The In4M Study: Integrating 4 Methods to Assess Physical Function in Cancer Patients

NCT05214144

Informed Consent Forms

Yale University version November 16, 2022

Mayo Clinic version January 12, 2022

COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

YALE UNIVERSITY SCHOOL OF MEDICINE
YALE-NEW HAVEN HOSPITAL

Study Title: The In4M Study: Integrating 4 Measures to Assess Physical Function in Cancer Patients

Principal Investigator (the person who is responsible for this research):

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Yale School of Medicine
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Cary Gross, MD 203-737-7624

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to help us understand how to measure the impact of treatment on patients' physical function who are undergoing chemotherapy.
- **2 in person** visits are required.
- Your initial visit will take **2** hours maximum.
- You will be required to answer surveys and wear a Fitbit Inspire 2 during this study
- There are some risks from participating in this study. You may feel inconvenienced by filling out surveys and completing the in-person six-minute walk test. Additionally, wearing the Fitbit may be uncomfortable for you.
- The study may have benefits to you. Knowledge gained from this study may help doctors to better counsel future patients on what to expect regarding their physical function during treatment. Additionally, through Hugo you will have access to your medical records across all the institutions where you receive care. Wearing the Fitbit may also give you additional useful information regarding your health and fitness.
- There are other choices available to you outside of this research. The alternative to participating in the proposed study is to not participate. Participation and non-participation will have no impact on the course of treatment that you receive.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?
We are asking you to take part in a research study because you have been diagnosed with breast cancer or lymphoma at Yale New Haven (Smilow) Hospital and are planning on receiving chemotherapy treatment. We are looking for 50 patients with newly diagnosed breast cancer and 50 patients with newly diagnosed lymphoma who will be starting chemotherapy treatments. 100 total patients will be enrolled in this study.

Who is paying for the study?
The U.S. Food and Drug Administration (FDA)

What is the study about?
The purpose of this research study is to help us understand how to measure the impact of treatment on patients' physical function who are undergoing chemotherapy.

Cancer doctors and researchers have traditionally focused on describing how well treatment works, and its side effects, but do not always focus on how patients will feel and function during treatment. Physical function – the ability to carry out day-to-day activities that require physical effort – is an important part of daily life.

What are you asking me to do and how long will it take?
If you agree to take part in this study, this is what will happen:

In this study, we will use four different ways to study physical function – including information about your physical function from surveys completed by you, data about your physical function from a Fitbit wearable device, a physical function score assigned by your doctor, and results from a 6-minute walk test that you will complete twice in clinic during this study.

If you choose to participate in this study, you will be enrolled in a separate health data aggregating platform called Hugo Health that you can access on your mobile device or a computer that will gather together information (with your permission) from your online health records from your doctor's office, along with your responses to questionnaires from the researchers conducting this study and information about your activity/sleep from a Fitbit activity tracker that we will provide you. Hugo serves 2 purposes: 1) to gather together health-related data specific to this study to help researchers better understand physical function during cancer treatment; and 2) to provide a mechanism for you to collect all of your health data in one place even after you are no longer participating in this study.

A description of study procedures is listed below in chronological order:

Setup process for the Hugo data sharing platform and Fitbit:

1. Using your own mobile device or a laptop available through the research team, a study coordinator will help you register for the Hugo platform and, if you choose to, download the app. Registration for Hugo will require you to enter basic information including first name, last name, email address, and to choose a password. You will then be prompted to accept the standard terms and conditions as well as a privacy notice for the Hugo platform.
2. Using your personal mobile device (phone or tablet), you will check your email and click the confirmation link to activate your new Hugo account. If you are unable to access your email on your own mobile device, a laptop will be available for you to use. If you do not

have an email account and wish to create one, the study coordinator can help you set one up from a variety of free email providers.

