Version Date: 06/01/2021

CONSENT FOR RESEARCH
Penn State College of Medicine
The Milton S. Hershey Medical Center

Title of Project: Comparative effectiveness of social physical play and traditional exercise programming

Principal Investigator: Liza Rovniak, Ph.D, MPH

Address: Division of General Internal Medicine, 500 University Drive, Hershey, PA 17033

Telephone Numbers: 717-531-8161
After hours call (717) 531-8521. Ask for the Internal Medicine doctor on 24-hour call.

Subject's Printed Name: _____

We are asking you to be in a research study.

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you.

This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.

1. Why is this research study being done?

The purpose of our study is to compare two exercise programs to see which one people stick with longer and which improves fitness more. One program is a traditional group fitness program including aerobic and strength activities and the second program consists of playing sports that have been modified to be easier and safer. The study is led by Dr. Dr. Liza Rovniak at Penn State and is funded by the National Institutes of Health.

Approximately 470 people will take part in this research study at Hershey Medical Center.

2. What will happen in this research study?

We will ask a few things about you and your health. After your first visit with us, we will ask you to complete a 30-minute online survey which will include questions about how much you exercise, how much you enjoy physical activity, what exercise programs you prefer, how competitive you are with exercise, and how confident you are about exercising. In addition, you will be asked questions about your demographics (like age, gender), your mood (like depression and anxiety), your friend and family network, loneliness, and whether you smoke. You're free to skip any questions that you prefer not to answer. If your blood pressure is very high or if your survey answers suggest that you have a major problem with depression or anxiety, we will send both you and your provider a letter with this information so that you can discuss it with your provider.

We will ask you to complete a study visit and fitness test. As a COVID-19-related risk mitigation and safety measure, we will complete a pre-participation health screening consisting of a COVID-19-specific symptom questionnaire and temperature assessment using a touchless thermometer at the start of the study visit. At the study visit, we will measure your blood pressure, weight and do a fitness test. The fitness test will require you to walk on a treadmill with a mask over your face to measure chemicals in the air you breathe out. This helps us to know when to stop the test. We will gradually increase the speed and the incline of the treadmill until you either feel that you can't go any further, your heart rate goes too high, or the chemicals in your breath suggest that you are exhausted. This should take no more than 15 minutes.

We will ask you to measure your activity. After the baseline visit, the 6-month visit, and the 12-month visit, you will be given a device to wear on your waist that measures how much physical activity you do. You will be asked to wear it for the next 7 days for at least 12 hours per day while awake and then return it by mail, in an envelope we will give you. We will send you an email or call you in the next few days to be sure that you're not having any trouble with the activity monitor. You may also be asked to wear a device on your waist during the exercise program session. You will be asked to wear it for the duration of the exercise session; we will collect the device at the conclusion of the session.

You will be randomly assigned to one of two different exercise programs. After research staff confirms receipt of your physical activity measurement device and completion of your 30-minute online survey, you will be randomly assigned to receive one of the two fitness programs, either a traditional exercise program consisting of aerobic activities, or a program that consists of playing sports that have been modified to be easier and safer. This means whichever fitness program assignment you receive will be determined purely by chance. You will have an equal chance, 1:1 ratio of being in either fitness programs. In both programs you'll be in groups of other people who are participating in the same research study. As a COVID-19-related risk mitigation and safety measure, we will host both fitness programs exclusively outdoors during the spring and summer months. We, too, have implemented modifications (e.g., physical distancing and masking mandates at all times, which includes periods of physical activity) to the delivery of each of the fitness programs to adhere to the safety guidelines and considerations outlined by Penn State University, federal, state, and local governments, the CDC, and Pennsylvania DOH. As an additional COVID-19-related risk mitigation and safety measure, we will complete a pre-participation health screening consisting of a COVID-19-specific symptom questionnaire and temperature assessment using a touchless thermometer at the start of each exercise session. In the event that our research team learns of a positive test for or diagnosis of COVID-19 at any time point during the study, we will notify all study participants affiliated with the COVID-positive individual's exercise site. Once each month during the exercise sessions, you'll be asked to complete a short survey about any injuries you may have had since starting. The programs will be held up to 4 times per week, to overcome problems with each person's schedule, and you are free to attend up to four times weekly. You will be contacted by research staff following your first session to answer any questions and address any concerns. In this conversation, research staff will assist in addressing any identified barriers to attending future sessions. Additionally, you will be given the option to install the TeamSnap phone application in order to receive exercise session confirmation and cancellation notifications from research staff for the duration of the study.

