- All interested and eligible participants will receive a copy of the consent to review before coming to the study visit.
- At the clinical visit, a research staff will review the consent with the potential participant who will be asked to provide **informed, signed consent** before participating.
- Participation in this research is entirely **voluntary** and **ongoing.**
  - Participants can withdraw from study and request removal of information at any time.
- You will **review** the participants' rights with them at the community visit, **before** beginning the community survey.

9

Community Visit

- This visit must occur **after Part 1,** can be **0-31 days** after and can take place at a community or clinical location or **online** → *it will be online for now!*
- This visit will be facilitated by you as a PRA.
- You will administer an online survey (1-1.5hrs).

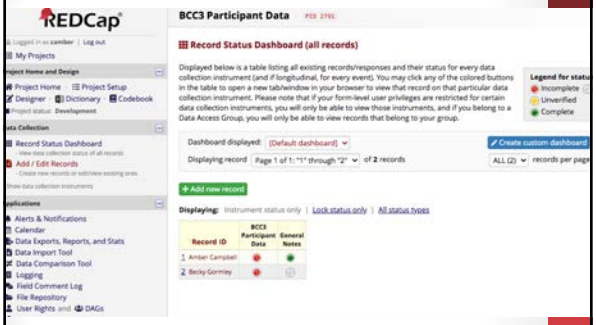
10

Being Assigned Participants

- As participants are recruited and have their clinical visits, we will assign them to a PRA who will conduct the community visit with them.
- We will rotate through a list of PRAs (made in random order).
- If a PRA indicates a period of time that they will be away/not able to do visits, their name will be temporarily skipped in the assignment order.
- You can let us know the number of interviews you'd like to do in a week, and we can accommodate accordingly.
- You will receive the name of your participants via email and you can access their contact info on REDCap.

11

Finding Participant Contact Info



12

Keeping Track of Scheduled Interviews

Each time you schedule an interview, write down:

- Date
- Time
- Meeting location
- Participant's initials or first name only (non identifying)
- Participant's contact info

You can write this in your personal planner or calendar.
We have a REDCap database where you can log in and access this information and keep track of visits, payments, etc.

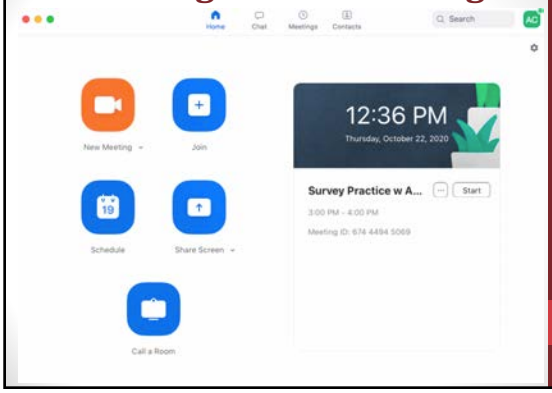
13

Where & When Interviews Should Happen

- During the **day** (not night)
- **Online** on **Zoom** or **Skype**
  - For the meantime, study visits will be done online!
  - When it is safe to meet in person, visits can be at clinics or organizations out in the community

14

Scheduling a Zoom Meeting



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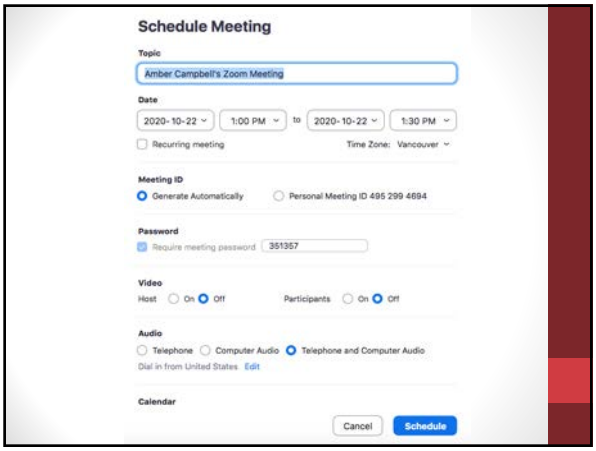

