UNIVERSITY OF CALGARY
FACULTY OF KINESIOLOGY
Health and Wellness Lab

Informed Consent Form for Participation in a Research Study

EXCEL: EXercise for Cancer to Enhance Living well Study

(A study to evaluate the benefit of a community-based exercise program for cancer survivors in rural and remote Canada)

Protocol ID: *HREBA.CC-20-0098*

Principal Investigator: Dr. Nicole Culos-Reed, PhD
Health & Wellness Lab, Faculty of Kinesiology
University of Calgary
Phone: 403-220-7540

Sponsor/Funder(s): The Canadian Institutes of Health Research/ Canadian Cancer Society and the Alberta Cancer Foundation

You are being invited to participate in a research study because you have you have indicated that you are interested in participating in a community-based or online exercise program for cancer surivors. This consent form provides detailed information about the study to assist you with making an informed decision. Please read this document carefully and ask any questions you may have. All questions should be answered to your satisfaction before you decide whether to participate.

The study staff will tell you about timelines for making your decision. You may find it helpful to discuss the study with family and friends so that you can make the best possible decision within the given timelines.

Taking part in this study is voluntary. You may choose not to take part or, if you choose to participate, you may leave the study at any time without giving a reason. Deciding not to take part or deciding to leave the study will not result in any penalty or any loss of medical or health-related benefits to which you are entitled.

The principal investigator, who is one of the researchers, or the site research coordinator, will discuss this study with you and will answer any questions you may have. If you do consent to participate in this study, you will need to sign and date this consent form. You will receive a copy of the signed form.

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

The growing population of cancer survivors in Canada has brought attention to the long term toll of cancer and its treatment on the body, mind, and overall health of survivors. Exercise is an effective intervention that can optimize the health and well-being of cancer survivors and possibly reduce rates of cancer recurrence and secondary cancers.

The Health Research Ethics Board of Alberta – Cancer Committee (HREBA-CC), which oversees the ethical acceptability of research involving humans, has reviewed and granted ethics approval for this study.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to evaluate the benefit of a community-based or online exercise program for cancer survivors who live in rural and remote locations. The study is called EXCEL and includes an evidence-based exercise program (Alberta Cancer Exercise, ACE; Ethics ID: HREBA-CC-16-0905). ACE has been successfully implemented in urban centres throughout Alberta. Our aim is to provide an exercise program to cancer survivors living in rural and remote locations to promote adoption of an active lifestyle in order and improve health outcomes. EXCEL will increase accessibility to exercise as a supportive cancer care resources for all cancer survivors.

WHAT ARE OTHER OPTIONS IF I DECIDE NOT TO PARTICIPATE IN THIS STUDY?

You do not have to take part in this study in order to receive continued medical care. You may choose not to participate in this study. Your healthcare provider will discuss lifestyle recommendations with you. Right now, usual treatment is to receive counseling on the value of physical activity and healthy living after the completion of cancer treatments.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 1500 people across Canada will take part in this study.

WHAT WILL HAPPEN DURING THIS STUDY?

STUDY INTERVENTION
If you agree to take part in this study, you will undergo screening and fitness testing and will be referred to a suitable exercise program. The exercise program will take place either online or at selected community-based fitness facilities. You will take part in a twice weekly exercise program for an 8 to 12-week period, and will be followed for study outcomes for up to a year. The duration of the program will depend on the session you register for – we will offer 8 to 12 week programs, throughout the year. The exercise program will be tailored to your fitness level and designed to address your personal fitness or lifestyle goals.

All participants will have measurements taken at the start of the study, at the end of the exercise program, 24-weeks and one year, to see the effect of exercise on their physical activity levels and quality of life. Participants taking part in the study will have the option to receive a follow-up questionnaire after completing the exercise program each year for up to 5 years (remaining length of the study).

STUDY PROCEDURES

Established Procedures
The following established procedures may be done as part of this study, and are dependent on availability of a qualified exercise professional and the necessary testing equipment at your site.

For online-only participants, these assessments may be adapted, as indicated below. If the results show that you are not able to continue participating in the study, the research coordinator will let you know.

- Body composition measurement: We will measure your height and body weight. These measurements take between 2 and 3 minutes to complete. For online participants, you will report both to us.