You will be asked to complete brief online surveys. We will email you after 3 and 9 months to ask you to complete brief online surveys about the program, how much you enjoy exercise, any injuries you've had, and about other physical activity you've been doing. These online surveys will take about 10 minutes and can be completed at your convenience.

We will ask you to complete two additional study visits. At 6 and 12 months, we will ask you to come back to Penn State Hershey Medical Center for a visit where you will complete a fitness test and have your height, weight and blood pressure measured. As before, if your blood pressure is very high or if your survey answers suggest that you have a major problem with depression or anxiety, we will send you a letter with this information so that you can discuss it with your provider.

What are my responsibilities if I take part in this research? If you take part in this research, your major responsibilities will include completing the visits and fitness testing at baseline, 6 and 12 months, completing an online survey at the beginning of the project, and briefer surveys each month. You're free to skip any questions that you prefer not to answer. We will also ask you to do your best to attend the sessions of your assigned fitness program.

3. What are the risks and possible discomforts from being in this research study?

Exercise: Our exercise program follows recommended guidelines for physical activity, but there is always the possibility that any increase in physical activity may result in an injury. Like any exercise program, it can cause any of the following: pain and soreness in muscles and joints, pain and soreness in feet, neck and spine, ligament injury or sprain, fracturing a bone, concussion, heat exhaustion, dehydration, shortness of breath, dizziness, abnormal heart responses, nausea, vomiting, a temporary elevation in blood pressure, excessive fatigue, chest pain, low blood glucose, heart attack, abnormal heart rhythm, or a fatal event. To minimize risk, each exercise site is led by a member of the study team that is trained in CPR and has an emergency kit. Exercise sessions will be video recorded for quality control and to show potential participants what to expect. You can choose not to be filmed.

Stress Testing: Risks from stress testing include the following: Abnormal heart responses to the exercise, muscle soreness or muscle pulls resulting from the exercise, excessive fatigue, dizziness, nausea, vomiting, chest pain, heart attack, stroke or death due to performing physical exercise, temporary elevation of blood pressure. It is also possible for the ECG to show an abnormality that later tests show is false.

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 data stored electronically will be maintained to the degree permitted by the technology used. The exercise groups will be encouraged to keep any personal information shared during group discussions confidential. Absolute confidentiality cannot be guaranteed.

Questionnaires: If you are uncomfortable answering questions on the surveys, you are free to skip any questions that you would prefer not to answer.

Randomization: You may have a preference for one group over the other and be assigned to the group you're less enthusiastic about. To participate you need to be willing to try the group you're assigned to, but this may be a disappointment to you.

4. What are the possible benefits from being in this research study?

4a. What are the possible benefits to me?

There is no guarantee that you will benefit from this research. The possible benefits you may experience from this research study include increasing fitness, as each person in the study will get access to a group fitness program and exercise has many benefits including weight loss, more energy, less anxiety, less depression, stronger bones and others.

4b. What are the possible benefits to others?
The results of this research may lead to changes in programs that are offered at fitness facilities and may help individuals make more informed choices about the fitness programs they participate in. If one program is much more effective at increasing fitness than the other, that might make people more interested in starting with one type of program instead of another.

5. What other options are available instead of being in this research study?
You may choose not to be in this research study.

