STUDY TITLE: Congenital Heart Disease Physical Activity and Lifestyle Study (Phase 2)

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

STUDY TITLE: Congenital Heart Disease Physical Activity and Lifestyle Study (Phase 2)

PRINCIPAL INVESTIGATOR: Jamie Jackson, Ph.D.

CONTACT TELEPHONE NUMBER: 614-722-3076 or 614-722-3587 (M-F, 9:00-5:00 pm)

STUDY SPONSOR: National Heart, Lung & Blood Institute

SUBJECT'S NAME: _____ DATE OF BIRTH: _____

NOTE: The words "you" and "your" are used in this consent form. These words refer to the study volunteer whether a child or an adult.

Key Information About This Study

The following is a short summary of this study to help you decide whether or not to participate. More detailed information follows later in this form.

The purpose of this study is to compare 2 different interventions to increase physical activity among teens and emerging adults with moderate and complex congenital heart disease (CHD): 1) a physical activity tracker (e.g., a Fitbit) and 2) a physical activity tracker along with videoconferencing sessions with a coach. We are also interested in knowing what teens and their parents, as well as emerging adults think about participating in interventions like these.

Study participation: You will receive a Fitbit, which is yours to keep, as well as complete a survey and wear an accelerometer at the week 9, week 22, and 6-month follow-up assessment points. You will also complete an exercise stress test at the week 22 assessment. If you are randomized into the intervention group, you will complete 8 videoconferencing sessions with a physical activity coach spaced out over 20 weeks and participate in a focus group.

Study visits: You will be asked to complete two study visits, one which will occur in your home and one at the hospital for the week 22 assessment, at which time you will complete an exercise stress test. Each visit will last approximately 1 hour. If you are randomized into the intervention group, you will also participate in a focus group held on a different date than the exercise stress test. This focus group will last approximately 1.5 hours. See a more detailed discussion later in this form.

The main risk(s) of the study are feeling upset when answering questions about your diagnosis or medical treatment, detecting a previously unknown problem in the heart, and physical discomfort. Other risks are listed later in this form.

The benefit(s) of the study are receiving a Fitbit, personalized physical activity recommendations, and a free exercise stress test.

If you are interested in learning more about this study, please continue reading below.

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1) INTRODUCTION

We are inviting you to be in this research study because you were eligible for and completed Phase 1 of the Congenital Heart Disease Physical Activity and Lifestyle Study, as well as was medically cleared to participate based on the opinion of your cardiologist and results of an exercise stress test.

Participation is voluntary, and your care at Nationwide Children's Hospital (NCH) will not be affected by your decision to participate or not participate. Using this form as a guide, we will explain the study to you. If you have any questions about the study, please ask. Once you understand this study, we will ask you to decide whether you would like to participate or not. By signing this form, you agree to be in this study. If you do not want to be involved with this study, all regular and standard medical care will still be available to you here or at another institution. You also have the right to leave this study at any time, even if you agree to join now.

You will be given a signed and dated copy of the consent form.

2) WHERE WILL THE STUDY BE DONE AND HOW MANY SUBJECTS WILL TAKE PART?

This study will be done at Nationwide Children's Hospital and we hope to enroll 110 participants.

3) WHAT WILL HAPPEN DURING THE STUDY AND HOW LONG WILL IT LAST?

To determine whether or not each intervention helps increase physical activity in teens and emerging adults with CHD, we need two groups of teens and emerging adults. One group will receive a Fitbit and the other group will receive a Fitbit and have videoconferencing sessions with a coach. The Fitbit is an activity tracker worn on the wrist. To determine which group you are in, you will be randomized. Randomized means that each teen or emerging adult will be picked by chance, like drawing straws or tossing a coin, to receive either a Fitbit or a Fitbit along with videoconferencing sessions. You have a 50% chance of being in either group.

