



## The University of Arizona Consent to Participate in Research

**Study Title:** Physical activity and cancer among Native American cancer survivors (Phase 2)

**Principal Investigator:** NAU: Hendrik de Heer and Anna Schwartz; UA: Jennifer Bea

**Sponsor:** National Cancer Institute

**This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

### Why is this study being done?

This study will determine if a culturally adapted physical activity program is effective among a broader group of Native cancer survivors for the improvement of physical fitness and quality of life. Family and friends who wish to join the survivors in the program will be given the option to enroll in the study as well. Family and friends are asked to join to help support the cancer survivors complete the study program.

There are cancer health disparities among Native Americans for various cancers and we would like to better understand how to improve cancer survivorship in this underserved community.

The physical activity intervention in the program was initially designed based on information gathered from Navajo cancer survivors in focus groups and interviews related to physical activity preferences, barriers, and needs. It also follows the American College of Sports Medicine guidelines for physical activity in cancer survivorship. The program has been adapted for other Native communities based on cultural expert feedback at the program sites on the materials and program.

### What will happen if I take part in this study?

If you decide to take part in this study, you will be assigned to a 12-week physical activity program that starts right away (the 'immediate start group' or start in 6 weeks (the 'delayed start group')). You will have an equal chance to start right away or in 6 weeks.

You will learn about how to incorporate physical activity into your life and to monitor your activity. You may choose to be physically active at home or at a central location, depending on personal preference. A physical activity support packet will be provided online or in print depending on your preference.



Measurements will take place at baseline, 6 and 12 weeks. You will be asked to fill out questionnaires regarding your medical history, physical activity and quality of life at the beginning, during, and at the end of the study. We will also ask you questions about your satisfaction with the program at the end.

We will also take the following measurements at the beginning, middle and end of the study:

- body size: height (be taken twice), weight, waist, and hip circumference,
- body fat and muscle: We will use bioelectrical impedance analysis (BIA), which is available in many gyms and home goods stores. It is like stepping on a scale, but an extremely small electrical current passes through the body and the device measures the impedance to the flow of this current to estimate body fat and muscle.
- fitness: walk test (6-minutes), sit to stand test (you will move from a seated position in chair (you will have two practice attempts), to a standing position as many times as you can in 30 seconds).
- counts from 7-day activity monitor (i.e. pedometer, accelerometer)
- blood pressure and metabolic measurements
- demographic questions
- blood marker of health: a finger-stick test, similar to testing for blood sugar in diabetes, will be used to look at hemoglobin A1c (HbA1c), sometimes referred to as just A1c. Finger stick may be repeated in order to obtain your HbA1c levels.

### **How long will I be in the study?**

The study is 18 weeks long and the exercise program takes 12 weeks.

### **How many people will take part in this study?**

We plan to enroll 100 participants in this study from 4 different sites in Northern Arizona (Leupp, Flagstaff, Tuba City, and Winslow).

### **Can I stop being in the study?**

**Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The University of Arizona, Northern Arizona University, or Arizona Oncology. If you are a student or employee at any of these institutions, your decision will not affect your grades or employment status.

### **What risks or benefits can I expect from being in the study?**

Although taking a finger-stick blood sample causes no serious problems for most people, it can cause some bleeding, bruising, dizziness, infection or discomfort at the puncture site. There are no known risks of body composition assessment by bioelectrical impedance in healthy populations. However, although, the electrical current is so small that it is undetectable, those with a pacemaker or automatic implantable cardiac defibrillator will not be allowed to have a BIA analysis done. The initiation of any exercise program includes risk of: soreness; injuries to





muscles, bones, and joints; heat prostration; or, rarely, other more serious conditions (e.g. heart attack stroke), however, risks of not exercising outweigh risks of appropriate exercise according to ACSM and the American Cancer Society. Several studies have shown that exercise does not cause lymphedema (swelling) or make lymphedema worse, however, we will follow American College of Sports Medicine physical activity guidelines for cancer survivors to minimize lymphedema related risks. Exercise goals will be adjusted as needed. Gradual exercise progression and monitoring are designed to minimize all of the exercise related risks mentioned. Your exercise training support packet will also describe signs and symptoms that tell you when you should stop exercising and seek help, such as overheating. Minimizing any risks are a priority in the study. Local staff at all sites are familiar with Native culture and can help explain the risks. You can withdraw at any time without any negative consequence. There are no financial obligations to participate in the study.

You may or may not benefit as a result of participating in this study. You will receive important information about your health that you may share with your doctor and your families. We believe you will also benefit from learning about how healthy habits like physical activity can impact cancer prevention and control. What we learn from this study, will be important in making programs that can help others be healthy.

