CEDARS-SINAI MEDICAL CENTER

CONSENT FORM FOR RESEARCH

Title: PANCREATIC-ENZYME REPLACEMENT THERAPY WITH PANCREAZE (PANCRELIPASE) DELAYED-RELEASE IN ADDITION TO STANDARD OF CARE FOR BORDERLINE RESECTABLE, LOCALLY ADVANCED , AND ADVANCED PANCREATIC ADENOCARCINOMA PATIENTS (PANCAX-3) WITH CACHEXIA AND EXOCRINE PANCREATIC INSUFFICIENCY

STUDY SUPPORT PROVIDED BY: VIVUS

PRINCIPAL INVESTIGATOR: ANDREW HENDIFAR, MD

STUDY CONTACT PHONE NUMBER AT CSMC: 310-423-2217

AFTER HOURS CONTACT (24 HOURS): 310-423-2217

This research study is funded by Vivus. Vivus only reimburses Cedars-Sinai Medical Center for the costs associated with running the study; Vivus is not providing additional compensation to Cedars-Sinai Medical Center or the Principal Investigator for their participation in the study.

1. WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

We are doing this study to examine the effects of Pancreaze (pancrelipase) Delayed-Release Capsules, which is a standard of care pancreatic-enzyme replacement therapy, on patients diagnosed with advanced pancreatic cancer. We want to know whether adding Pancreaze capsules as supplements to meals and snacks will improve weight stability, functional changes, and quality of life, in addition to standard of care treatment for pancreatic cancer patients.

You are being asked to take part in this research study because:

- You have a diagnosis of borderline resectable, locally advanced, or advanced pancreatic cancer; and
- You have exocrine pancreatic insufficiency and cachexia (weight loss) over a period of 6 months.

The study will enroll up to 40 people in total.

Pancreaze is approved by the U.S. Food and Drug Administration (FDA) for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions. We are doing this study to learn more information about how Pancreaze works in patients with both exocrine pancreatic insufficiency and pancreatic cancer.

2. WHAT WILL HAPPEN DURING THE STUDY?

This section provides a general overview of what will happen during your participation in this study. Information included below should be considered along with the flowchart of procedures attached as an Appendix.

The flowchart shows a timeline for research-related or standard of care procedures that are involved in your participation in this study. **Research-related procedures** are those performed solely for the research. They would not be performed if you did not take part in the study. **Standard of care (routine)** procedures would be performed both as part of this study and if you do not participate in this study.

A table describing common medical procedures done solely for the purposes of monitoring and assessing your condition during this study is attached as an Appendix to the end of this consent form. Standard of care procedures that will be repeated or done at greater frequency are listed in the flow chart Appendix.

Overview of study:

If you choose to participate in this study, you will undergo the following:

- Standard of care treatment with Pancreaze (pancrelipase) capsules per each main meal and snack, daily for a total of 24 weeks. (Treatment may continue per standard of care after 24 weeks). You will record the doses you take in a daily log for the study.
- Complete questionnaires about your quality of life, taste and smell assessments, bowel habits, and a 24-hour food diary, as well as an assessment of hand grip and walking speed, every other treatment cycle (approximately every two months)
- Provide blood and stool samples for research purposes every other treatment cycle (approximately every two months).
- Provide blood samples for clinical assessments at Baseline, Day 1 of every treatment cycle, and at the End of Study Visit (30 days after treatment ends).
- In addition, you will wear a wrist-worn wearable biosensor (FitBit) to monitor your physical activity starting on Day 1 until the end of the treatment period (approximately 24 weeks). You may keep or return the wearable activity monitor at the End-of-Study Visit. You may choose to consent to continued data collection during the study follow-up period as an optional sub-study (described in detail in Appendix C).
- After completion of the study, study staff will review your medical record and/or call you every 6 months for 36 months to see how you are doing.

In order to properly follow the study's protocol (research plan), all participants will receive treatments and procedures that have been pre-determined by the protocol. In effect, the protocol describes which medications or procedures you will receive, rather than those decisions being made by your personal doctor or based on your preference. There may be options available outside of this study that you will not be able to receive while participating in this study. We do not believe you should be at any increased risk due to this limitation.