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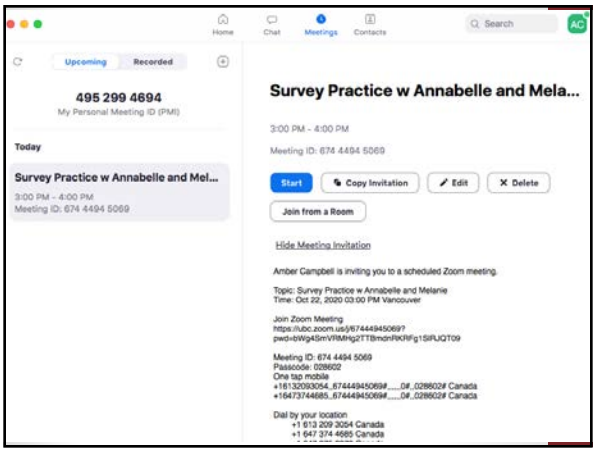


17

How to keep your personal contact info private

- **Create a work email:**
  - Ex) amberbcc3@gmail.com
- **If on the phone, block your number before making calls:**
  - Dial *67, then listen for 3 beeps, then dial the phone number. It's free!
  - OR on some phones you can turn No Caller ID on.

18

Thank you!

- Any questions?
- Now let's look at REDCap!

BC CARMA CHIWOS COLLABORATION

19

2.8: Safety & Wellbeing

BCC3 PRA Training

Safety & Well-Being

BC CARMA CHIWOS COLLABORATION

1

BCC3 works to ensure that everyone involved with the study

feels safe

and has the

safest work environment

and

best mental and emotional health possible

while engaged in BCC3 research activities.

2

Safety means:

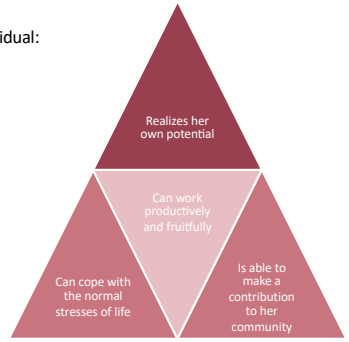
Freedom from physical harm

Freedom from being victimized through hostility, aggression and harassment

3

Wellbeing means:

Every individual:



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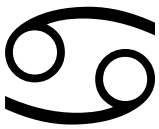
Safety & Wellbeing of Participants



5

Mental Health Support & Resources

- Participants will receive a list of support services in their region who have agreed to see participants if there is a mental health concern during or after completing the survey.
- Letting the participant guide the survey, and respect their choice to answer or not answer questions, or continue or not continue.

6

Safety & Wellbeing of Peer Research Associates

7

Communication with Regional Coordinator

- We want to keep in touch!
  - Regular meetings
  - Debriefing before / after each interview
  - Weekly/bi-weekly team emails
  - Open door policy
- If a more urgent matter occurs please get in touch ASAP!

8

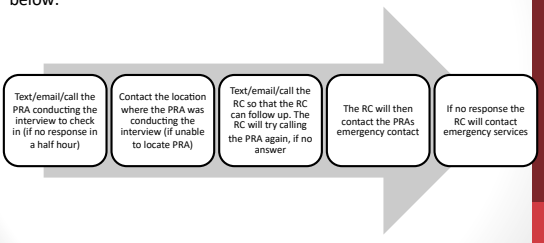
Buddy System

- ✓PRAs will pair up as buddies (AKA peer-supports) for one another other.
- ✓At least 24 hours before an interview, PRAs will notify the RC and their buddy to let them know the **date, time, and location's contact details** of their interview and also provide one **emergency contact person**.
- ✓On the day of the interview, before it begins, the PRA will contact their buddy to let them know they are beginning the interview.
- ✓Once the interview has been completed the PRA will contact their buddy to say the interview is over and how it went.

9

Buddy System

If the supporting PRA does not hear back from the interviewing PRA 3 hours after the start of the interview they should follow the steps below:



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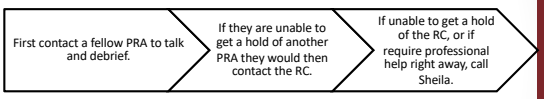
Phone Tree System

- A phone tree: a document which identifies a network of people that have been organized in a way to best facilitate rapid dissemination of information.
- A phone tree will be created for each of the three provinces illustrating the first people to contact in an emergency situation.