3. Once your Hugo account is confirmed, the study coordinator will then walk you through the remaining steps to complete study enrollment in the Hugo platform.
4. The study coordinator will show you how to access and complete your enrollment questionnaire. You can choose whether this questionnaire will be sent to you through email or text message. The questionnaire is a multiple-choice survey in a web browser. The study coordinator will help you with any technical questions you may have when you begin the survey.
5. The study coordinator will then help you set up an account with Fitbit, including connecting the Fitbit to both your phone and the Hugo platform.
6. The Hugo platform will prompt you to link your patient portal accounts by presenting a list of participating health systems. You can select the systems where you have received care and enter your patient portal login and password. If you have forgotten your password, you can request a reset link be sent to your email account. The study coordinator can assist in setting up a new YNHH MyChart account, obtain your YNHH MyChart username, and help reset your YNHH MyChart password, if needed.
7. After your health records have been linked, the Hugo platform will display your health data. The study coordinator will help you with the study information and be available to answer any questions related to data sharing and any privacy concerns.
8. The study coordinator will help you set up accounts for other health systems if needed
9. You will be asked to agree to share data from Hugo with the researchers. The medical record data being shared may include medications, problems, procedures, encounters, lab results, diagnoses, vital signs, and possibly other data that become available. From the Fitbit, the data being shared may include movement (steps per-day), weight, and BMI.
10. If you have health insurance coverage through Medicare (available to those 65 years or older and younger people with disabilities and people with End Stage Renal Disease), the study coordinator will also help you connect to your Centers for Medicare and Medicaid Services (CMS) Blue Button account. Blue Button gives you access to your Medicare claims data. With your permission, Hugo can gather information from your claims data to provide information on health care you receive while participating in the study.
11. At the end of this consent form, we will ask you to give the researchers permission to see the health information and survey responses that you connect or provide to the Hugo platform.
12. During your baseline visit at the clinic, you will also be asked to fill out a series of short surveys. You will also be asked to complete the 6-minute walk test if you are present in-person. If not, then we will omit the 6-minute walk test at baseline. These are the same surveys and the same walk test you will complete at home at various intervals over the course of the study. The walk test is a simple test of physical performance, measuring a comfortable level of physical activity for you. You will be asked to walk at a normal pace for six minutes and we will measure the distance you travel.

Please note: Researchers will not be watching or evaluating your symptoms as part of this study, including your responses to the questionnaires. None of the information collected in this study will be shared with your medical team. If at any point you begin to experience new symptoms, or any medical issues arise, please contact your doctor. In case of a life-threatening emergency, call 911 immediately.

Continuous Study Process

After the initial in-office set up is complete, you will be asked to perform the following tasks at home. If you have any questions or experience technical issues at any time, please reach out to the study team via email at CERSI@yale.edu.

For all 9 months of this study, we ask that you wear your Fitbit as often as possible both during the day and while sleeping. We also ask that you turn on the Bluetooth feature on your phone or tablet at least once a week or as often as possible to allow your Fitbit to send data to your phone. A study coordinator will be able to help you set up this Bluetooth feature.

In addition to the Fitbit data, you will be asked to complete a set of surveys every week for the first 8 weeks of the study followed by monthly surveys for 7 months, and every month following that until the study ends, for a total of 9 months. The surveys will be part of the set you complete at your baseline appointment at the clinic, but you will not be asked to take every survey each time. We expect that it will take you no more than 45 minutes to complete your entire set of surveys for each timepoint. We will also ask you to repeat the 6-minute walk test in clinic with a study coordinator at Month 3. We estimate that your participation in the study, including completing the enrollment and set-up process, and answering the questionnaires should take you no more than 12 hours over the 9 months of the study.

What are the risks and discomforts of participating?

The primary risk is loss of confidentiality and privacy. The risk to your privacy is that the Hugo system collects personally identifiable information (like your name and where you go to the doctor) or protected health information (like the conditions you have and medications you take). The Hugo platform is not considered a "covered entity" under the Health Insurance Portability and Accountability Act of 1996 (HIPAA); this means that the HIPAA privacy rule does not apply to this platform. The Hugo platform does take all necessary precautions, including industry-standard encryption, to minimize privacy and security risks to your stored personally identifiable information. To learn more about Hugo's commitment to the security and privacy of your data, you can visit the following links: Security Statement (https://hugo.health/security), Privacy Notice (https://hugo.health/privacy-notice), Terms of Service (https://hugo.health/terms-of-service/).