Fitbit Charge HR or a similar model: The biosensor being used in this study may include the FitBit Charge HR or a similar model, an activity monitor that you wear on your wrist. The Fitbit records real-time data relating to movement, altitude, heart rate, and sleep quality and transmits that to the study

team when you synch the Fitbit with your Smart phone. The study team will teach you how to sync your Fitbit with your smartphone as well as how to charge its battery.

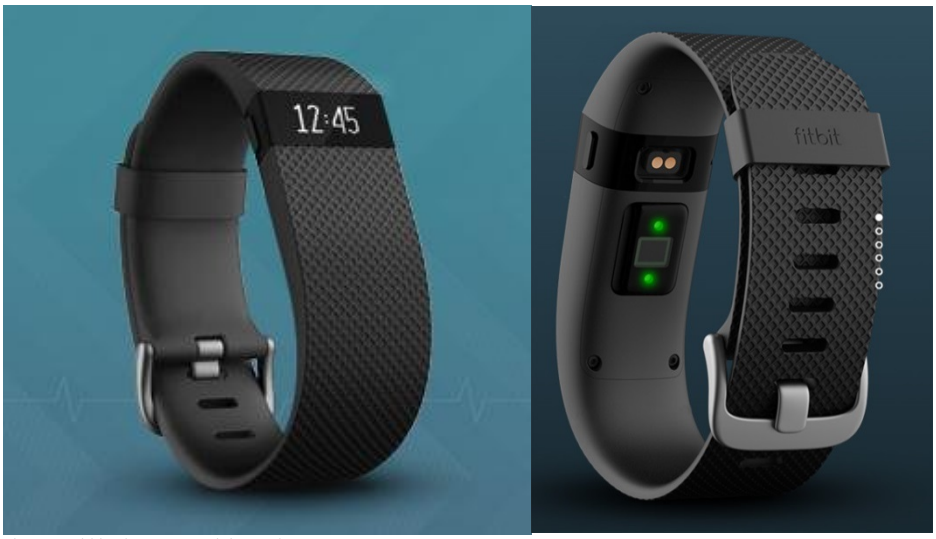

Figure 1: Fitbit Charge HR activity tracker

Another purpose of this study is for researchers to analyze biomarkers from your blood, to provide insight into how Pancreaze works in your body. A biomarker is a biological molecule found in blood, other body fluids, or tissues that may be a sign of a condition or disease. Approximately 15-30 cc (3 – 6 teaspoons) of blood will be drawn for the biomarker test. The researchers do not know if using the biomarker test is better, the same, or worse than if you did not have the biomarker testing done.

Screening and Enrolment	→	**Treatment and Data Collection** Approximately 24 weeks - Physical exam, blood/stool collection, 24-hr food recall, taste and smell alteration, questionnaire, and grip and walking speed, fitness tracking	→	**End of Study** 30 days after study treatment period ends - Physical exam, blood/stool collection, 24-hr food recall, taste and smell alteration, questionnaire, hand grip and walking speed, fitness tracking	→	**Follow-up** Every 6 months for 36 months - Physical exam, weight measurement, fitness tracking (optional), medical record review and/or telephone call

Optional Sub-study
Details of optional sub-studies are described in an Appendix to this consent form. You are not required to participate in the sub-studies in order to take part in this research study.

How long will you be in the study?
We think you will be in this study for/until about 6 months from screening to the end of treatment, and then will be followed for 36 months after treatment ends to collect data about your well-being. The total time includes up to 4 weeks for screening, 6 months of treatment (which may continue after this

24-week period per standard of care), an End-of-Treatment visit where you will return the research pill bottles, and an End-of-Study evaluation which will take place 30 days after your last treatment. You may continue to receive Pancreaze for longer than this treatment period at the discretion of your doctor, without additional research procedures. After that, the study team will review your medical records and/or contact you by phone every 6 months for up to 36 months to see how you are doing. Keeping in touch with you and checking on your condition every so often helps us look at long-term effects.

