The University of Texas at Arlington (UTA)

Informed Consent for Studies with Adults

TITLE OF RESEARCH PROJECT
Project KNOWN – KNOW and OWN your movement-related metrics via wearable.

RESEARCH TEAM
PRINCIPAL INVESTIGATOR
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IMPORTANT INFORMATION ABOUT THIS RESEARCH PROJECT
The research team at the Physical Activity and Wearable Sensors (PAWS) Lab at UT Arlington invites you to participate in a research study named "Project KNOWN" to test a remotely delivered physical activity intervention that uses wearable sensors and text messages. You can choose to participate in this study if you (1) are 18 years or older; (2) have been diagnosed with cancer; (3) have completed primary treatment for at least three months; (4) do not currently engage in regular physical activity; (5) do not have diabetes; and (6) have a smartphone with daily internet access.

You might want to participate in this study if you want to become more physically active in your daily life and provide valuable information to help us promote an active lifestyle for cancer survivors. However, you might not want to participate in this study if you are particularly uncomfortable with needles, and do not have time to attend the study visits in person at the UT Arlington campus.

Your participation in this study is completely voluntary. Before choosing to take part in this study, you should take your time to consider the information provided by this form and the research team and discuss with the research team any concerns you may have. If you do not want to participate or you want to stop participating at any time, you can. You will not be punished in any way if this happens. Please ask questions if there is anything that you do not understand.

TIME COMMITMENT
There are four on-campus visits (visit 4 optional) for this study, two 2-week self-monitoring assessment periods, and one 12-week intervention period. The first visit will take about 1-1.5 hours to complete. After this first in-person visit, there is a 2-week self-monitoring period. A second in-person visit will be scheduled at the end of the 2-week self-monitoring period and will take about 30-60 minutes to complete. After the second in-person visit, the intervention period will start and will take a total of 12 weeks. A third in-person visit will be scheduled after the 12-week intervention period and will take about 60 minutes to complete. There will be another 2-week self-monitoring period after the third in-person visit, followed by the last in-person visit, which will take about 30 minutes to complete. The whole study period is 16 weeks.

RESEARCH PROCEDURES
If you decide to participate in this research study, below is the list of activities that will take place:

1.) On-campus Visit 1 (baseline assessment). At this visit, you will provide your blood sample and fill out a series of survey questions about yourself and how your feel about or experience things in your life. Please note that you must fast (have nothing to eat or drink but water) for 8 hours before this visit. You will also complete a set of physical fitness assessment, which involves walking for 6 minutes, standing-up from and sitting-down on a chair, and pulling a metal handle using your fingers. You will be given a wrist-worn activity tracker and a Libre continuous glucose monitor (CGM) sensor to wear for the next 2 weeks. You can insert the CGM sensor yourself, following the instructions from the manufacturer, or study staff will help you do this. To insert a CGM sensor, you will

   a. Choose a placement site around the back of your upper arm.
   b. Insert the small flexible sensor under your skin using the applicator tool provided.

Upon insertion of the CGM sensor, the study staff will activate the sensor for you. There will be no other actions required from you while you wear the sensor for the next 2 weeks. This visit should take about 90 minutes total.

OPTIONAL PROCEDURE: During this visit, you will be asked if you want to opt in for a DEXA (Dual-Energy X-ray Absorptiometry) scan to determine how much fat and other tissues you have in your body. You will lay on a table where a machine will scan your body. This scan will take approximately 10 minutes. If you wish, you will be able to get a copy of the results upon completion of the entire study. You can also have the option to perform this DEXA scan during your second in-person visit. If you are a non-menopausal female of childbearing age, you will need to perform a pregnancy test using our provided over-the-counter pregnancy test kit to ensure you are not pregnant before the DEXA scan.