6. How long will I take part in this research study?
If you agree to take part, it will take 12 months total.
There are 3 study visits (baseline, 6 and 12 months) that will take approximately 45 minutes to complete. In addition to the study visits, we will ask you to complete the following survey assessments, at the following time points: a 30-minute online survey following each of the 3 study visits; a 10-minute online survey at 3 and 9 months; and a monthly online survey that will take less than 20 minutes in month 1 and then less than 5 minutes during other months.

There are 208 possible exercise classes (4 per week for 12 months) which you may attend.

7. How will you protect my privacy and confidentiality if I decide to take part in this research study?

7a. What happens to the information collected for the research?
Efforts will be made to limit the use and sharing of your personal research information. In our research files at The Milton S. Hershey Medical Center (HMC) and Penn State College of Medicine (PSU) we will include these identifiers: your name, address, phone number, email address, study code number, date of birth, and medical record number.

- A list that matches your name with your code number will be kept electronically in REDCap (a password-protected and encrypted electronic research data program). Research staff will use REDCap to both collect and store data.
- Your research records will be labeled with your name, date of birth, medical record number, address, email address and phone Dr. Rovniak's research office.

We will communicate the results of any critical values of blood pressure, heart rate, anxiety or depression to you. Staff will have paper copies of some research documents and data that will be stored in a locked cabinet in Dr. Rovniak's research office; all personal health information (PHI) will be separated from data collected.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be

disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

7b. How will my identifiable health information be used?

If you give your consent, health information that can be traced to you will be collected for this research study. In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so. We will use and disclose your information only as described in this form and in the HMC Privacy Notice.

The research team may use the following health information:

- Past, present, and future medical records
- New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

The following people/groups may check and copy records about this research.

- HMC/PSU research staff involved in this study
- The HMC/PSU Institutional Review Board (IRB), a group of people who review the research study to protect subjects' rights and welfare
- The HMC/PSU Human Subjects Protection Office
- The HMC/PSU Research Quality Assurance Office
- Non-research staff within HMC/PSU who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- Federal and state agencies (such as the U.S. Food and Drug Administration, the Office for Human Research Protections, the Department of Health and Human Services, the National Institutes of Health, and other U.S. or foreign government bodies that oversee or review research)
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Researchers from other campuses of Penn State University who are part of this study
- A group that oversees the data (study information) and safety of this research
- Organizations that provide independent accreditation and oversight of hospitals and research
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)

These groups may also review and/or copy your original PSU/HMC records while looking at the results of the research study. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information. We share your information only when we must, and we ask anyone who receives it from us to protect your privacy.

Because research is an ongoing process, your permission for the use, storage and sharing of your health information will continue indefinitely.

Your privacy rights:

- You have the right to refuse to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you will not be able to take part in this research study.
- You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing using the address) on the front of this form. Once permission is withdrawn, you cannot continue to take part in the study.
- If you withdraw your permission, we will stop collecting health information about you for this study; we may continue to use and share your health information that we already have if it is necessary for safety and scientific soundness of the research study; and we will not be able to take back information that has already been used or shared with others
- You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. However, you may not be allowed to see or copy certain health information that is a part of this research study. This is only for the period of the study. You will be allowed to see that information when the entire research study is complete.

8. What are the costs of taking part in this research study?

8a. What will I have to pay for if I take part in this research study?

There is no cost to you for taking part in this study.

8b. What happens if I am injured as a result of taking part in this research study?

It is possible that you could develop complications or injuries as a result of being in this research study. If you experience a side effect or injury and emergency medical treatment is required, seek treatment immediately at any medical facility. If you experience a side effect or injury and you believe that emergency treatment is not necessary, you should contact the principal investigator listed on the first page of this consent form as soon as possible and the principal investigator will arrange for medical treatment

<u>HMC/PSU compensation for injury</u>

- There are no plans for HMC/PSU to provide financial compensation or free medical treatment for research-related injury.
- If an injury occurs, medical treatment is available at the usual charge.
- Costs will be charged to your insurance carrier or to you.
- Some insurance companies may not cover costs associated with research injuries.
- If these costs are not covered by your insurance, they will be your responsibility.

