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CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

STUDY TITLE: Increasing Physical Activity in Rural Pennsylvanians: The PA Moves Trial – Patient Participant Protocol

PRINCIPAL INVESTIGATOR
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QUESTIONS ABOUT THE STUDY?
You can contact the study investigator listed above if you have any questions about the study, concerns, or complaints.

You can contact your local Primary Health Network if you have any questions about your health.

Andover Primary Care: 440-293-2444
Beaver Falls Health Center Primary Care: 724-843-4400
Clarion Community Health Center: 814-223-9900
Ebensburg Health Center: 814-846-5060
Ellwood City Health Center: 724-824-8185
Greenville Community Health Center: 724-588-5250
Hoffman Memorial Health Center: 724-526-5600
Jacksonville Family Medicine Center: 724-726-0300
Lewistown Community Health Center: 717-447-0340
Mercer Primary Care: 724-662-2650
New Castle Primary Care: 724-658-4564
Oil City Health Center: 814-670-7950
Petroleum Valley Medical Center: 724-756-2940
Punxsutawney Community Health Center: 814-938-3310
Sandy Lake Community Health Center: 724-376-7111
Schuylkill Community Health Center: 570-544-9123
Shamokin Community Health Center: 570-486-4588
Sheakleyville Health Center: 724-253-3428
Shenandoah Health Center: 570-671-0300
Titusville Community Health Center: 814-827-8400
Transfer Health Center: 724-962-3553
Tri-County Community Health Center: 814-743-5449

SOURCE OF SUPPORT:
The institution and investigators are receiving a grant from the National Institutes of Health National Cancer Institute to support this research.

RESEARCH CONSENT SUMMARY (KEY INFORMATION)

- The purpose of this voluntary research study is to see if a referral from your doctor and telephone-based coaching sessions can help you to be more physically active.
- Participation in this study is voluntary
- Study procedures include:
    - At the beginning, middle, and end of the study, you will wear a device that measures your physical activity for a week and fill out surveys. We will also access your medical records at these times to collect information about you including clinic visits and any disease diagnoses.
    - We have set up a telephone-based physical activity coaching program called the MoveLine. We will ask you to have 5 – 10 of these sessions (they will call you). After these sessions are over, you will fill out a survey.
    - You will be encouraged to increase your physical activity.
- For this study, the main risks to know about are:
    - Increased physical activity can cause muscle soreness or injury.
    - Some of the survey questions may make you feel uncomfortable. You may skip those questions and still participate in this study.
    - You may experience skin irritation with wearing the physical activity measuring device.
    - There is always a risk of loss of confidentiality from participating in research. We take many steps to keep your information private.

INTRODUCTION

- This research is being done to address physical inactivity in rural communities.

People living in rural areas are diagnosed and die from cancer at higher rate than people living in cities. Physical activity has been shown to decrease the risk and occurrence of a variety of cancers, including bladder, breast, colon, endometrial, gastric, kidney, and prostate cancers. Being inactive can cause over 10% of breast and colon cancer cases.

Compared to people living in cities, people living in rural areas tend to be less physically active. They're also more likely to be overweight/obese or have diabetes. Adults who are overweight, obese, or diabetic often have changes in the way their bodies deal with insulin, glucose metabolism, and inflammation. Physical activity is thought to reduce the risk of cancer by improving these issues over time.

Primary care providers and their staff can identify a patient's need for more physical activity, but may not have the time or resources to give advice or assistance. We have set up a telephone-based physical activity coaching program, called the MoveLine, to give inactive participants advice and assistance in becoming more physically active.

The purpose of this study is to determine if referring inactive participants to the MoveLine will help them to be more physically active over time.

- You are being asked to participate in this research study because you are overweight/obese or diabetic, physically inactive, go to a participating primary care provider, and live in a rural area.
- Approximately 880 people living in rural areas will take part in this research.
- If you choose to join this study, your participation will last for about 2 years.

RESEARCH ACTIVITIES

You are not required to make any on-site visits to a clinic for this research.

You will be asked to fill out surveys and wear a device called an accelerometer that measures your physical activity 3 times over 2 years.