11

Phone Tree Example

If a PRA feels activated by an interview, they could:



Please note that the above process is an **example**. Depending on what you need, and how you are feeling, it may be important to immediately get in touch with the research coordinator **or with Sheila.**

12

General Safety Guidelines

- Use the buddy system
- Feel free to cancel or reschedule an interview if you feel unsafe
- Position yourself between the door and the participant so you can have easy access to the exit if required
- Keep the door slightly ajar in order for others to hear if participant becomes loud and/or aggressive
- It is best not to do an interview in a space where you are completely alone with a participant unless you know the participant and feel very safe and comfortable
- Do not leave your belongings (laptop, phone, bag) unattended with the participant

13

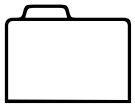
Regular PRA Meetings

Having regular meeting with all the PRAs in your province will offer the opportunity for:

- capacity building workshops
- dialogue
- team building
- brainstorming around the future direction of BCC3

14

Have a List of Contacts Ready

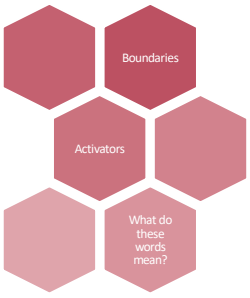


Contact List

- Coordinator:
- 24/7 Emergency Counseling:
- Counseling:
- PRA Buddy:
- Other Self-Care Resources:

15

Boundaries & Activators



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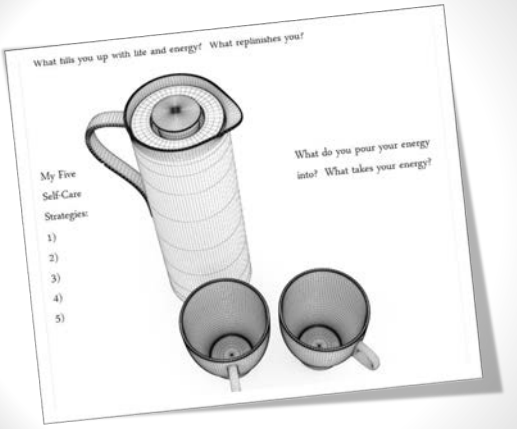
Grief & Loss

http://youtu.be/gsYL4PC0hvk

17



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2.9: Challenging Interviews

BCC3 PRA Training

SAFETY, WELL-BEING, & CHALLENGING SCENARIOS

Nov 6th, 2020

BC CARMA CHIWOS COLLABORATION

1

Retrieved from: https://www.mondaycampaigns.org/destress-monday/unwind-monday-5-4-3-2-1-coping-technique

2

Scenario 1

An individual who is 16 years old approaches you about the study, but doesn't have a parent/guardian to provide consent for them.

3

What would you do?

- Tell them you have to be above 16 to provide consent, so they can sign for themselves
- Tell them you have to be above 18 to provide consent, so they would need to have a parent/guardian
- Tell them anyone can participate at any age without consenting
- Tell them they can bring a note from their parent/guardian as proof of their consent

4

5

Scenario 2

The participant you're working with has just come back from a smoke break . When you get to the section about smoking on the survey, they tell you that they don't smoke.

6

What do you do?

- Tell them they're obviously lying since they just stepped out for a cigarette, and smell like smoke.
- Tell them that you saw them smoking, and ask again if they are sure about their answer.
- Ask more probing questions.
- Accept the answer they have provided and click that option on the survey.
- Accept the answer they have provided and click that option on the survey, but make a note to tell a BCC3 team member that this answer is likely not the most accurate one.

7

8

Scenario 3

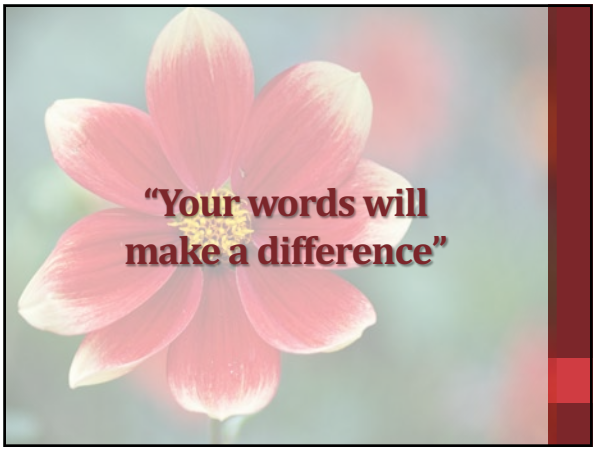
The participant is nodding off, antsy, not paying attention, or trying to rush through the answers.

9

What would you do?

- Ask if the participant would like to rebook the interview
- Knock on the table or clap loudly to get their attention, and continue
- Ask how you can help them get through this
- Call a BCC3 team member for help

10



11

Scenario 4

A participant asks how you would answer a question **after** they've just answered it.

12

What would you do?

- Tell them your answer
- Discuss the topic with them, without giving your answer
- Tell them you can't disclose this due to your position as a PRA
- Just move on (it's none of their business!)

13

14

Scenario 5a

You are completing the survey with a participant, when a stranger crashes your virtual meeting.

15

What would you do?

