Appendix C: Informed Consent and HIPAA Authorization

UNIVERSITY OF PENNSYLVANIA
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:
A feasibility trial using remote patient-reported outcomes and wearable technology-reported step data to compare engagement, utilization, and functional status in patients with incurable lung and gastrointestinal cancers

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Why am I being asked to volunteer?
You are being invited to participate in a research study. Your participation in this study is voluntary, which means that you can choose whether or not to be in the study. Before you can make your decision, you will need to know the study’s purpose, your role in the study, and possible risks and benefits from participating. The following sections will explain the study in detail. After reviewing this information, you will see an option to select whether or not you would like to participate in the study. If you choose to participate and are enrolled, you may withdraw from the study at any time.

What is the purpose of the study?
The purpose of the study is to learn more about self-reporting of symptoms via mobile phone among patients receiving treatment for lung and gastrointestinal (GI) cancers.

How long will I be in the study?
The study will last for 6 months.

What am I being asked to do?
• During the enrollment process, you will be asked to fill out a brief questionnaire, which should take 2-3 minutes to complete.
• If you meet necessary requirements for the study, you will be asked to fill out a short questionnaire at the start of the study, and again at 3 and 6 months. This should take less than 5 minutes to complete each time and be conducted via text message.
• You may be asked to wear a Fitbit device throughout the study period that can track steps, distance, active minutes, sleep, and heart rate data.
• Finally, you may be asked to use your mobile phone to report information about specific symptoms you may be experiencing. A weekly text message will prompt you to fill out a short
electronic symptom survey by mobile phone, which should take only a few minutes to complete. This information will be transmitted to your electronic medical record and made available for your care team to use to help manage your symptoms; all other information collected as part of the study will be kept confidential.

What are the possible risks or discomforts?
The risks of participation are expected to be minimal. There is a minor risk of loss of confidentiality and privacy. The research team will take every necessary precaution to make sure your confidentiality and privacy are maintained. Information from the weekly mobile-phone based symptom surveys will be transmitted to the electronic medical record and thus made available to your clinical team; all other information will be kept confidential. Your personal information will be used only by study team members, who have been trained to use secure protocols to maintain the privacy of your data. We will use commercial-grade encryption to protect your information similar to that which is used to protect electronic health records. Whenever possible, data will be de-identified to protect your privacy.

Also, it is important to realize that self-reporting your symptoms via mobile phone as part of the study is NOT a replacement for usual means of communication with your doctor. If you are having symptoms that you think need urgent medical attention, you will need to contact your doctor directly.

What if new information becomes available about the study?
During the course of the study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available. You will always have the right to change your mind about participating in the study.

What are the possible benefits of the study?
Weekly self-reporting of symptoms via mobile phone may improve communication with your doctor and may help your doctor manage your symptoms over time. However, this intervention is experimental and thus its benefits are uncertain. You may not get any direct benefit from being in this research study.

What other choices do I have if I do not participate?
Your alternative to participating in the study is not to participate in the study. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled.

Will I be paid for being in the study?
Yes, there is a compensation of up to $50 in the form of a $25 payment after completing your questionnaires at 3 and 6 months after enrollment. If you are randomized into an intervention arm, you will also be permitted to keep your Fitbit device at the end of the trial.

Will I have to pay for anything?
There is no cost for you to participate in the study. However, you will receive weekly communications via text message, and standard text message charges may apply.

Can I leave the study before it ends?
Yes, participation in the study is voluntary. You can decide to stop participating at any time and for any reason. If you choose to leave the study, we will not delete information we have already collected from
you, but we will stop collecting any new information and will stop contacting you. To stop participating in the study, please contact the study staff.

**How will my personal information be protected?**
We will do our best to make sure that the personal information we collect about you is kept private and secure. Your personal information will only be given out if necessary (e.g., if required by law to prevent possible injury to you or others).

Your information will be kept in a secured, password-protected file at the University of Pennsylvania. Your information will be transmitted and stored using very secure systems. The network servers where your data are stored sit behind firewalls that do not allow unauthorized access and are physically located in a secure server room that can only be accessed by critical staff members. The investigator and staff involved with the study will keep your personal information collected for the study strictly confidential. All of these personnel will have completed research and confidentiality training.

Please refer to information below that explains more specifically how your personal information will be used:

- Way to Health (W2H) study and data storage portal supported by the Penn Medicine Academic Computing Services (PMACS) infrastructure
- Twilio Cloud Communications (to send you text messages)
- The Office of Human Research Protections at the University of Pennsylvania
- Federal and state agencies (for example, the Department of Health and Human Services, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes.
- Lens is used by W2H to enable data visualization. Lens is built on an open-source offering called Metabase. This offering is fully hosted within PMACS environment and follow the same guidelines and privacy / encryption procedures and policies described above.

Once your personal information is disclosed to others outside the University of Pennsylvania, it may no longer be covered by federal privacy protection regulations. You can review the privacy policies of these companies here:


**What information about me may be collected, used or shared with others?**
During enrollment, you will be asked to report your name, telephone number, and date of birth, as well as background information such as gender, race, education and income level. Additional information about your medical history, including details about your cancer diagnosis and its treatment, will be collected from your electronic medical record by the study team. Finally, data will be collected during the study regarding your symptoms, quality of life and care utilization.

**Why is my information being used?**
Your information will be used by the research team to contact you during the study. Your information and results of surveys are used: a) to do the research, b) to oversee the research, c) to see if the research was done right, and d) to evaluate and manage research functions.

**Who may use and share information about me?**
Your information will be used by authorized members of the University of Pennsylvania study team. The following individuals may use or share your information for this research study:

- The investigator for the study and the study team
- Other authorized personnel at Penn, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of the School of Medicine, might receive my information?
If required by law and/or necessary for oversight purposes, your information may be shared with federal and state agencies (for example, the Department of Health and Human Services, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies. Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations. The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?
Your authorization for use of your personal health information for this specific study does not expire. Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania’s Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?
Yes. You may withdraw or take away your permission to use and disclose your information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study. Any information collected before your withdraw from the study may be used by the study team for research purposes.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to participate in this research study.

Who can I contact with other questions about the study?
If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling 215-898-2614.

You will be provided a copy of this Informed Consent and HIPAA Authorization Form describing your confidentiality and privacy rights for this study. By clicking the button stating that you want to participate in the study and signing your name below, you will have consented to enroll. This means you are permitting the School of Medicine to use and disclose personal health information collected about you for the research purposes as described above.
CONSENT
This consent form will be saved electronically and a copy will be provided to you for your records.

Please select your choice and then click the NEXT button on the right to continue.

- [ ] I want to participate
- [ ] I do NOT want to participate

Name: __________________________ Signature: __________________________ Date: __________