If you are Native American and agree to participate in this study, there may be risks associated with the research that impact your community. Risks may include legal, financial, social, or physical harm. Information may be published that conflicts with your communities' culture, traditions, mythologies, or spiritual beliefs. Because this study was developed in partnership with Native communities, and publications are subject to Navajo Nation Human Research Review Board approval, we do not expect any of these harms.

### **Will I be paid for taking part in this study?**

Yes. You will be paid \$20 for the completion of the baseline measurement visit, \$30 after completing 6 week measurements, and \$40 for completing the final study measurement visit (12 weeks). Gas cards (\$10) will also be provided to the driver at each measurement visit. You could receive up to \$120 total if you come to every visit (5 visits) and drive yourself. These amounts may be provided as gift cards for ease of delivery. By law, payments to participants may be considered taxable income.

You will be able to keep your physical activity tracker at the end of your participation. There are other incentive items, such as water bottles and t-shirts, and trainers will help you set appropriate exercise related goals and work to keep you motivated in the program. Food and drinks will occasionally be provided at community events.

### **What are the costs of taking part in this study?**

The study will take some of your time, approximately 1 hour for each of the measurement visits and the time it takes to exercise. You will need transportation to measurement visits. Gas cards (\$10) will be provided to the driver for the measurement visits to offset these costs. If you



choose to exercise at a central location, you will have transportation costs to get there, but you may choose to exercise at home.

**What happens if I am injured because I took part in this study?**

If you suffer an injury from participating in this study, you should seek treatment. The University of Arizona has no funds set aside for the payment of treatment for this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

**Will my data or specimens be stored for future research?**

No bio specimens or data from this study will be stored.

**What other choices do I have if I do not take part in the study?**

No alternative interventions are available related to this study, however, you may choose not to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

**Will my study-related information be kept confidential?**

All the information we collect is confidential. Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

*Also, your records may be reviewed by the following groups:*

- *Navajo Nation Human Research Review Board, NDOH, P.O. Box 1390, Window Rock, AZ 86515; Phone: (928) 871-6929.*
- *Office for Human Research Protections or other federal, state, or international regulatory agencies*
- *The University of Arizona Institutional Review Board and Northern Arizona University Institutional Review Board*
- *The sponsor supporting the study, their agents or study monitors*

All study related information will be stored in locked file cabinets, in locked rooms, at Northern Arizona University with only the principal investigator and study personnel having key access or a secure, HIPAA compliant electronic data capture. Study related computers will be password protected. Participants will be assigned a study identification number at the time of study enrollment. Data will be entered into the database using the study ID#. Only the principal investigator and her representatives will have access to a data file linking the participant's name and ID#. None of the published results will include identifying information.

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.

HSPP Use Only:  
Consent Form T502a v 2016-07





To help us protect your privacy, we have obtained a Certificate of Confidentiality (CoC) issued by the National Institutes of Health (NIH). The CoC is issued to protect the investigators on this study from being forced to tell anyone about your participation in this study, even under a subpoena. The information will be used by the sponsor, the University, and regulatory agencies that support or oversee the research.

Even when a CoC is in place, you and your family members must continue to actively protect your own privacy. If you voluntarily give your written consent for an insurer, employer, or lawyer to receive information about your participation in the research, then we may not use the CoC to withhold this information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities for reporting of child abuse or neglect, or as required by law to prevent harm to self or others.

**Who can answer my questions about the study?**

For concerns, questions, comments or injuries related to this study, please contact the Navajo Nation Human Research Review Board chairperson, Ms. Beverly Becenti-Pigman, at [bbp\\_pqih@yahoo.com](mailto:bbp_pqih@yahoo.com) or 928-697-2525.

The Navajo Nation Research Review Board may be contacted at NDOH, P.O. Box 1390, Window Rock, AZ 86515; Phone: (928) 871-6929. The study Principal Investigator, Hendrik 'Dirk' de Heer, may be contacted at Northern Arizona University at 928-523-1499 or 480-414-3993 and [dirk.deheer@nau.edu](mailto:dirk.deheer@nau.edu).

If you are injured as a result of participating in this study, please contact your health care provider immediately to determine if you need treatment. Contact the Navajo Nation Human Research Review Board chairperson, Ms. Beverly Becenti-Pigman, at [bbp\\_pqih@yahoo.com](mailto:bbp_pqih@yahoo.com) or 928-697-2525. Please contact the study, as well, so that your exercise program can be appropriately adjusted, by calling Hendrik (Dirk) de Heer, PhD, at (928)-523-1499.

An Institutional Review Board responsible for human subjects research, Navajo Nation Human Research Review Board and The University of Arizona Human Subjects Protection, reviewed this research project and found it to be acceptable, according to applicable state and national regulations and University policies designed to protect the rights and welfare of participants in research.

**Signing the consent form**

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