3. WHAT ARE THE POSSIBLE RISKS?

Risks of common medical procedures performed solely for research purposes are described in a table attached to the end of this consent form as an Appendix D. Side effects and risks of standard of care procedures are not described in this consent form.

This section describes the possible risks and/or discomforts we anticipate you could experience that are related to the study procedures.

Risks of Questionnaires:
If you feel uncomfortable or embarrassed answering any question, you may skip it. The questionnaire will be labeled with a unique study number that will link your identity so that only the study team can recognize you.

Research blood sample collection:
Blood drawing may cause some pain and has a small risk of bleeding, bruising, or infection at the puncture site. There is also a small risk of fainting.

Biosensor (Fitbit):
The biosensor (Fitbit) will collect real-time data about your activity levels. For the current study, we are using the Fitbit Charge HR or similar model. Fitbit Inc. is the manufacturer of this wearable biosensor. The company routinely collects data from all users that are useful to improving their products and user experience. They clearly define on their website what data they will collect, and state they will not sell user data. For the purpose of this study, aside from birthdate (used to calculate heart rate) there will be no personal identifiers provided to the manufacturer. The Principal Investigator will use a subject code and study-specific email address instead of your name and actual email address to register the device and to access the data from the manufacturer's data storage.

To learn more about the privacy and safety policies from the manufacturer of the Fitbit, please visit http://www.fitbit.com/privacy for the privacy policy in full.

Every reasonable effort will be made to protect your data. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic storage, there is a risk of breach of data security. See the section, "Will my Information be Kept Confidential?" for more information.

Possible Risk of Allergic Reaction:
According to the manufacturer's website, people who have had allergic reactions to any wearable device or jewelry should consult with their doctor before wearing a new device. Symptoms of any

allergic reaction can include a rash, hives, itching, and/or difficulty breathing, closing of the throat, swelling of the lips, tongue or face, and rarely death. If you experience any difficulty breathing, closing of the throat, swelling of the lips, tongue or face, or hives, you should stop wearing your study biosensor and immediately seek emergency medical attention

Reproductive and Lactation Risks
Taking part in this research study can affect an unborn baby. Therefore, you should not become pregnant or father a baby while on this study. If you or your partner is capable of becoming pregnant you will need to use birth control. Check with the researcher about approved birth control methods to use while participating in this study.

Women should not breastfeed a baby while on this study.

Unknown Risks to the Developing Embryo or Fetus (an unborn baby)
If you are pregnant, or become pregnant during participation in this research, the study drug might involve risks to an embryo or fetus, which are currently unknown. It is important that you contact the researcher immediately if you believe you might be pregnant.

Risks of Discontinuation of Current Medication
In order to participate in this research study, you will be advised to stop taking any fat-soluble vitamin supplements for your condition. This may result in a worsening of your condition. Your doctor will take every precaution to ensure that the appropriate treatment will be given to you.

Follow-up Visit for Discontinuing Participants
While you are free to discontinue your participation at any time, we encourage you to complete a Final Study Visit. During this visit, we will conduct tests to collect safety data, and discuss any information that may be important to share with your treating physician.

4. ARE THERE BENEFITS IN TAKING PART IN THE STUDY?

You should not expect to benefit from taking part in this research study.

We hope the information learned from this research study will benefit other individuals with pancreatic cancer in the future by helping us to learn about the effects of Pancreaze in addition to standard of care for patients who have pancreatic cancer.

5. WILL I BE INFORMED OF RESEARCH RESULTS?

Some of the research tests done in this study follow standard clinical procedures and are performed in certified clinical labs. These test results may be shared with you and may be placed in your Cedars-Sinai medical record. Other research tests done in this study are for research purposes only and are performed in a research only lab where the results are not intended for clinical use. These research-only results will not be shared with you or included in your Cedars-Sinai medical record.

