Consent to Participate in a Research Study
Colorado State University

TITLE OF STUDY: Aging^{PLUS}: Testing the Effectiveness of a Program to Promote Healthy Aging

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WHY AM I BEING INVITED TO TAKE PART IN THIS RESEARCH? You are invited to participate in this research study because you are an adult between the age of 45 and 75 who is living in the Fort Collins community.

WHO IS DOING THE STUDY? This study is being done by The Adult Development and Aging ProjecT (ADAPT) at Colorado State University. The research team is from the Human Development and Family Studies Department, and is directed by Dr. Manfred Diehl. Other members of the research team include Dr. Matthew Hickey and Dr. Kaigang Li from the Department of Health and Exercise Science, Project Coordinator Katherine Thompson from the Department of Human Development and Family Studies, as well as graduate research assistants and undergraduate research assistants.

WHAT IS THE PURPOSE OF THIS STUDY? This study tests the effectiveness of a new program that promotes healthy aging. The program is designed to provide information about healthy aging and to motivate participants to enact healthy lifestyle changes, such as becoming more physically active.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST? The study takes place on the CSU campus and will last approximately 10 months, but only at certain times will you be asked to work with the research team. The total approximate time commitment will depend on which group you are randomly assigned to. Your total participation will range from 1-2 hours per week, totaling a maximum of about 60 hours distributed over the entire length of the study. A timeline of your engagement and the main activities is shown on page 6 of this form.

WHAT WILL I BE ASKED TO DO? This study uses a randomized assignment plan. This means that you have an equal chance of being assigned to one of two educational groups. The programs of both groups provide information on how to optimize healthy and active aging. Both groups will be given by a trained member of the research staff. The assignment to groups is done randomly (like flipping a coin) by a computer program.

There are a number of things that you will be asked to do:

1. Before you start with any of the educational programs, we will invite you to two meetings on the CSU campus. During the first meeting, we will ask you to fill out several paper-and-pencil questionnaires and complete two computer tasks. In

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addition, we will fit you with an Actigraph that you will wear for the next 7 days. You will also receive a daily activity notebook to fill out during this time. This first meeting will take 1 ½ to 2 hours.

2. During the 7 days of wearing the Actigraph, you will be contacted by a member of the research team to check for any issues with the Actigraph and you will also receive a text message on each of the 7 days where you will be asked to send a photo of your daily activity log via text message to the research team. After you have worn the Actigraph for 7 days, you will return it to us and complete a second session on campus. During the second meeting, we will ask you to do a submaximal bike test so that we can assess your cardiorespiratory fitness. An exercise specialist will monitor the assessment. The test procedure includes 4 minutes of cycling on a standard and low work rate with a pedal frequency of 30 W, then followed by 4 minutes of cycling on a higher individually chosen work rate. Heart rate will be measured regularly during the test. We will also ask you to complete some short physical assessments, including tests to assess grip strength, balance, and gait speed. This second meeting will last about 1 ½ hours. After both sessions have been completed you will start the educational portion of the program.
3. In the education sessions (Weeks 1-4), you will meet each week in groups of 10-12 participants for about 2 hours to receive information on healthy aging, including information on how to enact lifestyle changes, such as starting a regular physical activity program. After completing the education program, you will again fill out a set of questionnaires.
4. In Weeks 5-7, you will not be required to complete any assessments or questionnaires. At Week 8, you will again complete two on-campus meetings with research staff. In the first session, you will fill out a set of questionnaires and complete computer tasks. During Week 8, you will also wear the accelerometer again for 7 days, complete a daily activity log and provide daily photos of that log via text message to the research team. After completing the 7 days of activity tracking we will ask you to come back to campus for the second session, which consists of another set of physical assessments and a submaximal bike test. Each of these meetings will last 1 ½ to 2 hours.
5. Some randomly selected participants will be invited to wear an accelerometer for one week in each of the following 6 months. In addition, these participants will fill out a daily activity notebook and send daily activity log photos to the research team during the same week.
6. All participants will be asked to come back for a final follow-up 6 months after they completed the first 8 weeks. This follow-up will again consist of two sessions. The first session will be for filling out a set of questionnaires and completing computer tasks. Participants will also wear the accelerometer and complete the daily activity log and text message procedure for a final 7-day period. The second session will be for the final physical assessments and submaximal bike test. Each of these meetings will last 1 ½ to 2 hours.

ARE THERE REASONS WHY I SHOULD NOT TAKE PART IN THIS STUDY?