While participating in this study, you will be asked to fill out multiple surveys, which will take some time and may be inconvenient. Some of the surveys may include sensitive questions that you feel uncomfortable answering. If you feel uncomfortable answering any specific survey question, you will be able to skip these questions and continue with the rest of the survey. You may also find it inconvenient to wear the provided Fitbit device or connect it to your phone or tablet.

How will I know about new risks or important information about the study?

We will tell you if we learn any new information that could change your mind about taking part in this study.

How can the study possibly benefit me?

A possible benefit of this study is, with the use of the Hugo platform, you will have easy access to your medical information collected by Yale-New Haven Health and outside health records if you choose to. Using the provided Fitbit, you may also gain additional awareness and information regarding your health and fitness.

How can the study possibly benefit other people?
The benefit to science and other people may include improving the assessment of physical function in cancer patients which may allow doctors to better counsel future patients on what to expect regarding their physical function during treatment.

Are there any costs to participation?
You will not have to pay for taking part in this study. However, there may be additional costs to you. These can include costs of transportation and your time to come to the study visits.

This study will not affect your health care costs in any way. You will still be responsible for any costs associated with any routine follow-ups or doctor visits, and there will be no additional follow-ups or doctor visits scheduled as part of this study. You will still be responsible for any co-pay required by your insurance company for standard treatments. You are also responsible for data charges that may be incurred for utilizing online features of Hugo or Fitbit when not connected to Wi-Fi.

Will I be paid for participation?
You will receive financial incentives to complete surveys and sync your Fitbit. A schedule of financial compensation will be provided to you. The total amount available to you is $150 over the duration of the study. After completing each round of surveys, the funds will be distributed to you via a payment card issued and accessible to you via your Hugo account. You are responsible for paying state, federal, or other taxes for the payments you receive for being in this study. Taxes are not withheld from your payments.

What are my choices if I decide not to take part in this study?
If you decide not to participate in this study, you will still have access to medical care and to your medical records as you would normally. You may decline to participate in the study for any reason without affecting your medical care.

What information will you collect about me in this study?
The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Electronic medical records from all health systems that you import into Hugo, including from Yale-New Haven Health System
- Medicare claims data that you import into Hugo using CMS Blue Button
- Electronic questionnaires that you respond to regarding your health
- Records about phone calls or emails made as part of this research
- Data collected from the provided Fitbit during the 9-month duration of the study

How will you keep my data safe and private?
Data transferred as part of this study will be sent using a secure, encrypted, and password-protected system. Identifiable information gathered for this study will be kept confidential and disclosed only with your permission. When the results of the research are published or

presented, no information will be included that would reveal your identity, unless your specific consent for this activity is obtained.

The data collected in your Hugo account, including data from any portals you connect and responses to any questionnaires you complete, will not be transferred back to your medical record. This means that your doctors will not see your responses to the study questionnaires or the information from your Fitbit.

Information about you and your health which might identify you may be used by or given to:

1. Representatives from Yale University, the Yale Human Research Protection Program and the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
2. The Principal Investigators, research staff, and collaborators at both Yale University and the Mayo Clinic, who are assisting with this study
3. Hugo Health, the company that owns the platform, in accordance with its Privacy Policy
4. The US Food and Drug Administration (FDA) authorities performing study audits will have access to your personal information. Audits are done to ensure the study is conducted safely and your rights are being protected
5. The U.S. Department of Health and Human Services (DHHS) agencies

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and, therefore, may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential. In addition, even though Hugo Health is not required to comply with HIPAA, they maintain the highest standards of confidentiality and security of your information and will never share your data beyond this study without your expressed explicit permission as described in their privacy notice provided when you sign up for Hugo.

This study is being conducted on behalf of the US Food and Drug Administration. Any personally identifiable information will be removed before data is shared with collaborators.

This authorization to use and disclose your de-identified health information collected during your participation in this study will never expire. There is no set time for destroying the information that will be collected for this study. Identifiers will be removed from the identifiable private information and after such removal, the information you contribute to this study could be used for future research or to help inform regulatory actions and can be distributed to another investigator for future research studies without additional informed consent from you or a legally authorized representative. Outside investigators will not know who you are. Private information such as your name, birth date or medical record number will not be shared with them.

☐ **By checking this box, I acknowledge my contribution to science and that my de-identified data collected as part of this study may be used in future research without further consent from me.**

How will you use and share my information?
We will use your information to conduct the study described in this consent form.