Unanticipated Incidental Findings
If, unexpectedly, we find that results of your research procedures could suggest important medical information and we determine there is something you or your doctors can do in response to this finding, we will contact you using the last contact information provided by you. If necessary, we may recommend additional clinical testing to confirm the research finding. The cost of any additional testing and any related treatment will be your responsibility.

6. WHY WOULD MY PARTICIPATION BE STOPPED?

Your participation in this study may be stopped at any time by the researcher or the sponsor without your consent for any reason, including:

- The study is stopped or suspended;
- Funding for the study is reduced, stopped or withdrawn;
- If it is in your best interest;
- You do not consent to continue in the study after being told of changes in the research that may affect you;
- You do not follow the study procedures;
- You experience toxicity that make your continuation in this study unsafe;
- You become pregnant;
- You cannot be located to document survival after a period of 2 years (lost to follow-up).

You may choose (or you may be required) to withdraw from certain parts of the study, but invited to continue with other parts. For example, you might stop taking a study drug, but continue with follow-up visits or allow us to continue to collect data from your medical records. Separate written consent will be requested if your continued participation will involve procedures not described in this consent form.

7. ARE THERE ANY OTHER OPTIONS?

Your participation is voluntary, so you have the right to decline to participate or to withdraw from this research study at any time without any penalty or loss of benefits to which you would be entitled outside of the study. Choosing not to participate will not affect the care you receive at Cedars-Sinai Health System.

If you decide not to take part in this study, you have other choices. For example:

- you may choose to be treated following the usual clinical approach, such as being prescribed Pancreaze without taking part in the study.
- you may choose to take part in a different study at CSMC or elsewhere, if one is available
- you could decide not to be treated.
- you may choose to pursue supportive or palliative care for your condition. Such care is focused on reducing suffering and improving the quality of life of individuals with chronic or life-threatening illnesses. The primary intent of palliative care is not to cure a disease or to prolong life. Palliative therapy is focused primarily on managing symptoms.

The researcher will discuss these options and their risks and benefits with you.

8. WILL MY INFORMATION BE KEPT CONFIDENTIAL?

We will do our best to make sure that the personal information collected as part of this study is kept private. However, we cannot guarantee total privacy. A copy of your research consent and authorization forms may be filed in your electronic medical record at CSMC. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other identifiable personal information will not be used. Organizations that may look at and/or copy your medical records for research oversight, quality assurance, and data analysis include: accrediting agencies, government and regulatory groups (such as Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), etc.), safety monitors, companies that sponsor the study, and authorized representatives of the sponsor.

Attached to this consent form is an "Authorization Form" that outlines with whom your information may be shared for the purposes of this research and under what circumstances.

We might share your information and/or research samples collected in this study with other researchers at Cedars-Sinai, other academic institutions, or third party commercial entities for future research without additional informed consent from you. Information that identifies you will be removed and will not be shared with other researchers or anyone outside of Cedars-Sinai.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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 Website at any time.

9. WHAT IF I BECOME ILL OR INJURED BECAUSE OF TAKING PART IN THIS STUDY?

Contact your study doctor at once if you feel that you are ill or have been injured because of taking part in this study. If it is a medical emergency, call 911 or go to an emergency room. Promptly notify your study doctor of your situation at the phone number listed on page 1 of this consent form.

Who pays for my research related illness or injury?
A research-related injury or illness is a direct result of either the Study Drug or a procedure performed only as a part of this study and that is not part of your standard clinical medical treatment. Injury or illness related to your underlying medical condition or caused by non-research-related activities (such as treatment generally provided outside of the study) would not be considered research-related. If you are being treated for a research-related injury or illness, you will not pay for the costs of your appropriate medical or emergency room care. CSMC and the sponsor have no plans to pay for losses such as lost wages or pain and suffering. You do not waive any of your legal rights by signing this form.

10. FINANCIAL CONSIDERATIONS

Costs of Participation

Please review the attached Appendix flowchart for a listing of items, drugs and services that will be billed to you and/or your insurance and those that will be covered by the study sponsor.