When you sign this form you are not giving up any legal right to seek compensation for injury.

9. Will I be paid to take part in this research study?

You will receive $25 for completing your first visit, $50 for completing your 6-month visit, and $100 for completing your 12-month visit, for a total of $175 for study visits. Compensation for the study visits will be provided following receipt of the physical activity measurement device. The payment will be provided by Greenphire ClinCard. If you do not complete the study for any reason, you will be paid for the parts you have completed.

Reimbursement will be issued by an external company called Greenphire, which will issue your reimbursement. You will be issued a ClinCard, which is a debit card that your funds are loaded onto and can be used at your discretion. The research team will give Greenphire some personal information about you, as described below. Greenphire will only use your personal information to process this reimbursement and will not share it with anyone for any other purpose. Details of the debit card system are explained on an additional sheet. If you lose the card, you may be responsible for the replacement fee.

When a visit or event is completed, funds will be approved and loaded onto your card. The funds will be available within 2-3 business days. In order to assign a ClinCard to you and load funds onto the ClinCard, Greenphire will need your Study/Subject ID, Name, Address, date of birth and Social Security Number. You will have the option to receive updates related to payment alerts via text message and/or email message. Standard text messaging rates will apply. In order to send you messages Greenphire will need your Mobile Phone Number and/or E-mail Address.

Payment received as compensation for participation in research is considered taxable income. If payments from Greenphire exceed $600 in any one calendar year, Greenphire will file a 1099 (Miscellaneous Income) form on behalf of Penn State.

10. Who is paying for this research study?

The institution and investigators are receiving a grant from the National Institutes of Health.

This research study is designed to test an exercise program made by Dr. Christopher Sciamanna (one of the investigators on this project). Dr. Sciamanna has an investment in a company, such as stock, which has begun to investigate the possibility of creating a business that provides exercise programs. The amount of money the investment is worth might be affected by the results of this study. This means that Dr. Sciamanna could gain or lose money depending on the results of this study. This financial interest has been reviewed by the PSU Institutional Review Board and Conflict of Interest Review Committee. If you would like more information, please contact the Conflict of Interest Program at (717) 531-0003, extension 283526.

11. What are my rights if I take part in this research study?

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

Your research doctor may take you out of the research study without your permission. Some possible reasons for this are: you are unwilling to adhere to COVID-19-related safety procedures, continuing the

research would be harmful, or you did not follow instructions set by research staff at your first visit regarding the return of the physical activity measurement device.

During the course of the research you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.

12. If I have questions or concerns about this research study, whom should I call?

Please call the head of the research study (principal investigator), Dr. Liza Rovniak at 717-531-8161 or the Internal Medicine doctor on 24-hour call at 717-531-8521 if you:

- Have questions, complaints or concerns about the research.
- Believe you may have been harmed by being in the research study.
- Have questions about your privacy and the use of your personal health information.

You may also contact the research protection advocate in the HMC Human Subjects Protection Office (HSPO) at 717-531-5687 if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns or general questions about the research.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

You may visit the Penn State College of Medicine's Clinical Research web site at http://med.psu.edu/clinical-research/faqs for:

- Information about your rights when you are in a research study;
- Information about the Institutional Review Board (IRB), a group of people who review the research to protect your rights; and
- Links to the federal regulations and information about the protection of people who are in research studies. If you do not have access to the internet, copies of these federal regulations are available by calling the HSPO at (717) 531-5687.

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.

INFORMED CONSENT AND AUTHORIZATION TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject or subject representative and have answered any questions he/she has about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

Signature of Person Giving Informed Consent and Authorization

Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Signature of Subject

By signing this consent form, you indicate that you voluntarily choose to be in this research and agree to allow your information to be used and shared as described above.

_____	_____	_____	_____
Signature of Subject	Date	Time	Printed Name