Teens and emerging adults will be shown how to use the Fitbit and the tracking app, which will be downloaded on a smartphone or computer. The information uploaded to the tracking app will be accessed by study staff. In addition to the Fitbit, teens and emerging adults who also receive videoconferencing sessions will talk with a coach using Skype or FaceTime over 8 weeks. The first 4 sessions happen weekly. Sessions 5 and 6 happen in weeks 6 and 8. Sessions 7 and 8 occur in weeks 12 and 20. Sessions will be audio recorded. To schedule these sessions, the coach will communicate with you by phone calls or text messages which will also be used to send reminders and brief messages to get you thinking about your physical activity. After the week 22 assessment if you are in the Fitbit + sessions group, you will be asked to participate in a focus group. For participating in a focus group you will be compensated $50 for your time. This is listed below in more detail.

Regardless of which group you are in, you will also be asked to complete three assessments: one at week 9, one at week 22 (end of the study), and one at a 6-month follow-up. For the assessment at week 9, you will be asked to complete surveys and wear an accelerometer for 7 days. You will be compensated $50 for your time. At week 22, you will be asked to complete surveys, wear an accelerometer for 7 days, and have an exercise stress test. You will be compensated $100 for your

time. At 6 months, you will be asked to complete surveys and wear an accelerometer for 7 days. You will be compensated $75 for your time. These are activities are listed below in more detail.

Surveys
You will be asked to complete an online survey that takes less than 1 hour to complete. The survey will ask you your beliefs about your heart condition, physical and emotional health, physical activity, other health behaviors, readiness to be physically active, and evaluation of the intervention. *Results of the surveys will NOT be included as part of your medical record.*

Accelerometer
An accelerometer is a small device, similar to a Fitbit or other physical activity tracker, that measures how often and to what extent a person is physically active. You will be asked to wear the accelerometer around your waist for 7 days. *Results of the accelerometer will NOT be included as part of your medical record.*

Exercise Stress Test & Exercise Recommendations
The exercise stress test completed in the first study you recently finished will be interpreted by an exercise physiologist so that an exercise recommendation can be given. An exercise recommendation includes the frequency, duration, and type of physical activity for you that is recommended on a daily or weekly basis. You will receive an exercise recommendation regardless of what group you are randomized to (Fitbit or Fitbit + videoconferencing sessions). This recommendation will give you information about optimal levels of physical activity. *The exercise recommendation WILL be included in your medical record and labeled as "Research."*

Similar to the first study you recently completed, you will be asked to complete another exercise stress test at the end of study period. During the exercise stress test, you will be asked to walk on a treadmill for approximately 30 minutes. You will have electrodes placed on your chest. The treadmill incline will be increased every 3 minutes and vital signs (including your heart rate, blood pressure, and oxygen saturations) will be taken throughout the test. You will only be asked to perform to your own ability. *Results of the exercise stress test WILL be included in your medical record and labeled as "Research".*

The exercise stress test may provide information that we were not specifically looking for in this study. This information is called "incidental findings". We will discuss these results with you if we believe that they may have a significant impact on your health. If you ask us to do so, we can also help you set up follow-up meetings with your cardiologist or other medical professionals who are not involved in this study but who can discuss this information with you. These follow-up visits will not be part of this study. Therefore, you and your insurance company would be responsible for any fees and costs related to them.

As part of this study we may contact you via phone and text message. You may also be contacted via videoconferencing (e.g., Google Hangouts). In order to make sure that your privacy is maintained, please do not share your passwords with others.

4) WHAT ARE THE RISKS OF BEING IN THIS STUDY?

We believe that there is very little chance that bad things will happen as a result of being in this study.

It is possible that you could feel upset when answering questions about your diagnosis or medical treatment, but it may be more likely that you will find the questions or feedback process a little boring. If you find any of the questions upsetting or don't want to answer a question, you don't have to, and the study coordinator will be available to discuss this with you further.

An exercise stress test is a commonly used procedure among survivors of CHD. You may experience normal levels of physical discomfort during the exercise stress test. As part of the exercise stress test, you will be encouraged to reach the limitations of your physical capacity, which can be uncomfortable. You will be monitored by clinical staff during the duration of the test and recovery.