Only items, drugs and services that are reasonable and necessary for your medical care throughout the study will be billed to your insurance. You remain responsible for all deductibles, co-pays, and balances under your health benefit plan. If your insurance company does not pay, you will be billed for those charges. You should check with your health benefit plan if you have questions or concerns about your insurance coverage.

Compensation for Participating

You will not be paid for taking part in this research study.

Financial Interest in the Research

The PI and institution have no potential financial conflict of interest with respect to this study.

11. WHAT IF I HAVE QUESTIONS OR PROBLEMS?

Please contact the investigator listed on the first page of this form for questions or concerns about the research.

If you have questions, problems, or concerns that you want to discuss with someone who is not associated with this study, or want to offer suggestions or feedback, please contact:

Cedars-Sinai Human Research Protection Program (HRPP)
Phone: (310) 423-3783
Email: ResearchConcerns@cshs.org

The Cedars-Sinai HRPP has been established to protect the rights and welfare of research participants. You may also contact the Cedars-Sinai HRPP if you want to offer input or obtain information regarding the study.

12. CONSENT PROVISIONS

If you sign this form below, it means that:

(1) You have taken the time to carefully read and understand the information presented in this informed consent form; you should discuss it with others, and if appropriate seek a second opinion to make an informed decision;
(2) The information concerning the research study and its involved procedures has been fully explained to you and your questions have been answered to your satisfaction;

(3) You have received and understand all of the information you desire regarding your participation in the research study;
(4) You have considered the potential risks, any anticipated benefits and alternatives (and their relative risks and benefits) of participation;
(5) You are voluntarily agreeing to participate in this research study;
(6) You understand that by consenting to participate in the research, you are not giving up any of your legal rights;
(7) You understand that you have the right to be informed of significant new findings related to this research study which may affect your willingness to continue participating in this study; and
(8) You have been provided with a copy of the "Experimental Subject's Bill of Rights", if applicable to this research study, and have been provided with an opportunity to ask questions regarding the Bill of Rights.

We will give you a copy of this signed and dated consent form**,** and the Experimental Subject's Bill of Rights.

SIGNATURE PAGE

Consent Form for Research and
Authorization for Use and Disclosure of Identifiable Health Information (Research)

SIGNATURE BY THE PARTICIPANT

Main Research Study: *I hereby agree to participate in the research study described to me during the informed consent process and described in this informed consent form.* ***You will be given a signed copy of this form.***

Name of Participant (Print)	Signature	Date Signed

Applicable for Optional Follow-Up Activity Tracker Sub-study: *I hereby agree to participate in the optional sub-study described to me during the informed consent process and described in the attached Appendix to this form.*

Name of Participant (Print)	Signature	Date Signed

Authorization for Use and Disclosure of Identifiable Health Information (Research): *I hereby agree that my identifiable health information may be used and/or disclosed in accordance with this "Authorization for Use and Disclosure of Identifiable Health Information (Research)" form attached as Appendix to this form.*

Name of Participant (Print)	Signature	Date Signed

Applicable for Optional Follow-Up Activity Tracker Sub-study: *I hereby agree that my identifiable health information may be used and/or disclosed for the optional sub-study described to me during the informed consent process and described in the attached Appendix to this form:*

Name of Participant (Print)	Signature	Date Signed

SIGNATURE BY THE INVESTIGATOR: *I attest that all the elements of informed consent described in this form have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.*

Name of Investigator (Print)	Signature	Date Signed

SIGNATURE BY THE INTERPRETER/WITNESS

(Signature of an interpreter is only required when a non-English speaking subject is consented with the assistance of an interpreter and an IRB-approved 'short form.' The witness may be any person who is conversant in both English and the language of the Non-English speaking subject, such as the interpreter (the certified hospital interpreter), study staff, a family member, or other person. The witness signs the consent forms to confirm that the oral interpretation occurred.)