- Calmly ask the "troll" to leave
- Close down the page immediately and shut your computer down, and get in touch with participant ASAP to let them know you will send another link/meeting ID

16

Scenario 5b

You are completing the survey virtually with a participant, when someone walks in behind them (eg: partner, child).

17

What would you do?

- Wait to see how the participant reacts (maybe they don't mind having another person in the room)
- Let the participant know that certain sections of the survey could ask very personal questions, or could activate their emotions and feelings
- Point out that someone has walked into the room (what if they didn't notice?)

18

19

Questions?

BC CARMA CHIWYS COLLABORATION

20

2.10: Self-Care

Self Care

COVID Fatigue Realities and Strategies

BC CARMA CHIWOS COLLABORATION

1

Definition and concepts of Self Care

Self Care

- WHO defines self care as "the ability of individuals, families and communities to promote health, prevent disease, maintain health, and to cope with illness and disability with or without the support of a healthcare provider"

What does it encompass?

- Hygiene (general and personal)
- Nutrition (type and quality of food)
- Lifestyle (sporting, leisure activities)
- Environmental Factors (living conditions, social habits, etc)
- Socio economic factors (income level, cultural beliefs, etc)
- Self medication

2

Core Principles of Self Care

Fundamental principals for self care include aspects of the individual, e.g. :

- Self reliance
- Empowerment
- Autonomy
- Personal responsibility
- Self efficacy

As well as, the greater community, e.g. : (impacts on)

- Community participation
- Community involvement
- Community empowerment

3

So, what is self care and, why is it so essential in this work?...

- Self care is any activity that that we do deliberately in order to take care of our mental, emotional and physical health.

"Self Care is something that refuels us,
rather than takes from us"
Agnes Wainman

- In a nutshell, Self Care is a key to living a balanced life and a means of managing stress and other negative factors that influence our mental, emotional and physical health.

Why is it so essential in this work?...

4

Self Care Inventory

- Take 5 minutes to write down 5 things that you feel you consistently "go to" for self care strategies and jot them down. Try not to over think this – what comes to mind first when you think of self care and what do you do on a regular basis in your self care routine?
- How often do you practice self care?
- Do you have a self care plan or is it more "as needed"?
- What do you think a self care routine or practice looks like and have you ever implemented a self care routine?

Share and discussion – 10 minutes

5

COVID Fatigue & Self Care

What is COVID Fatigue?

- COVID Fatigue is related to burn out.

"It comes about from this long period where we've had prolonged and intense stress with no end in sight…Our brains are not wired to maintain a high level of anxiety over a prolonged period of time"

Kate Hermanson, PHD at UC Davis Health psychologist in the dept of Physical Medicine and Rehabilitation.

- COVID Fatigue is real and it's impacts can have serious effects on our mental health impacting behaviors that could be risky and life threatening to ourselves and others.

Question?: What does COVID Fatigue look like to you, and how have you dealt with it in your day to day life? Reflection & discussion.

6

Resources for Self Care and COVID Fatigue – (working doc)

- www.healthandstroke.ca COVID Fatigue, Dr. Scott Lear, Oct. 26, 2020
- www.refinery29.com COVID Fatigue Isn't an Excuse to Forget About the Pandemic, Elizabeth Guling, Nov. 12, 2020
- www.universityaffairs.ca, What Canadian Researchers are discovering about the psychosocial effects of the pandemic. Wendy Glauser, Nov. 18, 2020

7

Self Care tips for your personal toolkit:

- Bath
- Meditation
- Quiet time
- Self soothing massage, lotion
- Eating, sleeping, drinking water (taking care of self)
- Dance
- Cleaning / organizing
- Mani + pedi
- Journaling
- Being flexible!
- Going for walks in nature
- Spending time with family / friends (calling them)
- Doing a workout / exercise / yoga

8

Self Care tips for your personal toolkit:

- Eating healthy food + treats ☺
- Quiet time (walk and listening to music or sounds of nature)
- Listening to Louise Hay
- Cooking & eating good food
- Gratitude – thanking food and drink, Mother Nature
- Listening to music (mood dependent)
- Breathing exercises
- Ground myself with a smudge + medicines
- Talk to friends to vent
- Bake for neighbours
- Listen to ACDC and DANCE
- Get up and walk or sit in nature inbetween Zoom meetings

9

Self Care tips for your personal toolkit:

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- Bake for neighbours
- Listen to ACDC and DANCE
- Get up and walk or sit in nature inbetween Zoom meetings