If you are *not* interested in learning about healthy aging or increasing your physical activity level at all, then you would *not* be a good fit for this research study. Also, there is

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an equal chance that you are assigned to one of the two educational programs. This means that if you are not willing to take the chance of being assigned to either group, then you should not sign up for the study. Finally, if you cannot or you are not willing to make the time commitment to complete all of the procedures described above, then you should not sign up for the study. You need to be aware that this study requires a good deal of commitment.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

- Part of your involvement in this study involves potentially becoming more physically active. As a result, there is a risk that you may experience physical discomfort or injury, such as muscle soreness or injury. However, we have taken several steps to prevent this from happening. For instance, we will teach you about safely incorporating physical activity into your lifestyle, and we will ask you to let us know if you are experiencing any pain or discomfort throughout the study. To make sure that becoming more physically active is safe for you, we also will require that you get your physician's approval. If we cannot obtain approval from your physician, or if you do not have a physician, we will require you to sign a separate waiver of liability that acknowledges that you deem yourself physically able to participate in independent physical activity.
- There are also minor risks involved with completing the submaximal bike test. However, risks associated with submaximal tests are much lower than the risks associated with typical maximal (cardiac stress) tests. The risks associated with maximal testing include a very small chance of an irregular heartbeat during exercise (< 1% of all subjects), and other rare risks of a stress test are heart attack (< 5 in 10,000) and death (< 2 in 10,000). But the submaximal test performed in this study is at a lower intensity and therefore has a lower risk.
- There are risks to confidentiality associated with sharing private information in the group education sessions. Although we are instructing the people who take part in the groups to not carry any information that was shared with them outside the group, it is possible that the information you share in the small group setting will not be kept confidential by some of the group members. However, you can choose to share as little or as much information with the group as you feel comfortable. In addition, by signing this form, you agree to keep any information shared by other group members private and to not discuss it outside of the group sessions with individuals who are not a part of the group.
- Additionally, text messages are not encrypted or secure during their transmission, and could be intercepted. Importantly, however, participants will only be sending pictures of data that will not contain identifiable information and that will be sent to a password protected email.
- It is not possible to identify all potential risks in research procedures, but the researcher(s) have taken reasonable safeguards to minimize any known and potential, but unknown, risks.

ARE THERE ANY BENEFITS FROM TAKING PART IN THIS STUDY? There are no direct benefits from taking part in this study. However, during your participation in either group you will have the opportunity to learn new things about how people can age

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more successfully. Therefore, we hope that you will learn new information and ways of doing things that will help you to incorporate healthier habits into your daily life.

DO I HAVE TO TAKE PART IN THE STUDY? Your participation in this research is completely voluntary. If you decide to participate in the study, you may withdraw your consent and stop participating at any time without penalty or loss of benefits to which you are otherwise entitled.

WHAT WILL IT COST ME TO PARTICIPATE? You do not have to pay anything to take part in this study. However, if you experience an injury or if you need medical care as the result of any part of the research study, then you will be responsible for paying for the necessary treatment.

WHO WILL SEE THE INFORMATION THAT I GIVE? We will keep private all research records that identify you, to the extent allowed by law.

For this study, we will assign a code to your data (for example, #1001) so that the only place your name will appear in our records is on the consent form and in our data spreadsheet which links you to your code. Only authorized members of the research team will have access to the link between you, your code, and your data. The only exceptions to this are if we are asked to share the research files for audit purposes with the CSU Institutional Review Board ethics committee, if necessary. In addition, for funded studies, the CSU financial management team may also request an audit of research expenditures. For financial audits, only the fact that you participated would be shared, not any research data.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you.

You should know, however, that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court OR to tell authorities if we believe you have abused a child, or you pose a danger to yourself or someone else.

Your identity/record of receiving compensation (NOT your data) may be made available to CSU officials for financial audits.

CAN MY TAKING PART IN THE STUDY END EARLY? In rare cases, you may be asked to stop participating in the study. For instance, if you miss multiple required sessions without notice, or if it is determined that you are disruptive during group sessions, then you may not be allowed to continue in the research study.

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WILL I RECEIVE ANY COMPENSATION FOR TAKING PART IN THIS STUDY? You may earn up to $280 for your participation in this study. The payments will be given to you in installments throughout the study so that you will not have to wait until the end. For example, you will receive your first payment after you have completed the first two meetings. The payments are intended as a reimbursement for your time and will be given to you as long as you choose to be in the study.

WHAT HAPPENS IF I AM INJURED BECAUSE OF THE RESEARCH? The Colorado Governmental Immunity Act determines and may limit Colorado State University's legal responsibility if an injury happens because of this study. Claims against the University must be filed within 182 days of the injury.

WHAT IF I HAVE QUESTIONS?
Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions about the study, you can contact the investigator, **Dr. Manfred Diehl, at (970) 491-1767.** If you have any questions about your rights as a volunteer in this research, contact the CSU IRB at: RICRO_IRB@mail.colostate.edu; 970-491-1553. We will give you a copy of this consent form to take with you.

WHAT ELSE DO I NEED TO KNOW?
Your signature acknowledges that you have read the information stated and willingly sign this consent form. Your signature also acknowledges that you have received, on the date signed, a copy of this document containing **6** pages.

_____ _____
Signature of person agreeing to take part in the study Date

_____
Printed name of person agreeing to take part in the study

_____ _____
Name of person providing information to participant Date

_____
Signature of Research Staff

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ADDENDUM

Timeline for Participants' Time Commitment/Schedule of Events

MONTH

01	02	03	04	05	06	07	08	09	10
BA	TR	PTA	A random half of the participants will be selected for a self-monitoring group.						M6 FU

BA = Baseline Assessment
TR = Training: AgingPLUS Program
PTA = Post-Training Assessment (Week 8)
M6FU = Month-6 Follow-Up

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