Name of Witness (Print)	Signature	Date Signed

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APPENDIX: EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

In accordance with California Health and Safety Code 24172, any person who is required to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks to the subject reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

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AUTHORIZATION FOR USE AND DISCLOSURE OF IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH

- **USE AND DISCLOSURE OF HEALTH INFORMATION**

If you agree to this Authorization, you give permission to the Sponsor, Principal Investigator, other investigators and their research team described in the Consent Form for Research ("Research Team") to use or disclose your identifiable health information ("private information") for the research study titled "Pancreatic-enzyme replacement therapy with pancreaze (pancrelipase) delayed-release in addition to standard of care for borderline resectable, locally advanced, and advanced pancreatic adenocarcinoma patients (PANCAX-3) with cachexia and exocrine pancreatic insufficiency." which is described in the Consent Form for Research ("Consent Form") to which this Authorization is attached. In particular, you authorize the research team acting under the direction of the Principal Investigator to review your medical records and collect your private information from the following sources:

- ☒ Laboratory tests
- ☒ Pathology reports
- ☒ Imaging reports (e.g., x-rays or scans)
- ☐ Photographs or videos of your image
- ☒ Doctor/clinic records
- ☒ Hospital/medical records
- ☐ Mental health records
- ☐ Billing records
- ☒ Other tests or other types of medical information: FitBit activity tracker data, study questionnaires

- **WHO WILL HAVE ACCESS TO YOUR PRIVATE INFORMATION?**

Your private information will be used by and/or shared with the Research Team.

In addition to the research team, if applicable, the following parties may receive your private information and inspect your records:

- The reviewing Institutional Review Boards and Cedars-Sinai offices with authority to oversee research compliance.
- U.S. government agencies, such as the Food and Drug Administration and the Department of Health and Human Services.
- Researchers at other organizations who are participating in this research study.

- The Study Sponsor, its business partners, and Cedars-Sinai's business partners for matters related to research study oversight, data analysis and use of research results in product development, and payment or reimbursement.
- Representatives from regulatory agencies in other countries may join in the review of your research records, including research-related medical reports and information, with the Sponsor and/or the FDA.

Cedars-Sinai is required by law to protect your private information. However, the recipients described above may re-disclose (or share) your information with other parties unless such sharing is prohibited by law.

- **WHEN WILL MY AUTHORIZATION EXPIRE?**

By signing this document, you authorize the use and sharing of your private information until the end of the research study and any related optional sub-study you choose to participate in.

- **REVOKING AUTHORIZATION**

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, the research team may still use or disclose private information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to the Principal Investigator of the research study by writing to the Office of Research Compliance and Quality Improvement, 6500 Wilshire Blvd, Suite 1800, Los Angeles, Calif. 90048 and/or emailing to ResearchConcerns@cshs.org.

- **NOTICE OF RIGHTS AND OTHER INFORMATION**

You do not have to agree to this Authorization, but if you do not agree, you may not participate in the research study. The Research Team may not condition (withhold or refuse) treating you on whether you agree to this Authorization.

If you agree to this Authorization, please sign on the appropriate signature line on the Signature Page. You will receive a copy of this Authorization.

- **OPTIONAL SUB-STUDY**

In addition to the main research study, you have the option to agree to participate in one or more optional sub-studies as explained to you during the informed consent process. Your decision to take part in the optional sub-study(ies) does not impact your ability to participate in the main research study.

If you agree that your identifiable health information may be used and/or disclosed for the optional sub-study described in the informed consent process and above, you will be required to sign a second time in the signature section.

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APPENDIX : OPTIONAL SUB-STUDY – FOLLOW-UP ACTIVITY TRACKER USE

INTRODUCTION

This Appendix is provided to you as a supplement to the main study consent form. In addition to the main study, you are also invited to take part in this optional sub-study. **You do not have to agree to this optional sub-study to be in the main study. Your medical care at Cedars-Sinai Medical Center (CSMC) will not be changed in any way as a result of your decision.**

Before you make a decision, please read the rest of this Appendix and ask the researchers any questions to help you understand the sub-study.

This Appendix will be given with the study consent form. If you agree to participate in the optional sub-study, then you will be asked to sign separate sub-study signature lines in the main consent form.