10

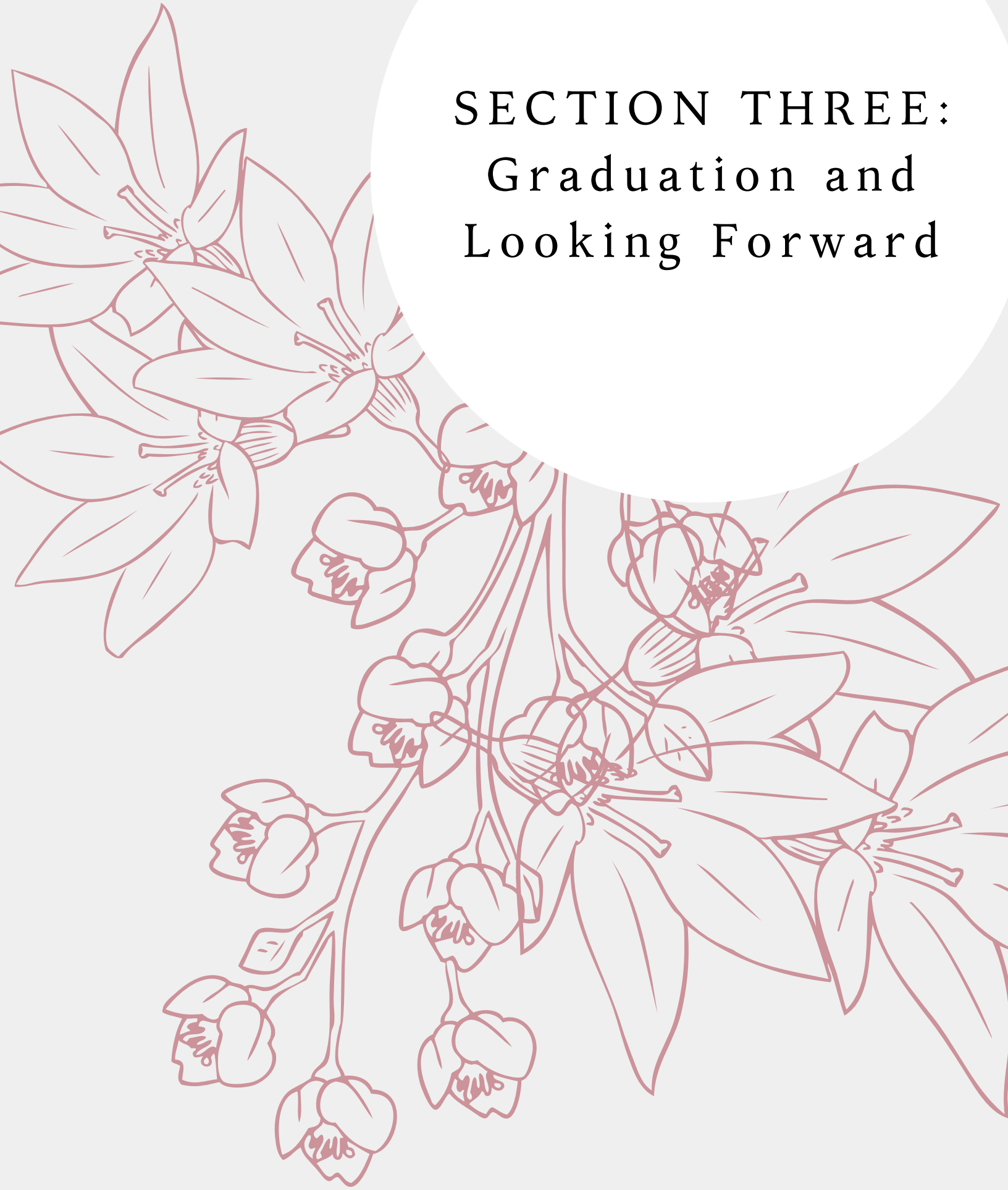
11

2.11: Review & Wrap Up

Working Group notes:

Our last training session was focused on a review of topics that the PRAs identified as priority topics for review.

SECTION THREE: Graduation and Looking Forward



Working Group notes:

To celebrate and honour the work that the PRAs have done, we scheduled a celebratory graduation session with the entire BCC3 Research Team.

During this celebration, each PRA was honoured with a certificate, and a card filled with 'warm fuzzies' written by the various team members. Each PRA was also asked to share and reflect on one success from training, one challenge that they are working on, and one vision or goal that they are hoping for as they officially begin their PRA work.

The meeting concluded with reviewing next steps, and what to expect.

SECTION FOUR:
Ongoing Training

Working Group notes:

The BCC3 PRA Training Working Group is committed to principles of mentorship and capacity building, and aims to provide further opportunities at monthly team meetings to continue building the skills and opportunities for BCC3 PRAs to meaningfully engage in research, and provide opportunities for the BCC3 PRAs to share their expertise and experiences with the research team.