- Aerobic endurance measurement: We will have you perform a 6-minute walk test in a hallway on a flat surface to determine your fitness level. This is a submaximal test, meaning that you will walk at a moderate pace for the 6-minute time period. The walk test takes around 10 minutes to complete. For online participants, we will use a modified 2-minute step test. This is also a submaximal test, where you will step in place with high knees for 2 minutes.

- Musculoskeletal fitness measurement: we will measure your grip strength, measure your lower body endurance (30s Sit to Stand), and assess your flexibility using a sit-and-reach test and shoulder elevation measure. We will also assess your balance using a one-legged stance balance test. These tests take around 20 minutes to complete. For online participants, you will complete the same musculoskeletal tests except for the grip strength. Tests will be modified based on your equipment at home.

Questionnaires

You will be sent an email to complete a questionnaire package at the start of the study, at the end of the exercise intervention, 24 weeks, and one year. You will have the option to complete the follow-up questionnaire package each year for the duration of the study (up to 5 years). The purpose of the questionnaire is to understand how the program affects different aspects of your life.

- The revised Edmonton Symptom Assessment Scale: This questionnaire asks you to rate symptoms related to your cancer and cancer treatment. This questionnaire is usually administered as part of your standard care. This questionnaire takes about 3 minutes to complete.
- Physical activity level: We will ask you about your physical activity level using the Godin Leisure-time Exercise Questionnaire. This 6-item questionnaire asks specific questions about the type, intensity, frequency and duration of your average weekly physical activity. This questionnaire takes around 2-3 minutes to complete.
- Cancer-related Fatigue: We will assess your rating of fatigue using the Functional Assessment of Chronic Illness Therapy-Fatigue. This 13-item questionnaire asks specific questions about the impact of your cancer related fatigue on your daily life. This questionnaire takes around 5 minutes to complete.
- Cancer-related Quality of Life: We will assess your general well-being and quality of life using the Functional Assessment of Cancer Therapy-General Scale. This 27-item questionnaire will ask you about your physical, social/family, emotional and functional wellbeing. It will take around 8-10 minutes to complete.
- Cancer-related Cognition: We will assess how your cognitive function using the Functional Assessment of Cancer Therapy-Cognitive Scale. This 37-item questionnaire will ask you

about your ability to think, reason and remember and how that may impact your quality of life. It will take around 10 minutes to complete.
- Exercise Barriers and Facilitators: We will assess what makes it difficult to exercise and what assists you in exercising, with an Exercise Barriers and Facilitators questionnaire.
- Cost effectiveness: We will assess the cost effectiveness of the program using the EQ5D. This 5-item questionnaire asks questions about your mobility, self care, usual activities, pain/discomfort and anxiety/depression. This questionnaire should take 2-3 minutes to complete.
- At the end of the exercise intervention, you will be provided an additional questionnaire asking about your intentions to stay physically active. At the 24-week time point, you will be provided an additional questionnaire asking about what actions you actually took to stay active over the past 12-weeks.

The information you provide is for research purposes only and will remain strictly confidential. Some of the questions are personal; you may choose not to answer them.

Even though you may have provided information on a questionnaire, these responses will not be reviewed by individuals not involved in this study, e.g., your health care practitioner/team. If you would like them to know this information, please bring this to their attention.

Health Tracking App

You may be provided a year subscription to an app called Zamplo, which assists in tracking your symptoms and physical activity levels. It can also be used to set reminders for appointments and exercise class times. All of your data is encrypted and stored in an encrypted database. Only you and any of your appointed caregivers will have access to your personal information.

Activity Tracking Watch

Some participants will be asked if they would like to use an Garmin Vivo Fit4 watch throughout the intervention. The watch will keep track of the amount of activity you participate in each day. If you are asked to participate in using the activity tracking watch, the study team will provide you with instructions to use/wear, and request it be sent back at the end of the intervention. The data that is collected will be transferred to the University of Calgary's We-TRAC Server (Level 4 Security; REB20-0572) and only authorized individuals will have access to the data for analysis through software programs. You will be assigned a participant ID for use with the activity tracker, and no identifying information will be linked to your data.

Additional Study Needs

You give permission to the study research coordinator or member of the study team to attempt to contact you in relation to additional study needs.