Information about you and your health which might identify you may be used by or given to:

1. Representatives from Yale University, the Yale Human Research Protection Program and the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
2. The Principal Investigators, research staff, and collaborators at both Yale University and the Mayo Clinic, who are assisting with this study
3. Hugo Health, the company that owns the platform, in accordance with its Privacy Policy
4. The US Food and Drug Administration (FDA) authorities performing study audits will have access to your personal information. Audits are done to ensure the study is conducted safely and your rights are being protected
5. The U.S. Department of Health and Human Services (DHHS) agencies

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Why must I sign this document?
By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?
The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff by phone or e-mail.

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to ensure the integrity of the study and/or study oversight.

What if I want to refuse or end participation before the study is over?
If you do become a study participant, you are free to withdraw from this study at any time during its course. To withdraw from the study, you can call your study coordinator to let them know that you would no longer like to take part. At this time the researcher can help walk you through how to stop receiving surveys from Hugo for this study.

When you withdraw from this study, no new health information identifying you will be gathered after that date. Information that has already been collected will be retained and used as noted above.

If you withdraw from this study, you will still have access to your Hugo account and your data sources will continue to sync with Hugo. The data will not be used for this study after the date you withdraw, but you can continue collecting your data within your Hugo account if you so choose. If you no longer wish for your data to be collected within Hugo, then you can disconnect your data sources within your account at any time. You can also cancel your Hugo account at any time and request that Hugo destroy all of your data. If you delete your Hugo account before your participation in this study ends, you will be automatically removed from the study.

Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors or with Yale-New Haven Health or the care that you receive.

What will happen with my data if I stop participating?
All data up to the date of withdrawal will be included in the study.

Who should I contact if I have questions?
Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator Cary Gross, MD at 203-737-7624 and research coordinator Sirad Hassan at 240-422-4943.

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

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.

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to participate in this study.

We will give you a copy of this form.

Participant Printed Name	Participant Signature	Date
Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

MAYO CLINIC

Name and Clinic Number
Protocol #: **Subject ID:** **Version #:** **Version Date:**

Approval Date: **January 12, 2022**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: The In4M Study: Integrating 4 Measures to Assess Physical Function in Cancer Patients

IRB#: 21-010404

Principal Investigator: Dr. Gita Thanarajasingam and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to help us understand how to measure the impact of treatment on patients' physical function who are undergoing chemotherapy.
What's Involved	In this study, we will use four different ways to study physical function – including information about your physical function from surveys from you, data about your physical function from a Fitbit wearable device, a physical function score assigned by your doctor, and results from a 6-minute walk test that you would complete twice in clinic during this study.

	You will be asked to connect your medical records to the Hugo Platform so the study investigators can review the data pertinent to your cancer care and tolerability of any cancer-related treatment. You will also be asked to complete multiple questionnaires related to your health and side effects of cancer-related treatments. Finally, we ask that you wear an activity tracking device, a Fitbit device, to measure your physical activity such as total steps and distance walked in a day and your heart rate.
Key Information	There are some risks from participating in this study. You may feel inconvenienced by filling out surveys and completing the in-person six-minute walk test. Additionally, wearing the Fitbit may be uncomfortable for you. The study may have many benefits to you. Knowledge gained from this study may help doctors to better counsel future patients on what to expect regarding their physical function on treatment. Additionally, through Hugo you will have access to your medical records across all the institutions where you receive care. Wearing the Fitbit may also give you additional useful information, information regarding your health and fitness. There are other choices available to you outside of this research. The alternative to participating in the proposed study is to not participate. Participation and non-participation will have no impact on the course of treatment that the patient will receive. Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

Contact Information

If you have questions about ...	You can contact ...
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Gita Thanarajasingam, M.D. Phone: (507) 266-4800 **Study Team Contact:** Lindsay Emanuel Phone: (507) 422-6300 **Institution Name and Address:** Mayo Clinic 200 First Street, SW Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Subject Advocate (RSA)** **(The RSA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:

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.

Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you have been diagnosed with breast cancer or lymphoma at Mayo Clinic and are planned to receive chemotherapy treatment. About 200 patients will take part in this research study. The plan is to have about 50 patients with newly diagnosed breast cancer, and 50 patients with newly diagnosed lymphoma, who will be starting chemotherapy treatments take part in this study at Mayo Clinic.

Why is this research study being done?

The purpose of this research study is to help us understand how to measure the impact of treatment on patients' physical function who are undergoing chemotherapy. Cancer doctors and researchers have traditionally focused on describing how well treatment works, and its side effects, but do not always focus on how patients will feel and function during treatment. Physical function – the ability to carry out day-to-day activities that require physical effort – is an important part of daily life.

Information you should know

Who is Funding the Study?
The U.S. Food and Drug Administration (FDA) if funding this study.

Information Regarding Conflict of Interest:
Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

It will take you about 9 months to complete this research study.

What will happen to you while you are in this research study?

In this study, we will use four different ways to study physical function – including information about your physical function from surveys completed by you, data about your physical function from a Fitbit wearable device, a physical function score assigned by your doctor, and results from a 6-minute walk test that you would complete twice in clinic during this study.

If you agree to be in the study, you will be asked to participate in the following:

Setup process for Hugo data sharing platform and Fitbit:

1. Using your own mobile device (phone or tablet), or a laptop available through the research team, a study coordinator will help you register for the Hugo platform and, if you choose to, download the app to your own mobile device. Registration for Hugo will require you to enter basic information including first name, last name, email address, and to choose a password. You will then be prompted to accept the standard terms and conditions as well as a privacy notice for the Hugo platform.
2. Using your personal mobile device, you will check your email and click the confirmation link to activate your new Hugo account. If you are unable to access your email on your own mobile device, a laptop will be available for you to use. If you do not have an email account and wish to create one, the study coordinator can help you set one up from a variety of free email providers.
3. Once your Hugo account is confirmed, the study coordinator will then walk you through the remaining steps to complete study enrollment in the Hugo platform.
4. The study coordinator will show you how to access and complete your enrollment questionnaire. You can choose whether this questionnaire will be sent to you through email or text message. The questionnaire is a multiple-choice survey in a web browser. The study coordinator will help you with any technical questions you may have when you begin the survey.
5. The study coordinator will then help you set up an account with Fitbit, including connecting the Fitbit to both your phone and the Hugo platform.

6. The Hugo platform will prompt you to link your patient portal accounts by presenting a list of participating health systems. You can select the systems where you have received care and enter your patient portal login and password. If you have forgotten your password, you can request a reset link be sent to your email account. The study coordinator can assist in setting up a new Mayo Clinic Patient Portal account, obtain your Mayo Clinic Patient Portal username, and help reset your password, if needed.
7. After your health records have been linked, the Hugo platform will display your health data. The study coordinator will help you with the study information and be available to answer any questions related to data sharing and any privacy concerns.
8. The study coordinator will help you set up accounts for other health systems if needed
9. You will be asked to agree to share data from Hugo with the researchers. The medical record data being shared may include medications, problems, procedures, encounters, lab results, diagnoses, vital signs, and possibly other data that become available. From the Fitbit, the data being shared may include movement (steps per-day), weight, and BMI
10. If you have health insurance coverage through Medicare (available to those 65 years or older and younger people with disabilities and people with End Stage Renal Disease), the study coordinator will also help you connect to your Centers for Medicare and Medicaid Services (CMS) Blue Button account. Blue Button gives you access to your Medicare claims data. With your permission, Hugo can gather information from your claims data to provide information on health care you receive while participating in the study.
11. At the end of this consent form, we will ask you to give the researchers permission to see the health information and survey responses that you connect or provide to the Hugo platform.
12. During your baseline visit at the clinic, you will also be asked to fill out a series of short surveys. These are the same surveys and the same walk test you will complete at home at various intervals over the course of the study. You will also be asked to complete the 6-minute walk test. The walk test is a simple test of physical performance, measuring a comfortable level of physical activity for you. You will be asked to walk at a normal pace for six minutes and we will measure the distance you travel.

Continuous Study Process

After the initial in-office set up is complete, you will be asked to perform the following tasks at home. If you have any questions or experience technical issues at any time, please reach out to the study team via email at rstnestcersi@mayo.edu.