Ongoing training will be led by priorities as identified by the PRAs, including refresher training in any of the previously covered modules, and new modules covering knowledge translation and exchange, introduction to quantitative data analysis, and others.

If you are interested in learning about ongoing training, please contact a BCC3 research coordinator to learn more information:

Rebecca Gormley: rgormley@bccfe.ca || Amber Campbell: amber.campbell@cw.bc.ca

APPENDICES

Working Group notes:

The appendices to the training module include:

1. Examples of instructional forms created for the PRAs to assist with using Zoom (similarly created for all online platforms utilized in the study and training, ie. REDCap);

2. Documents supporting interview administration;

3. Post-training evaluation form; and

4. Additional material and resources for more information.

Appendix: Technical Sheet: Zoom Login and Connection

SFU ZOOM ACCOUNT LOGIN

Before you login, you will need your:

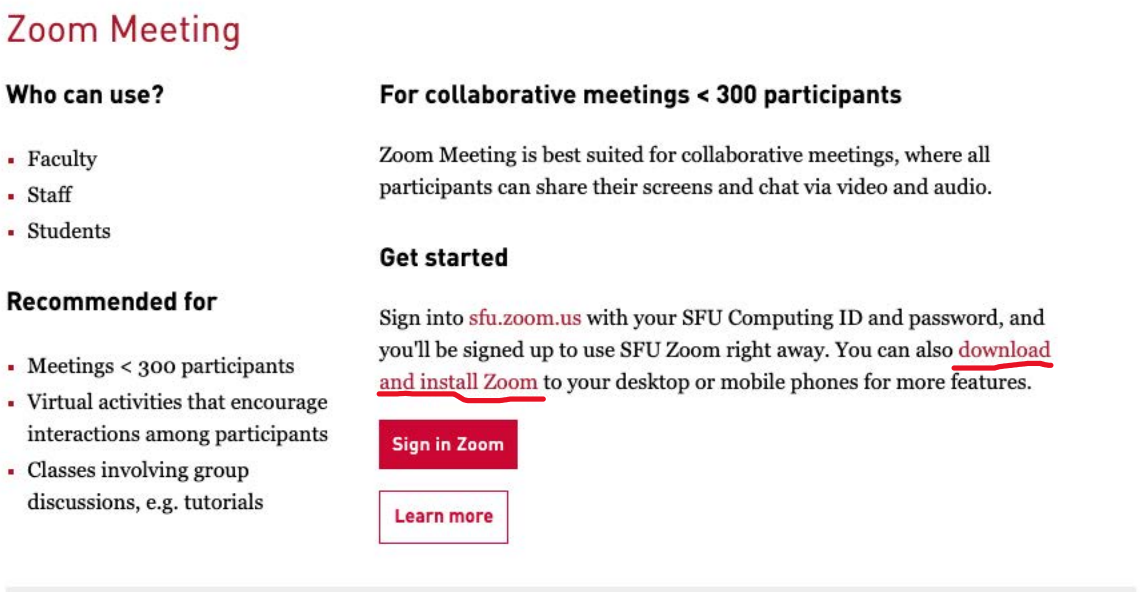
SFU Computing ID (also referred to as your 'username') and your SFU Computing ID password.

- If you have trouble finding you SFU Computing ID, please try this link: https://services.sfu.ca/cgi-bin/WebObjects/ITServices.woa/wa/ForgotUsername

- If you need to reset your SFU Computing ID password, please try this link: https://services.sfu.ca/cgi-bin/WebObjects/ITServices.woa/wa/ResetPassword

To begin: go to https://www.sfu.ca/itservices/technical/videoconferencing/zoom.html

About midway through the page you will see:



To use Zoom and book meetings / etc. you have a few options.

1. You can go to sfu.zoom.us and sign in.

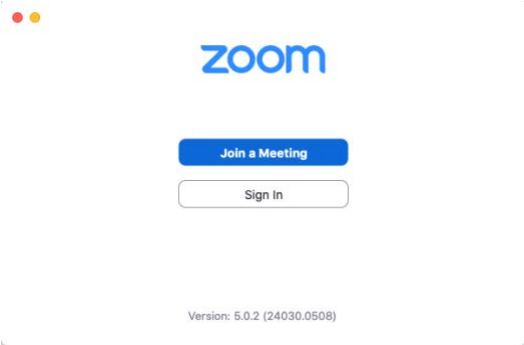
2. You can download the Zoom app on your laptop.
* I personally find it easier to download Zoom.