- Surveys will be done at the beginning of the study (Visit 1), 12 months from now (Visit 2), and 24 months from now (Visit 3).
    - They will be provided to you, can be completed at home, and will take about 20-30 minutes to do.
    - You are free to skip any questions that you would prefer not to answer.
- You will be asked to wear an accelerometer at the beginning of the study (Visit 1), 12 months from now (Visit 2), and 24 months from now (Visit 3).
    - It will be provided to you to wear for one week.
    - When the week is over, you will return it in the postage-paid envelope we will give to you.

If you are in the intervention group, you will be asked to do the following:

- Interact with the physical activity coach by telephone (the MoveLine).
    - Staff from the MoveLine will call you.
    - You will be asked to participate in 5-10 calls, each lasting between 10-15 minutes each.
    - During calls, MoveLine staff will:
        - Help you to identify options for physical activity at home and in the community
        - Coach you on increasing your physical activity
        - Adapt and modify your physical activity program, as needed
        - After your last MoveLine call, you will be asked to fill out a feedback survey (it will take about 5-10 minutes to do).

- Increase your physical activity to achieve 150 minutes of moderate intensity activity per week.
    - Your physical activity program can be adapted and modified weekly by changing the frequency, intensity, time, and type of activity.
    - Physical activity may take place anywhere, including at home or in the community.
    - You will be provided a free Fitbit or pedometer (if you don't have your own activity/step tracker) to aid in your movement goals.

STUDY RISKS

- Physical Risks: If you are in the intervention group, you could potentially experience muscle soreness or injury as a result of increasing your physical activity:
    - Likely:
        - Muscle soreness and injury from increased physical activity. The muscle soreness may last several days after each physical activity, but it is not likely to be severe enough to limit any usual daily activities.
        - There is also a risk of muscle injury from physical activity, such as a muscle sprain, strain, or excessive muscle soreness.
        - It is estimated that over any given month, 4% of adults who walk for exercise on a regular basis will get an injury severe enough to cause a change in activities of daily living for a week or more and that requires medical attention.
    - Less Likely
        - Individuals who do high doses of exercise (higher than what is recommended in this study) can experience dehydration, overexertion, shortness of breath, and fainting.
        - Moderate-intensity exercise does not pose a risk to the heart (cardiovascular system). In fact, NOT exercising poses more risk to the cardiovascular system than moderate intensity exercise.

- Completing Surveys: You may get tired or bored while you are completing the surveys. You do not have to answer any question you do not want to answer. You may skip the questions that make you feel sad or uncomfortable.

- Risk of Randomization: You will be assigned to an intervention group based on the clinic you go to for care. The group assignment you receive may prove to have more side effects than the other group. You may not like your group assignment. The research group has no control over group assignment and cannot change it.

- Loss of Confidentiality: There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained as required by applicable law and to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

- Skin Irritation: There is a risk that you will have some skin irritation because of the device we are asking you to wear to measure your physical activity (an accelerometer). You may wear a thin layer of clothing under the accelerometer if you prefer.

STUDY BENEFITS

There is no guarantee that you will benefit from this research. You may enjoy the physical benefits of increased physical activity, which may include decreasing the risk for chronic diseases and improving quality of life through exercise.

CONFIDENTIALITY

- Protecting your confidentiality: Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information. Here are a few of the ways that we will protect the confidentiality of research participants and study data:
    - Research data will be coded.
        - All participants will receive a unique study code number.
        - The list that matches your name with your study code number will be kept in a locked file cabinet.
    - Paper research records will be kept in locked file cabinets behind locked doors.
    - Role-based security: only those approved to access your records will be allowed to do so
    - Electronic data will be password-protected
- The following people/groups will have access to your research record
    - The investigator, study staff, and other University of Pittsburgh professionals who may be evaluating this study
    - Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information for the purpose of ensuring the appropriate conduct of this research study
    - The sponsor, the National Institutes of Health National Cancer Institute will be provided de-identified information for safety and progress reports
- Future Research: We may use your research information in future studies or may share your information with other investigators for future research without your additional informed consent. Before we use or share your information, we will remove any information that shows your identity.
- Per University of Pittsburgh policy, all research records must be maintained for at least 7 years following final reporting or publication of a project. However, records may be kept indefinitely.
- This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information or documents that may identify you to anyone not connected with the research. This means they cannot provide them as evidence in legal proceedings unless you say it is okay. However, the Certificate of Confidentiality does not prevent disclosures required by law, such as information about child abuse or neglect and harm to yourself or others.