An exercise stress test is designed to detect problems in the heart. Therefore, the test may find a problem in the heart that you were not aware of. Learning this information could be distressing.

Similar to the exercise stress test, engaging in moderate or vigorous activity may also cause symptoms of discomfort, including increased heart rate, the feeling of being short of breath, and sore muscles. If you are in the group receiving sessions with a coach, you will be encouraged to slowly increase the duration and intensity of your physical activity using the exercise recommendations, which were developed based on the results of the exercise stress test. The exercise recommendations will take into account any physical limitations for physical activity, given your CHD diagnosis and surgical history. However, if you have concerns about those symptoms during the study, you are encouraged to contact your cardiologist and follow the recommendations from the medical team for evaluation or receipt of care. We also ask you to inform the research team and allow us to reach out to your cardiologist to make sure it is safe for you to proceed with the physical activity portion of the study.

Although we will take every precaution, there is a small chance of loss of confidentiality of your study information.

If you are worried about anything while in this study, please call the study coordinator at the telephone number on page 1.

The use of cellular services and Google Hangouts was reviewed by a Nationwide Children's Information Technology Security team member and determined to be of no greater risk for breach of confidentiality than other forms of communication typically encountered in daily life, such as email. However, the privacy policies of cellular services, Google Hangouts, and other videoconferencing platforms are not as strong as those for medical or research records. Thus, there is the risk that someone else may be able to view communications related to this study. Also, it is possible that the actual transmission can be intercepted and looked at by people not associated with this study. Please do not share your passwords with others. If you have either lost your password or think that someone is viewing your communications, please let the study team know immediately.

You will be asked questions regarding your mood. If at any time during the study you notice changes in your mood, ideas, or behavior that are of concern to you, please call the Principal Investigator at 614-722-3585. Immediate help is available if you begin having thoughts or feelings of hurting yourself. Call one of the numbers below or go to the closest Emergency Room.

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Nationwide Children's Psychiatric Emergency Evaluation Center 614-722-1800
Hopeline/Lifeline – 1-800-784-2433 or 1-800-SUICIDE

Although we will take every precaution, there is a small chance of loss of confidentiality of your study information.

There may be other risks of being in this research study that are not known at this time.

5) SPECIAL INFORMATION ABOUT PREGNANCY:

Participation in this study will not be offered to females who are pregnant. If you become pregnant while taking part in this research, you will be withdrawn from this study.

6) ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

There are several potential benefits to participating in this study. You will receive a Fitbit, personalized physical activity recommendations, as well as have another exercise stress test. The stress test may identify problems with your heart that had not yet been found. The results of the stress test will be shared with your cardiologist and could be useful in managing your care. You may also benefit from increasing your level of physical activity.

7) WHAT ARE THE COSTS AND REIMBURSEMENTS?

All costs related to the research parts of this study will be covered by the research team. We will provide a parking voucher for when you come for the exercise stress test. For your time, you will receive $50 for the interim assessment, $100 for the week 22 assessment, $75 for the 6-month assessment, $50 for the focus group (if applicable), as well as reimbursement for travel for the stress test at the final assessment, which is based on mileage to/from the hospital and your home address. You will be issued a debit card specially designed for clinical research. When an assessment is completed, funds will be approved and loaded onto your card.

If you receive more than $600 in a calendar year from participating in studies at NCH, you will be asked for your social security number and you will be issued a 1099 tax form to file with your income taxes. Compensation is payable to the study participant.

8) WHAT HAPPENS IF BEING IN THIS STUDY CAUSES INJURIES?

We believe that there is very little chance that injuries will happen as a result of being in this study.

If you are hurt, have a medical event, or report concerning cardiac symptoms (e.g., chest pain, difficulty breathing above and beyond what would be expected during physical activity) while you are being physically active, you should seek medical attention from the providers who you typically see. This may be your pediatrician, primary care physician, or cardiologist. The study interventionists are not healthcare providers.