If you are going to download Zoom, here are a few tips:

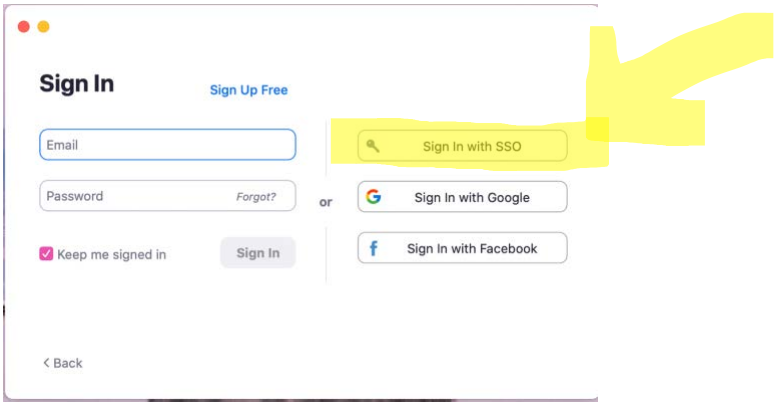
1. When you click on the link “download and install Zoom” (underlined in red above), it will take you to the Zoom website. Please follow all instructions and prompts to download the app on your computer.

2. Once it is downloaded, please try opening it from your desktop (or wherever you have it saved).

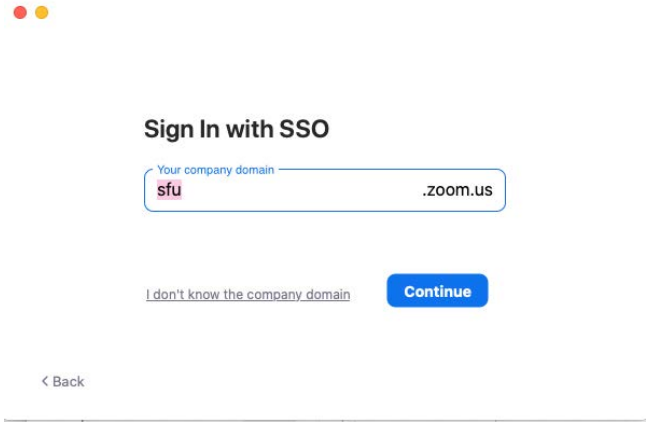
3. When you open, you will see this box: click “sign in”



4. After you sign in, you will be brought to the following box. To sign in, **you have to “sign in with SSO.”**

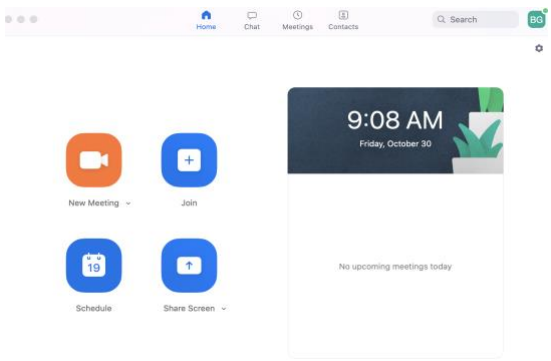


5. You will enter in “sfu” (see below) and click ‘continue’



6. Clicking continue will open up a web browser, and will instruct you here to enter in your Computing ID as the username, and then your password.

7. And then your Zoom app should launch, and you can start scheduling meetings and joining meetings!



Appendix: Documents Supporting Survey Administration

Checklist: What to Bring to the Interview

Must-have items for each interview:

- ☐ Interview Flowchart
- ☐ Two blank copies of the consent form
- ☐ List of resources to provide to participant
- ☐ Honorarium receipt form*
- ☐ **Charged and updated computer** with power cord and mouse
- ☐ $50 honorarium*
- ☐ Contact list (in case of emergency)
- ☐ Pen and scrap paper

* If online, Becky will be organizing the honorarium. Please confirm the mailing address for the cheque or the email address for e-transfer.