PARTICIPANT ACCESS TO RESEARCH RESULTS

Study results (either individual or aggregate) will not be provided to participants directly.

HIPAA

As part of this research study, we are asking your permission to use your medical records to see if you are eligible to be in this study. This permission does not expire. We will collect the following information: address, age, height, weight, hemoglobin A1c, chronic disease status, number of office visits, and medications.

We need to collect this information to determine whether you meet the conditions for participation in this study, to use your clinic results instead of collecting them for this study, and to track any diagnoses over the course of the study.

As part of this research study, some information we obtain from you will be placed into your medical records, including your progress through the MoveLine program.

Your medical information, as well as information obtained during this research study, may be shared with other groups for the purpose of monitoring this study, including authorized individuals from the National Cancer Institute, and the University of Pittsburgh Office of Research Protections. Authorized representatives of UPMC or affiliated health care providers may also have access to this information to provide service and addressing billing and operational issues.

We will protect the confidentiality of your records. This means we will keep your records secure and do all we can to prevent people who have not been given permission to be able to access it. We cannot guarantee the confidentiality of your information from this study including from your medical records once people outside UPMC or the University have viewed it.

However, you can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up to that point will continue to be used by the research team.

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

PAYMENTS

For your participation in this research study, you will receive $15 per day for each day the accelerometer is worn, up to a maximum of 7 days, for a total of $105 per visit. To receive payment, surveys for the corresponding visit must also be completed. Visits occur at the beginning of the study, at 12 months, and at 24 months. If all three visits are completed, you may receive up to a possible total of $315 over the course of the study. If you do not complete the study for any reason, you will be paid for the visit(s) you have completed.

UPMC utilizes an electronic payment card as a secure payment method to disburse research study compensation. The electronic payment card is administered by Vincent™ (formerly WePay). The study staff will discuss the use of the electronic payment card with you and answer any questions you may have about the payments.

Payment to participants is considered taxable income regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, such as the University of Pittsburgh or UPMC, that organization is required by law to file a “Form 1099 – Miscellaneous” with the IRS and provide a copy to the taxpayer. We are required to give your name and social

security number to the Accounting Office. Participants who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 76% of the expected payment.

COMPENSATION FOR INJURY

If you believe you have been injured as a result of the procedures that are performed for research purposes, immediately contact the Principal Investigator or one of the researchers listed on the first page. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided by UPMC hospitals. If you do not have access to a UPMC facility, you should seek emergency care from your local hospital and contact the study team. It is possible that UPMC or our local hospital may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs. At this time, there is no plan for any additional financial compensation. You do not waive any rights by signing this form.

WITHDRAWAL FROM STUDY PARTICIPATION

You can withdraw from this research study at any time. Any identifiable research information obtained as part of this study prior to the date that you withdrew your consent will continue to be used by the investigators for the purposes described above. If you want to withdraw, notify the study team. Your decision to withdraw will have no effect on your current or future relationship with the University of Pittsburgh or UPMC.

It is possible that you may be removed from the research study by the researchers if, for example,

- continuing the research would be harmful,
- your health status becomes worse,
- you did not follow the instructions of the study team,
- you experience serious side effects, or
- you meet any of the exclusion criteria (including moving out of a rural area)
- you become pregnant (please notify the study staff if you become pregnant during this study)

If you are withdrawn from the research, you will need to return the accelerometer we have loaned to you for the purposes of this research study, if you have one at the time of withdrawal.

CONSENT TO PARTICIPATE

The above information has been explained to me and all my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any part of this research study during this study. Any future questions, concerns or complaints will be answered by a qualified individual or by the investigator listed on the first page of this consent document at the telephone number given. I understand that I may always request that my questions, concerns or complaints be addressed by the investigator. I understand that I may contact the Human Subjects Protection Advocate of the Human Research

Protection office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation. By signing this form, I consent to participate in this research study and provide authorization to use my medical records. A copy of this consent form will be given to me.

_____	_____
Printed Name of Participant	Date

_____

Signature of Participant

INVESTIGATOR CERTIFICATION

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was started until after this consent form was signed.

_____	_____
Printed Name of Person Obtaining Consent	Role in Research Study
_____	_____
Signature of Person Obtaining Consent	Date