1. For all 9 months of this study, we ask that you wear your Fitbit as often as possible both during the day and while sleeping. We also ask that you turn on the Bluetooth feature on your phone or tablet at least once a week or as often as possible to allow your Fitbit to send data to your phone. A study coordinator will be able to help you set up this Bluetooth feature.

2. In addition to the Fitbit data, for this study you will be asked to complete a set of surveys every week for the first 2 months of the study followed by monthly surveys for 7 months for a total of 9 months. The surveys will be taken from the set you complete at your baseline appointment at the clinic, but you will not be asked to take every survey each time. We expect that it will take you no more than 45 minutes to complete your entire set of surveys for the each timepoint. We also will ask you to repeat the 6-minute walk test at in clinic with a research coordinator at Month 3. We estimate that your participation in the study, including completing the enrollment and set-up process, and answering the questionnaires should take you no more than 12 hours over the 9 months of the study

Please note:
Tests done only for research purposes are not meant to provide clinical information or help care for you. The study team members will not be watching or evaluating your symptoms as part of this study, including your responses to the questionnaires. Your answers to these questions are important for research but they are not monitored in real-time. The information collected in this study will **not** be shared with your clinical care team. If you have any concerning symptoms, questions about your cancer care, or any medical issues arise, please contact your clinical care team. In case of a life-threatening emergency, call 911 immediately.

What are the possible risks or discomforts from being in this research study?

The primary risk is this study is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

The risk to your privacy is that the Hugo system collects personally identifiable information (like your name and where you go to the doctor) or protected health information (like the conditions you have and medications you take). The Hugo platform is not considered a "covered entity" under the Health Insurance Portability and Accountability Act of 1996 (HIPAA); this means that the HIPAA privacy rule does not apply to this platform. The Hugo platform does take all necessary precautions, including industry-standard encryption, to minimize privacy and security risks to your stored personally identifiable information. To learn more about Hugo's commitment to the security and privacy of your data, you can visit the following links: Security Statement (https://hugo.health/security), Privacy Notice (https://hugo.health/privacy-notice), Terms of Service (https://hugo.health/terms-of-service/).

While participating in this study, you will be asked to fill out multiple surveys, which will take some time and may be inconvenient. Some of the surveys may include sensitive questions that you may feel uncomfortable answering. If you feel uncomfortable answering any specific survey question, you will be able to skip these questions and continue with the rest of the survey. You may also find it inconvenient to wear the provided Fitbit device or connect it to your phone or tablet.

Are there reasons you might leave this research study early?

You may decide to leave the study at any time. You should tell the Principal Investigator if you decide to stop, and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- If it is in your best interest,
- If you don't follow the study procedures,
- If the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

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

A possible benefit of this study is, with the use of the Hugo platform, you will have easy access to your medical information collected by Mayo Clinic and outside health records if you choose to. Using the provided Fitbit, you may also gain additional awareness and information regarding your health and fitness.

The benefit to science and other people may include improving the assessment of physical function in cancer patients which may allow doctors to better counsel future patients on what to expect regarding their physical function.

What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study If you decide not to participate in this study, you will still have access to medical care and to your medical records as you would normally. You may decline to participate in the study for any reason and at any time without affecting your medical care.

What tests or procedures will you need to pay for if you take part in this research study?

You will not have to pay for taking part in this study. However, there may be additional costs to you. These can include costs of transportation and your time to come to the study visits.

This study will not affect your health care costs in any way. You will still be responsible for any costs associated with any routine follow-ups or doctor visits, and there will be no additional follow-ups or doctor visits scheduled as part of this study. You will still be responsible for any co-pay required by your insurance company for standard treatments. You are also responsible for data charges that may be incurred for utilizing online features of Hugo or Fitbit when not connected to Wi-Fi.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

For your time and commitment to this study you will be eligible to receive fifteen payments. In order to receive these payments, we ask that you respond to all the surveys sent to you across all 9 months of this study. Once the enrollment survey is complete you will receive $10 and a Fitbit. On Weeks 2, 3, 5-8 and Months 4, 5, 7 and 8 you will receive $5. On Week 4 and Months 3 and 6 you will receive $20. Month 9 you will receive $30. In sum, you will receive a maximum total of $150 for your time for completing all study surveys.