A. PURPOSE OF THIS OPTIONAL SUB-STUDY

We are interested in collecting data on your daily activity, including step counts, stairs, sleep, heart rate, and active minutes, for 36 months after your end-of-study visit. We want to know if the study treatment increases daily activity on a long-term basis.

B. STUDY PROCEDURES INVOLVED IN THIS OPTIONAL SUB-STUDY

This section provides a summary of the procedures in this optional sub-study.

If you agree to participate in this optional sub-study, you will continue wearing the Fitbit through the follow-up period. You will be reminded via phone call or email to wear the Fitbit (biosensor) continuously for at least 7 days prior to each follow-up contact, which occurs every 6 months.

C. LENGTH OF THIS OPTIONAL SUB-STUDY

We think you will be in the optional sub-study for about 36 months. This involves the Fitbit during follow-up for at least 7 days every 6 months for 36 months.

D. POSSIBLE RISKS OR DISCOMFORTS OF THIS OPTIONAL SUB-STUDY

This section describes the possible risks and/or discomforts we anticipate you could experience that are related to the study procedures.

Risks related to FitBit use are described in the main consent form, including potential breach of your data and possible risk of allergic reaction. The main additional risk of participating in this optional sub-study is continued potential risk of breach of your data. Every reasonable effort will be made to protect your data. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic storage, there is a risk of breach of data security.

E. BENEFITS OF THIS OPTIONAL SUB-STUDY

You should not expect to benefit from taking part in this optional sub-study.

While no benefit is ever guaranteed, we hope the information learned from this optional sub-study will help us understand the long-term effects of the treatment for your condition, and ultimately benefit patients with pancreatic cancer in the future.

F. PAYMENT

You will not be paid for participating in this optional sub-study.

APPENDIX: Detailed Description of Common Medical Procedures Performed for Research Purposes and Associated Risks

The procedures listed below are often performed as part of routine care for a person with your condition. They are being repeated or performed more frequently as part of this research. However, the risks associated with each procedure should be comparable to what you would experience even if you were undergoing the procedure outside this research study.

Study Procedure	Related Risks
Blood draw: A needle is placed in the vein in your arm to draw blood	Blood drawing may cause some pain and has a small risk of bleeding, bruising, or infection at the puncture site. There is also a small risk of fainting.
Fasting: You will be asked to fast before study visits. You should not eat or snack for 8 hours before your study appointment. Take medications with water according to your normal schedule. You may drink water, but do not drink any other liquids during the fasting hours.	Occasionally people experience symptoms of low blood sugar while fasting, such as headache, dizziness, faintness, nausea, vomiting and blurred vision. If you have symptoms of low blood sugar while fasting: 1. Immediately drink a glass of juice and eat some food. 2. You may proceed with your study appointment as scheduled. The study coordinator will record what you ate or drank for your research records.
Concomitant Medications: You will be asked about your previous and current medications that you take.	There are no physical risks associated with these procedures.
15 ft Walk Test: A timed walk-test from first foot fall to last foot fall over 15 feet will be performed twice per assessment.	There is a rare possibility of fainting, while you perform the 15 ft walk test. Please note that all medical procedures will be done in the presence of the study Investigator and research team in order to minimize the occurrence of such untoward events.
Hand Grip Test: Three assessments for each hand using the hand-held dynamometer (a device for measuring your grip strength) will be completed and recorded.	There are no risks associated with this procedure.
Stool Collection: You will be provided with a stool sample collection kit including instructions for obtaining the sample and returning it to the study site.	No risks associated with this procedure.
Questionnaires: You will be asked to complete several questionnaires. We will ask you questions to evaluate your quality of life, dietary intake, taste and smell alteration, and bowel movements. We think it should take about an hour to complete the questionnaires. Questionnaires will ask you to respond to questions about your quality of life, daily activities, food intake, taste and smell functioning, physical/social/family/emotional/functional well-being, and bowel movements.	If you feel uncomfortable or embarrassed answering any question, you may skip it. The questionnaire will contain your name or other direct identifier.
Demographic Information: You will be asked about your age, gender, race, and ethnicity.	There are no physical risks associated with these procedures.