INFORMED CONSENT DOCUMENT

Project Title: **Physical Activity Intervention Tailored for Rural Men**

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This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you discovered our study from ResearchMatch, community email, or other advertisement and fit the inclusion/exclusion criteria and may benefit from an increase in physical activity in your life.

The purpose of this research study is to evaluate the feasibility, acceptability, and efficacy of a 12 week intervention on physical activity.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 50 people will take part in this study at the University of Iowa.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will include a 10-week intervention period a 12 month period of follow-up. You will be asked to:

- Attend a 30-minute initial session that will include signing the consent form and completing online surveys. This visit is done remotely through video conferencing or a phone call.
- Attend a 60-minute baseline testing session that includes an orientation to the ActivPal monitor (the research measurement device), a resting heart rate measure, and exercise testing (push-ups, sit-ups, and squats). This will be done remotely through video conferencing.
- Wear an activity monitor on your thigh for seven continuous days.
- Complete the 10-week intervention.
- Attend a 60-minute follow-up testing session, which will repeat the baseline testing procedures. This session will be done remotely (video conferencing).

WHAT WILL HAPPEN DURING THIS STUDY?

After you provide your consent, you will be asked to complete an online survey. The survey will ask several questions about you and your health. After completing the survey, you will schedule an assessment time. These assessments will be done remotely over a video conference. Before the assessment time, you will be mailed an activity monitor device. A member of our team will also help you download the app to go with the activity monitor. As part of this process, we will ask for your username and password for the app. This step is necessary in order for our team to collect your physical activity data (which we will use to determine whether the study is effective).

During the assessment visit, the researcher will provide instructions on how to wear the research grade activity. The assessment will also include:

- Resting Heart Rate: You will be instructed to take your own heart rate/pulse while seated
- Push-up test: You will be asked to do as many consecutive push-ups as possible
- Sit-up test: You will be asked to do as many sit-ups as possible during a 1 minute period
- Squat Test: You will be asked to do as many body weight squats as possible during a 1 minute period

Note: The completion of these assessments should only be done if it is safe for you to do so. We reserve the right not to conduct any test if it is deemed unsafe to do so.

You will complete the tests and surveys in your own home or office space of your choosing. You will want to select a space that you feel comfortable, safe, and have adequate room to complete the testing procedures.

After 7 days after the assessment, you will be sent an email that gives you access to the intervention, which is a series of online educational modules that can be accessed at any time during the intervention and given instructions on how to use your activity monitor to track your own physical activity.

After the 10-weeks of the intervention, we will schedule a follow-up assessment that includes the survey and testing procedures done during the baseline test. You will be given a full report and interpretation of your data that we collected at the conclusion of the study. You are permitted to skip any question on surveys or testing procedures without penalty.

At 3, 6, and 12 months, you will receive an email from us asking to complete a survey like the baseline survey that takes about 30 minutes to complete, and we will analyze the data from your activity monitor at those times as well.

Data Storage for Future Use

As part of this study, we are obtaining physical activity and attitudes of physical activity from you. We would like to study your activity and attitude in the future, after this study is over without further consent. Your information and/or data may be placed in a central repository or other national repositories sponsored by the National Institutes of Health or other Federal agencies. If this happens, it may be stripped of identifiers (such as name, date of birth, address, etc.). Other qualified researchers who obtain proper permission may gain access to your data for use in approved research studies that may or may not be related to in the purpose of this study.

These future studies may provide additional information that will be helpful in understanding physical activity behaviors, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your activity and response data might be used to develop products tests, or discoveries that could be patented and licensed. In some instances, these may have potential commercial value and may be developed by the Investigators, University of Iowa, commercial companies, organizations funding this research, or others that may not be working directly with this research team. There are no plans to provide financial compensation to you should this occur.

Your activity data and responses will be stored *without* your name or any other kind of link that would enable us to identify which sample(s) are yours. Therefore, if you give permission to store your activity and survey response data, it will be available for use in future research studies indefinitely and cannot be removed.

Please place your initials in the blank next to Yes or No for each of the questions below:

My physical activity and response data may be stored/shared for future research in behavior research.

My physical activity and survey data may be stored/shared for future research for any other purpose.

____ Yes ____ No

Audio/Video Recording or Photographs

One aspect of this study involves making video of you. This will be used only to ensure adequate analysis of responses during the focus groups. The videos will only be kept until the responses are transcribed. Once all focus group responses have been transcribed, the video recording will be destroyed.

If you do not grant permission, we will not include you in the focus groups, but we can include you in the rest of the study.

[ ] Yes [ ] No I give you permission to make a video of me during this study.

Future Studies

Your contact information will be kept in order to make you aware of future research you may be eligible for. You are not required to participate in these future studies and there will be a separate consent process for any studies that you may be invited to partake in.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

The physical risks include possible fatigue, and/or injury from participating in physical activity or

testing procedures. The intervention will promote engagement in low to moderate intensity physical activity which poses a low risk for injury.

There is a potential risk of emotional distress from completing the behavioral survey. There is a potential risk of emotional distress from modules focusing on mental health, but this risk is minimal. There is a risk of embarrassment during the testing procedures. We will minimize the risk by having only the researcher and you present in the video conferencing session, and the researcher will be in a private office.

For the intervention risks, all participants will be informed about the potential risks of increasing their physical activity. However, the physical activity recommended will be of moderate intensity which the Physical Activity Guidelines for Americans recommend for all adults. They will also be instructed to follow simple guidelines when doing physical activity. If something hurts, they should stop and only resume if it feels better. If they feel sick, they should seek medical attention.

There is a potential of loss of confidentiality of data. To minimize the risk of loss of confidentiality of data, we will take several steps including de-identifying and ID coding all electronic data, storing electronic data on a password protected warehouse accessible only to the PI and the investigative team**.**

WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you will benefit from being in this study. While there is no guarantee of a direct benefit from participating in this study, participants may improve their health and might feel better.

However, we hope that, in the future, other people might benefit from this study because there is little to no data on physical activity interventions tailored specifically to rural men. These results have the potential to develop a low-cost, widely available program that promotes health and well-being through physical activity promotion.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study. You will be able to keep the activity monitor used in the research valued at $70.

WHO IS FUNDING THIS STUDY?

Fraternal Order of Eagles is funding this research study. This means that the University of Iowa is receiving payments from the Fraternal Order of Eagles to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the Fraternal Order of Eagles for conducting this study.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will only collect data necessary to answer the research question. The data collected from participants will be kept confidential. All participants will be given a unique study ID# which will be linked to collected data. Databases that include ID numbers and collected data will be stored on a password protected and secure electronic warehouse accessible only to the principal investigator. All health information gathered as a part of this study will be stored in a secure/locked location accessible only to the key personnel of the investigative team. All collected data will be destroyed 5 years following completion of data analysis. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I Decide to Drop Out of the Study?

If you decide to leave the study early, there will be not be any harm to you, and we would ask that you notify the reason for discontinuing participation (if willing).

Will I Receive New Information About the Study while Participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: **Jacob Gallagher, M.S. at 319-467-0571** or Jacob-gallagher@uiowa.edu If you experience a research-related injury, please contact **Lucas Carr, PhD at 319-353-5432.**

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

_____	_____
(Signature of Subject)	(Date)