If you seek medical care for during the study, it is important to contact the coach to let them know. They will wait for clearance from your doctor before proceeding with the study.

If you are hurt or have a medical event during the exercise stress test, medical staff will be onsite to intervene. The exercise stress test is done in the cardiology clinic, is monitored by trained staff, and medical staff are available to assist.

If intervention during physical activity or during the exercise stress test is needed, this care will be billed to your health insurance company or whoever usually pays for your health care at the usual charges, but some insurance companies will not pay for care related to a study, as in the case of the exercise stress test. If the care is provided at Nationwide Children's Hospital, we make no commitment to pay for the medical care provided to you. No funds have been set aside to compensate you in the event of injury. If no one else pays for your care, you may have to pay for the cost of this care. This does not mean that you give up any of your legal rights to seek compensation for your injuries.

In most cases, this care will be billed to your health insurance company or whoever usually pays for your health care at the usual charges, but some insurance companies will not pay for care related to a study.

9) WHAT WILL HAPPEN IF NEW INFORMATION IS FOUND OUT ABOUT THE DRUG OR TREATMENT?

If new information is found out during this study that might change your mind participating or might affect your health, a study staff member will discuss it with you as soon as possible.

10) WHAT HAPPENS IF I DO NOT FINISH THIS STUDY?

It is your choice to be in this study. You may decide to stop being in this study at any time. If you decide to stop being in this study, you must call the Principal Investigator or the study coordinator. If you stop being in the study, there will not be a penalty or loss of benefits to which you are otherwise entitled.

If at any time the Principal Investigator believes that this study is not good for you, the study staff will contact you about stopping. If unexpected medical problems come up, the Principal Investigator may decide to stop your participation in the study.

11) OTHER IMPORTANT INFORMATION

Please tell us if you are in any other research study so a decision can be made about being in more than one study at the same time. We may need to notify the other study team to see if you can participate in this study.

If you are an employee of Nationwide Children's Hospital or the Research Institute at Nationwide Children's Hospital, your job or performance appraisal will not be affected in any way if you decline to participate or you withdraw your consent to participate in this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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 Web site at any time.

The final study results will not be shared with you individually. However, at some time, a final study summary will be given to all families involved, as well as available on the ClinicalTrials.Gov (http://clinicaltrials.gov) website.

The Principal Investigator is being paid by the National Heart, Lung & Blood Institute for the time and knowledge needed to do this study.

Nationwide Children's Hospital is a teaching hospital and we are committed to doing research. Doing research will enable us to learn and provide the best care for our patients and families. You may be asked to participate in other research studies in the future. You have the right to decide to participate or decline to participate in any future studies. We will not share your contact information with researchers outside Nationwide Children's Hospital.

12) HOW WILL MY STUDY INFORMATION BE KEPT PRIVATE?

Information collected for this study includes information that can identify you. This is called "protected health information" or PHI. By agreeing to be in this study, you are giving permission to Dr. Jamie Jackson and the study staff to collect, use, and disclose your PHI for this research study and for future research purposes (including purposes that are currently unknown) unless otherwise allowed by applicable laws. Information collected is the property of Nationwide Children's Hospital, one of its affiliated entities, or the Sponsor.

PHI that may be used or disclosed:

- Names (including yours, relatives', your cardiologist's)
- Your address (including city, state, zip code)
- Telephone numbers (yours, relatives')
- Dates (birthdate, dates of treatment)
- Email addresses (yours, relatives')
- Your medical record number

People or Companies authorized to use, disclose, and receive PHI collected or created by this research study:

- PI and study staff
- The Nationwide Children's Hospital Institutional Review Board (the committee that reviews all human subject research)
- Nationwide Children's Hospital internal auditors
- Sponsor (National Heart, Lung & Blood Institute)
- The Office for Human Research Protections (OHRP) (the federal government office that oversees human subject research)

Because of the need to give information to these people, absolute confidentiality cannot be guaranteed. Information given to these people may be further disclosed by them and no longer be protected by federal privacy rules.