☐ Yes ☐ No Participant's Initials: _____

WHAT ARE THE POTENTIAL SIDE EFFECTS FROM PARTICIPATING IN THIS STUDY?

You may experience side effects from participating in this study. Some side effects are known and are listed below, but there may be side effects that are not expected. You should discuss these with the principal investigator or research coordinator. The risks and side effects of the standard or usual treatment will be explained to you as part of your standard care. These risks are not included in this consent form.

The main side effect from exercise testing and training is secondary muscle soreness. You may notice that your muscles are sore for a couple of days after the testing session and during the first week or so of the exercise program. We expect that these symptoms will get better as you get used to the exercise. As well, the exercise program will be personalized to you to minimize excessive soreness and modified as needed if you experience any excessive muscle soreness or fatigue from your exercise sessions.

It is important that you know and understand the possible risks of the treatments (exercise) given in this study. The main risk associated with exercise is musculoskeletal injury (injury to the muscles, tendons, joints or bones). Your exercise sessions will be supervised and your program designed to minimize this risk by slowly increasing the amount and intensity of your exercise over time.

There is also a very small risk of heart issues (such as chest pain, irregular heart rate, heart attack) should you exercise too intensively. To avoid any risks associated with exercise, you will be screened to ensure it is safe and appropriate for you to take part in the exercise program. All exercise will be of a low to moderate intensity level to minimize the stress on the heart and body. If any issues develop during the study period, your exercise sessions may be postponed or discontinued.

If you have any negative side effects, you should call the principal investigator or research coordinator in charge of the study. The telephone numbers are on the last page of this form.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

Participation in this study may or may not be of personal benefit to you. Possible benefits include improved physical fitness and better energy. Based on the results of this study, it is hoped that in the long-term, patient care can be improved.

WHAT ARE MY RESPONSIBILITIES AS A STUDY PARTICIPANT?

If you choose to participate in this study, you will be expected to:

- Tell the study research coordinator about your current medical conditions;
- Tell the study research coordinator about all prescription and non-prescription medications and supplements, including vitamins and herbals, that you may be taking and check with the research coordinator before starting, stopping or changing any of these. This is for your safety as these may interact with the intervention you receive on this study;
- Tell the study research coordinator if you are thinking about participating in another research study;

- Attend all scheduled study visits, undergo all of the procedures described above and complete the questionnaires.
- Inform the study research coordinator of any injuries, side effects or health problems that you may be experiencing or that develop at any point during the intervention.

HOW LONG WILL I BE PARTICIPATING IN THIS STUDY?

The study exercise program will last for 8 to 12-weeks, depending on what session you have signed up for. You will be asked to come back to the fitness centre, or be assessed online, for a follow-up at the end of the exercise program, which will take 30 minutes. You will be asked to complete the questionnaires at baseline, at the end of the exercise program, 24-weeks, and 1 year. You will have the option to complete the questionnaires once a year for up to 5 years. If provided with a subscription to Zamplo for one year, you will be encouraged to use the app throughout the year to track your symptoms and physical activity levels.

WILL THERE BE ANY LONG-TERM FOLLOW-UP INVOLVED WITH THIS STUDY?

If you stop receiving the study intervention early, we would like to keep track of your health for up to the one year study period to look at the long term effects of the exercise intervention on your health. You will complete the fitness assessments and/ or the questionnaires at your community-site or online, as able.

In the event it is necessary to further evaluate the safety or efficacy of the community-based or online EXCEL program, access to additional information about your health status may be required. The study team may attempt to obtain study-related information about your health from you or from your care physician. This may include contacting you again by phone or email, but only if you have not withdrawn your consent for future contact. However, contacting you, your care physician or using other private sources of information, is optional, please indicate your decision using the check boxes below.

You give permission to the study research coordinator or member of the study team to attempt to obtain study-related information about your health status to further evaluate the safety or efficacy of the EXCEL program. This may include contacting your care physician, or by contacting you by phone or email (i.e., future contact).

☐ Yes ☐ No Participant's Initials: _____

Name/phone number of care physician: _____

CAN I CHOOSE TO LEAVE THIS STUDY EARLY?