- ☐ No, I do not want to opt in for the DEXA scan
- ☐ Yes, I agree to opt in for the DEXA scan

INITIAL: _____

2.) Baseline Self-monitoring Period (2 weeks). You will wear the activity tracker on your non-dominant wrist at all times (including sleep and showering) during this 2-week period. You will keep wearing the CGM sensor on the back of your upper arm. Both devices will continuously collect data automatically without needing to be charged. Therefore, there is no need for you to take off these two sensors for any reasons. Both devices are waterproof. However, please avoid activities that will put the CGM sensor

underwater for an extended period of time (e.g., ocean diving). Please do not change your normal behaviors during this 2-week baseline assessment period.

3.) On-campus Visit 2 (intervention visit). You will return the activity tracker and CGM sensor to us at this visit, following the 2-week baseline assessment period. You will receive a Fitbit wristband. The study staff will teach you how to use the Fitbit. The study staff will review with you the health benefits of regular physical activity, help you calculate your personal target heart rate range for exercise, and set an exercise plan with you.

You will be randomly assigned (as in the flip of a coin) to 1 of 2 study groups. This is done because no one knows if one study group is better, the same, or worse than the other group. You will have an equal chance of being assigned to either group. The study staff will explain which group you are in. If you are in **Group 1**, your visit will end after the educational session described above. If you are in **Group 2**, you will additionally receive another CGM sensor to wear for the next 4 weeks. The study staff will teach you how to use your smartphone to check your glucose information.

This visit will take about 30-60 minutes to complete.

4.) Intervention Self-monitoring Period (12 weeks). You will wear the Fitbit on your non-dominant wrist at all times during this 12-week intervention period. You will need to keep the Fitbit device charged and synced with the Fitbit smartphone application. We will monitor your Fitbit device status and remind you about charging and syncing, as needed. You will receive 2-3 text messages each week with information to encourage you to be physically active.

If you are in **Group 2**, you will need to additionally wear a CGM sensor during the first four weeks of this intervention period. You will need to use a smartphone application (LibreLink) to check your glucose information at least 4 times a day (i.e., upon awakening, afternoon, evening, and before sleep). You will need to replace the CGM sensor at the end of the first 14-day period. You will have the option to learn how to replace the sensor yourself, or you can schedule a visit to UT Arlington to have study staff replace the sensor for you. We will monitor your CGM sensor status and remind you about glucose checking, as needed.

5.) On-campus Visit 3 (post-intervention assessment). At this visit, you will provide your fasting blood sample and fill out a series of survey questions. We will also ask about your experience in the study. You will perform the same physical fitness assessment as in Visit 1. At the end of this visit, you will be given a wrist-worn activity tracker and a

CGM sensor to wear for the next 2 weeks. This visit will take about 60 minutes to complete.

6.) On-campus Visit 4 (optional). You will return the activity tracker and CGM sensor to us at this visit, following the 2-week post-intervention assessment period. You will receive your study compensation and DEXA results (if applicable) at this visit. This visit will take about 30 minutes to complete. You can have the option to mail us back the study devices instead of an in-person visit. We will then mail you the study compensation and DEXA results (if applicable).

Alternative option for blood draw: If we are not able to obtain your blood sample during any of the on-campus visit, you may have the option to visit a LabCorp facility of your choice and have your blood drawn there. If you choose this option, we will make the appointment for you. You will still need to fast (have nothing to eat or drink but water) for 8 hours for this visit.

POSSIBLE BENEFITS
You may start adopting a healthier lifestyle from participating in this study. Future cancer survivors may benefit from what is learned from this study.

POSSIBLE RISKS/DISCOMFORTS
While on this study, you are at risk for side effects. You should discuss these with the study team and your doctor. The known side effects are listed in this form, but they will vary from person to person.

The **continuous glucose monitor (CGM)** may cause infection, bleeding, pain or skin irritations (redness, swelling, bruising, itching, scarring, or change of skin color). If the sensor breaks, a sensor fragment could remain under the skin. This may cause some anxiety. Contact the study staff if the sensor breaks.

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn.

Fasting may cause your blood sugar to drop. You may feel tired, hungry, and/or nauseous.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study principal investigator.