For your participation in this study, you will receive payments sent through Tremendous to the e-mail address that was provided when setting up your Hugo account. Payments will come via a pre-paid Visa card sent to your email as a digital e-card. As surveys are completed, the balance will be automatically credited to your account which is linked to your email address. You will receive payments for completed surveys and syncing your FitBit. When these payments are ready, you will receive an email with instructions on how to receive your payment. You may redeem your payments at any time once you have an available balance.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). Accounts Payable at Mayo Clinic will be given your name, address and Social Security number in order to issue a check for your study participation. If you receive research payments totaling $600 or more in a calendar year, a tax Form 1099 will be sent to you. For Mayo Clinic employees, research payments are included in your paycheck with applicable taxes withheld and reported on your Form W2 after calendar year-end.

This study will not affect your health care costs in any way. You will still be responsible for any costs associated with any routine follow-ups or doctor visits, and there will be no additional follow-ups or doctor visits scheduled as part of this study. You will still be responsible for any co-pay required by your insurance company for standard treatments.

You are also responsible for data charges that may be incurred for utilizing online features of Hugo or Fitbit when not connected to Wi-Fi.

Will your information or samples be used for future research?

Identifiable information such as your name, Mayo Clinic number, or date of birth may be removed from your information or samples collected in this study, allowing the information or samples to be used for future research or shared with other researchers without your additional informed consent.

The specific information about you and your health that we will collect, use, and share includes:

- Electronic medical records from all health systems that you import into Hugo, including from Mayo Clinic
- Medicare claims data that you import into Hugo using CMS Blue Button
- Records collected from any pharmacies that you connect and import into Hugo
- Mobile questionnaires that you respond to regarding your health
- Records about phone calls or emails made as part of this research
- Data collected from the provided Fitbit during the 9-month duration of the study

Data will be maintained on secure, encrypted servers at Mayo Clinic for five years after the end of the study. At the end of the five years, data will be archived in secure storage at Mayo Clinic similar to clinical trial and other prospectively collected data.

De-identified data will be shared and stored at the FDA indefinitely for sharing both with internal investigators as well as external researchers. Your direct identifiers will be removed from your private information after such removal; the information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent

I acknowledge my contribution to science and that my de-identified data collected as part of this study may be used in future research or for regulatory purposes without further consent from me.

☐ Yes ☐ No Please initial here: _____ Date: _____

You will always have access to your health data in the Hugo platform should you choose. You will be given access to updates of the Hugo platform.

The data collected in your Hugo account, including data from any portals you connect and responses to any questionnaires you complete will not be transferred back to your medical record. This means that your doctors will not see your responses to the study questionnaires or the information from your Fitbit. This data will be shared with the study team, which will include our collaborators from Yale New Haven. This identifiable data will be viewable to our collaborators from Yale New Haven to allow for monitoring and compliance reasons. This data will not be shared outside of this group.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

Data transferred as part of this study will be sent using a secure, encrypted, and password-protected system. Identifiable information gathered for this study will be kept confidential and disclosed only with your permission.

The data collected in your Hugo account, including data from any portals you connect and responses to any questionnaires you complete, will not be transferred back to your medical record. This means that your doctors will not see your responses to the study questionnaires or the information from your Fitbit.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, 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. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Researchers involved in this study at other institutions. For the purposes of auditing the conduct of the study, the sponsor, The Food and Drug Administration and/or designee, may inspect any part of your personal information collected as part of this study. Individuals contracted to audit the study on behalf of the FDA, may access your personal information collected as part of this study, including the information shared with the research team from your Hugo account. Audits are done to ensure the study is being run well and that patient consent is collected and documented in an appropriate manner. These individuals are all obligated to maintain confidentiality by the nature of their work or are bound by confidentiality agreements.
- Hugo Health, the company that owns the platform, in accordance with its Privacy Policy.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?
Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts forever, unless you cancel it.

There is no expiration or end date related to the Sponsor's use of your health information received from Mayo Clinic as part of this study.

Enrollment and Permission Signatures

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

	/ /	: AM/PM
Printed Name	Date	Time

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

	/ /	: AM/PM
Printed Name	Date	Time

Signature