You can choose to end your participation in this research (called early withdrawal) at any time without having to provide a reason. If you choose to withdraw early from the study without finishing the intervention, procedure or follow-up, you are encouraged to contact the principal investigator or research coordinator. If you decide to stop participating in the study, we encourage you to talk to your doctor first. You may be asked questions about your experience with the study intervention.

You may withdraw your permission to use information that was collected about you for this study at any time by letting the research coordinator know. However, this would also mean that you withdraw from the study. Information that was recorded before you withdrew will be used by the researchers for the purposes of the study, but no additional information will be collected or sent to the sponsor after you withdraw your permission.

CAN MY PARTICIPATION IN THIS STUDY END EARLY?

In discussion with you, your doctor at the cancer care clinic or primary care network, either at his/her own initiative or at the request of the sponsor of this study, may withdraw you from the study at any time if it is in your best interests.The principal investigator may stop your participation in the study early, and without your consent, for reasons such as:

- You are unable to tolerate the exercise.
- You sustain an injury as a result of participation.
- You experience an adverse event during or after exercising.
- Your doctor no longer feels this is the best treatment for you.
- The sponsor decides to stop the study;

If this happens, it may mean that you would not receive the study intervention for the full period described in this consent form. If you are removed from the study, the principal investigator will discuss the reasons with you and plans will be made for your continued care outside of the study.

HOW WILL MY PERSONAL INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the principal investigator and study staff will only collect the information they need for this study.

Records identifying you, including information collect from your medical files/records, such as your Electronic Medical Records (EMR), Netcare, charts, etc., will be kept confidential to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organization may look at your identifiable medical/clinical study records at the site where these records are held for quality assurance purposes and/or to verify that the information collected for the study is correct and follows proper laws and guidelines:

- The Health Research Ethics Board of Alberta – Cancer Committee, which oversees the ethical conduct of this study

Authorized representatives of the above organization may **receive** information related to the study from your medical/clinical study records that will be kept confidential in a secure online server, under Dr. Culos-Reed in the Faculty of Kinesiology at the University of Calgary, and may be used in current or future relevant health research. Your name or other information that may identify you will not be provided (i.e., the information will be de-identified). The records received by these organizations will be coded with a number. The key that indicates what number you

have been assigned will be kept secure by the researchers directly involved with your study and will not be released. To protect your identity, the information that will be on your assessment forms and questionnaires will be limited to your study ID and initials.

Any disclosure of your identifiable health information will be done in accordance with federal and provincial laws including the Alberta Health Information Act (HIA). The organization listed above are required to have organizational policies and procedures to protect the information they see or receive about you, except where disclosure may be required by law. The principal investigator will ensure that any personal health information collected for this study is kept in a secure and confidential location (at the University of Calgary) as also required by law.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during the study will be used in analyses and will be published and/or presented to the scientific community at meetings and in journals, but your identity will remain confidential. It is expected that the study results will be published as soon as possible after completion. This information may also be used as part of a submission to regulatory authorities around the world to support the approval of this intervention.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated. Every effort will be made to keep your identifiable information confidential, and to follow the ethical and legal rules about collecting, using and disclosing this information. Studies involving humans sometimes collect information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how people respond to different interventions. Providing information on your race or ethnic origin is voluntary.

Data collected will be entered into the secure RedCap server held at the University of Calgary and data will only be used for research purposes. If you are given the opportunity to use m-health app, Zamplo, data will also be entered into the app. The developers, Hanalytics Solutions, are not data custodians. All of your data is encrypted and stored in an encrypted database. Only you and any of your appointed caregivers will have access to your personal information. No data is shared with any third party users without your consent. If at any point you wish to revoke your caregiver's access or remove your account (with all data destroyed) you may do so by contacting the research coordinator or principal investigator.

WILL MY HEALTHCARE PROVIDER(S) BE INFORMED OF MY PARTICIPATION IN THIS STUDY?

Your family doctor/health care provider will be informed that you are taking part in a study so that you can be provided with appropriate medical care. If you do not want your family doctor/health care provider to be informed, please discuss with your study team to find out your options.

WILL THERE BE ANY COSTS INVOLVED WITH PARTICIPATING IN THIS STUDY?