Other things you might find helpful during the interview:

- ☐ Other resources for training and reference, for example:
  - ☐ Script for ongoing informed consent
  - ☐ BCC3 Survey Key Terms
  - ☐ Phone tree
  - ☐ Zoom login information
- ☐ Water bottle
- ☐ Snack
- ☐ Kleenex

BCC3 SURVEY PROCESS CHECKLIST

Survey Steps	***Done?***	***Suggestions***	***Strengths***
Pre-visit • Connect with Amber to receive survey link in your email.			
Open the session • Greet the participant • Introduce yourself • Honour and give thanks to participant for coming • Housekeeping (approximately 1.5 hours long, washrooms, breaks, smoking, etc.) • Comforts (what's shared is confidential, stop at any time, stuff is going to come up & that's normal, time during and at end to debrief, ask questions, etc.) • Respond to questions			
Ongoing consent • Remind participants of process, can read through script • Answer any questions			
Open Participant File List • Verify contact information is correct (go through each field) • Ask if there are any other means of contact that we can add			
Open REDCAP • Open link from email • Enter login information (participant's BCC3 ID) • Read through survey introduction • Ask the survey questions • Click submit at the bottom of each section to save questions and open next section			

Once finished survey: • Enter visit details into Participant Database file, ask participant if they agree to be contacted about future follow-up visits, and check box saying "completed"			
Close the session • Honour and give thanks to participant for completing the survey • Inform participant about next steps • It is normal for stress to come up; self-care, safe coping, and doing things that make you feel good • Provide resource list • Administer participant's honoraria and obtain signed receipt •			
Post interview • **Check in with your buddy or a research coordinator to let them know the interview is completed** • Fill out **Form C** to track the interviews are completed			
GENERAL FEEDBACK / COMMENTS:			

Appendix: Post-Training Survey Evaluation

BCC3 Training Feedback – [Session Date]: We would love to hear your thoughts or feedback on how we can improve training for the next session!

Thank you so much!

Did you find that the training session was:

- Too fast
- Too slow
- About right
- Other:

Did you find that the training session was:

- Engaging
- I lost focus a few times
- I barely paid attention
- Other:

After the training session I felt that I learned what I expected to learn.

- Strongly agree
- Agree
- No opinion
- Disagree
- Strongly Disagree
- Other:

I felt that I was able to follow along with the material.

- Strongly agree
- Agree
- No opinion
- Disagree
- Strongly Disagree
- Other:

What is one learning that I will be taking away with me? *

Your answer

What can we do in the next training session to make it more enjoyable, help you learn better, etc.?

Your answer

Submit

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI
Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington 2002 (Note of Clarification on paragraph 29 added)
55th WMA General Assembly, Tokyo 2004 (Note of Clarification on Paragraph 30 added)
59th WMA General Assembly, Seoul, October 2008

A. INTRODUCTION

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects**,** including research on identifiable human material and data.

   The Declaration is intended to be read as a whole and each of its constituent paragraphs should not be applied without consideration of all other relevant paragraphs.

2. Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles.

3. It is the duty of the physician to promote and safeguard the health of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

4. The Declaration of Geneva of the WMA binds the physician with the words, “The health of my patient will be my first consideration,” and the International Code of Medical Ethics declares that, “A physician shall act in the patient's best interest when providing medical care.”

5. Medical progress is based on research that ultimately must include studies involving human subjects. Populations that are underrepresented in medical research should be provided appropriate access to participation in research.

6. In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.

7. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best current interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

8. In medical practice and in medical research, most interventions involve risks and burdens.

9. Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.

10. Physicians should consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

B. PRINCIPLES FOR ALL MEDICAL RESEARCH

11. It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.

12. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

13. Appropriate caution must be exercised in the conduct of medical research that may harm the environment.

14. The design and performance of each research study involving human subjects must be clearly described in a research protocol. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. The protocol should describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits.

15. The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the study begins. This committee must be independent of the researcher, the sponsor and any other undue influence. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No change to the protocol may be made without consideration and approval by the committee.

16. Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications. Research on patients or healthy

volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. The responsibility for the protection of research subjects must always rest with the physician or other health care professional and never the research subjects, even though they have given consent.

17. Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.

18. Every medical research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.

19. Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.

20. Physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results.

21. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects.

22. Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research study unless he or she freely agrees.

23. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the study on their physical, mental and social integrity.

24. In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

25. For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee.

26. When seeking informed consent for participation in a research study the physician should be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent should be sought by an appropriately qualified individual who is completely independent of this relationship.

27. For a potential research subject who is incompetent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the population represented by the potential subject, the research cannot instead be performed with competent persons, and the research entails only minimal risk and minimal burden.

28. When a potential research subject who is deemed incompetent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.

29. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research population. In such circumstances the physician should seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research should be obtained as soon as possible from the subject or a legally authorized representative.

30. Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

31. The physician may combine medical research with medical care only to the extent that the research is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.

32. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances:
    - The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or
    - Where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option.

33. At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.

34. The physician must fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never interfere with the patient-physician relationship.

35. In the treatment of a patient, where proven interventions do not exist or have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, this intervention should be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information should be recorded and, where appropriate, made publicly available.