Reason(s) why the use or disclosure is being made:

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PHI is needed to contact you (including in the future), locate medical records, and to track your cardiac care.

You may decide not to authorize the use and disclosure of your PHI. However, if it is needed for this study, you will not be able to be in this study. If you agree to be in this study and later decide to withdraw participation, you may withdraw your authorization to use your PHI. This request must be made in writing to the Principal Investigator at 431 S. 18th St., Near East Office Building, Columbus, OH, 43205. If you withdraw your authorization, no new PHI may be collected and the PHI already collected may not be used unless it has already been used or is needed to complete the study analysis and reports.

PHI will only be shared with the groups listed above, but if you have a bad outcome or adverse event from being in this study, the Principal Investigator and staff or other health care providers may need to look at your entire medical records. In the event of any publication regarding this or any future studies, your identity will not be revealed.

Certificate of Confidentiality:

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, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

13) USE OF INFORMATION/SAMPLES FOR FUTURE RESEARCH USE

Your study information and collected as part of this study will not be used or distributed for future research purposes, even if the identifiers are removed.

14) WHOM SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?

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If you have questions about anything while on this study or you have been injured during the course of this research, you may contact the Principal Investigator (Dr. Jackson) at 614-722-3585, Monday – Friday, between 9:00 am and 5:00 pm.

If you have questions, concerns, or complaints about the research; if you have questions about your rights as a research volunteer; if you cannot reach Dr. Jackson; or if you want to call someone else - please call (614) 722-2708, Nationwide Children's Hospital Institutional Review Board, (IRB, the committee that reviews all research involving human subjects at Nationwide Children's Hospital).

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Subject's Name_____Date of Birth_____

SUBJECT or SUBJECT'S PARENT OR PERSON AUTHORIZED TO CONSENT ON BEHALF OF THE CHILD (SUBJECT TO THE SUBJECT'S GENERAL MEDICAL CARE)

I have read this consent form and I have had an opportunity to ask questions about this research study. These questions have been answered to my satisfaction. If I have more questions about participating in this study or a research-related injury, I may contact the Principal Investigator. By signing this consent form, I certify that all health information I have given is true and correct to the best of my knowledge.

I have been given a copy of the Nationwide Children's Hospital Notice of Privacy Practices. If allowed by law, I understand that my right to any information that is created or collected by Nationwide Children's Hospital for this study can be temporarily suspended if necessary for the purposes of this research project. I also understand that my right to access to this information from this study will be reinstated upon completion of this research unless I have been told by the Principal Investigator that I will not receive study results.

I agree to participate in this study. I will be given a copy of this consent form with all the signatures for my own records.

Signature Block for Children ☐ N/A, Adult Subject

Your signature documents your permission for the named child to take part in this research.

_____
Printed name of child

_____ _____
Signature of parent or individual legally authorized to consent to the child's general medical care — Date & Time AM/PM

_____
Printed name of parent or individual legally authorized to consent to the child's general medical care

_____
Relationship to Participant

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact Legal Services if any questions arise.

_____ _____
Signature of second parent or individual legally authorized to consent to the child's general medical care — Date & Time AM/PM

_____
Printed name of second parent or individual legally authorized to consent to the child's general medical care

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_____
Relationship to Participant

If signature of second parent not obtained, indicate why: (select one)

- ❑ Not required by IRB
- ❑ Second parent is deceased
- ❑ Second parent is unknown
- ❑ Second parent is incompetent
- ❑ Second parent is not reasonably available
- ❑ Only one parent has legal responsibility for the care and custody of the child

_____ _____
Signature of person obtaining consent Date & Time AM/PM

_____
Printed name of person obtaining consent

Assent

_____ _____
Signature of subject Date & Time AM/PM

❑ Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.

Signature Block for Adult Participation ☐ N/A, Pediatric Subject

Your signature documents your permission to take part in this research.

_____ _____
Signature of subject Date & Time AM/PM

_____
Printed name of subject

_____ _____
Signature of person obtaining consent Date & Time AM/PM

_____
Printed name of person obtaining consent