You will not have to pay for the exercise program you receive in this study. Costs associated with attending the exercise program in the community or online will be covered. You will have to pay if you wish to continue to take part in any maintenance exercise classes offered after the baseline program. The cost to continue in a maintenance exercise program may vary among facilities (fee for service). There may be additional costs to you for taking part in this study such as:

- transportation
- parking costs at fitness centres
- meals
- babysitting, etc.

Possible Costs After the Study is Complete

You may not be able to participate in a maintenance exercise program, after your participation in the study is completed. There are several possible reasons for this, some of which are:

- Your caregivers may not feel it is the best option for you;
- You may decide it is too expensive and insurance coverage may not be available;
- The intervention may not be available free of charge.

The principal investigator will discuss these options with you.

WILL I BE COMPENSATED FOR PARTICIPATING IN THIS STUDY?

You will not be paid for taking part in this study. However in the case of research-related side effects or injury, as a direct result of participating in this research, you will receive all medical treatments or services recommended by your doctors.

Although no funds have been set aside to compensate you in the event of injury or illness related to the study treatment or procedures, you do not give up any of your legal rights for compensation by signing this form.

WHAT ARE MY RIGHTS AS A PARTICIPANT IN THIS STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study. You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of these results, please contact the principal investigator.

The results of this study will be available on a clinical registry; refer to the section titled “Where can I find online information about this study?”. Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form you do not give up any of your legal rights against the hospital, investigators, sponsor, involved institutions for compensation or their agents, nor does this form relieve these parties from their legal and professional responsibilities.

IS THERE CONFLICT OF INTEREST RELATED TO THIS STUDY?

There are no conflicts of interest declared between the principal investigator and sponsor of this study.

WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT ME AS A RESEARCH PARTICIPANT?

During the study, the researchers may learn something about you that they didn't expect. For example, the researchers may find out that you have another medical condition.

If any clinically important information about your health is obtained as a result of your participation in this study, you will be given the opportunity at that time to decide whether you wish to be made aware of that information.

WHERE CAN I FIND ONLINE INFORMATION ABOUT THIS STUDY?

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The study registration number to use this website is: NCT04478851

WHO DO I CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you should talk to the research coordinatior or principal investigator. These person(s) are :

Ms. Julianna Dreger CSEP-CEP (Research Coordinator)	Ph: 403-210-8482 Email: jdreger@ucalgary.ca
Dr. Nicole Culos-Reed, PhD (Principal Investigator)	Ph: 403-220-7540 Email: nculosre@ucalgary.ca

If you have questions about your rights as a participant or about ethical issues related to this study and you would like to talk to someone who is not involved in the conduct of the study, please contact the Office of the Health Research Ethics Board of Alberta – Cancer Committee at:

Telephone: 780-423-5727 Toll Free: 1-877-423-5727

SIGNATURES

Part 1 - to be completed by the potential participant.

	Yes	**No**
Do you understand that you have been asked to take part in a research study?	☐	☐
Do you understand why this study is being done?	☐	☐
Do you understand the potential benefits of taking part in this study?	☐	☐
Do you understand the risks of taking part in this study?	☐	☐
Do you understand what you will be asked to do should you decide to take part in this study?	☐	☐
Do you understand the alternatives to participating in this study?	☐	☐
Do you understand that you are free to leave the study at any time, without out having to give reason and without affecting your future health care?	☐	☐
Do you understand who will see your records, including health information that identifies you?	☐	☐
Do you understand that by signing this consent form you are giving us permission to access your health information if applicable?	☐	☐
Do you understand that by signing this consent form that you do not give up any of your legal rights?	☐	☐
Do you understand that your family doctor/health care provider will/may be informed of your participation in this study?	☐	☐
Have you had enough opportunity to ask questions and discuss this study?	☐	☐

By signing this form I agree to participate in this study.

Signature of Participant	PRINTED NAME	Date

Part 2 - to be completed by the principal investigator or designee who conducted the informed consent discussion. Only compete this section if the potential participant has **agreed** to participate.

I believe that the person signing this form understands what is involved in the study and has freely decided to participate.

Signature of Person Conducting the Consent Discussion	PRINTED NAME	Date

You will be given a copy of this signed and dated consent form prior to participating in this study.