The **DEXA scan** (optional procedure) has minimal to no risk. The test exposes you to a small amount of radiation where the X-ray beam crosses your body. This radiation exposure is is for

research only. This project calls for a single total body scan. The dose for one total body scan is equal to a whole-body radiation dose of about 1.5 millirems. A millirem (mrem) is a unit of whole-body radiation dose. For example, the average person in the United States receives a radiation exposure of 300 mrem per year from natural background sources. These sources can include the sun, outer space, and natural radioactive substances that are found in the earth's air and soil. 1.5 mrem is less than you would receive from 2 days of natural background radiation. In order to receive a DEXA scan, you must not be pregnant, and must also not have any of the following:

- Medical devices – ostomy devices, prosthetic devices, surgical devices, pacemaker leads, radioactive seeds, radiopaque catheters or tubes;
- Jewelry or metal clothing – metal buttons, zippers, snaps, earrings, necklaces;
- Foreign objects – shrapnel, buckshot, metal plates or pins.
- X-ray procedures within the last 7 days which use iodine, barium, or other nuclear medicine isotopes.

There is some small privacy risk associated with text messaging. Messages may not be encrypted and may not be completely secure in transit. Text messages are being sent through a third-party company, Mosio, which may have access to the content of the messages and your phone number. Your name will not be disclosed to Mosio. Standard text messaging rates will apply, and participants will be responsible for this cost.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen. All study data will be stored in password-protected computers and/or locked file cabinets. There will be no personal identifying information connected to your questionnaire answers.

This study may involve unpredictable risks to the participants.

While you are in the study, it is important that you report any illness or injury that occurs to the research team **immediately**. The University of Texas at Arlington does NOT offer compensation for any injuries resulting from your participation in this research. If you suffer a research-related injury, any resulting medical costs will be your responsibility or that of your insurance / third-party payer. Likewise, follow-up of any of the information returned to you about your vital signs or lab tests will be your and your insurance/third-party payer's responsibility. However, as a research subject, you will not lose any of your legal rights.

COMPENSATION

As compensation for your time and effort, you can receive up to $50 in gift card at the end of this study, after verifying your compliance of all study procedures. You will be able to keep the Fitbit device after the study is complete.

The Internal Revenue Service (IRS) considers all payments made to research subjects to be taxable income. Your personal information, including your name, address, and social security number, may be acquired from you and provided to UTA's accounting office for the purpose of

payment. If your total payments for the year exceed $600.00, UTA will report this information to the IRS as income and you will receive a Form 1099 at the end of the year. If you receive less than $600.00 total for payments in a year, you are personally responsible for reporting the payments to the IRS.

CONFIDENTIALITY

The research team is committed to protecting your rights and privacy as a research subject. We may publish or present the results, but your name will not be used. A study ID will be assigned to you and we will use this ID to link all of your data. A study-specific email account will be generated by the study team without any of your personal information. This study-generated email account will be used to register a user account with Fitbit and Abbott/Libre in order to use their smartphone apps. While absolute confidentiality cannot be guaranteed, the research team will make every effort to protect the confidentiality of your records as described here and to the extent permitted by law.

CONTACT FOR QUESTIONS

If you have any questions related to this research study, please feel free to contact Dr. Liao Yue at 817-272-8529 or yue.liao@uta.edu. For questions related to rights or to report any complaints, please contact the UTA Research Office at 817-272-3723 or regulatoryservices@uta.edu.

As a representative of this study, I have explained the purpose, the procedures, the benefits, and the risks that are involved in this research study:

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Signature & Name of Research Team Member Conducting Consent Process DATE

CONSENT

By signing this form, you are confirming that you understand the study's purpose, procedures, potential risks, and your rights as a research subject. By agreeing to participate, you are not waiving any of your legal rights. You can refuse to participate or discontinue participation at any time, with no penalty or loss of benefits that you would ordinarily have. Please sign below if you are at least 18 years of age and voluntarily agree to participate in this study.

_____

SIGNATURE & NAME OF VOLUNTEER DATE

**If you agree to participate, please provide the signed copy of this consent form to the research team. They will provide you with a copy to keep for your records.*