CONSENT FORM FOR RESEARCH

Study title: A Supervised Prehabilitation Program for Patients with Pancreatic Cancer

Study support provided by: Internal CSMC Funding

Cedars-Sinai Principal Investigator: Philip Chang, DO

Study contact phone number at Cedars-Sinai: 310-467-4498

1. Key Information

We are asking for your consent to take part in this research study. This section provides key information about the study. The rest of this form has more detailed information.

- **Voluntary:** Taking part in this research study is your choice. You can also stop taking part at any time. You will not lose any services, benefits or rights you would normally have if you chose not to take part or stop taking part.

- **Purpose:** The purpose of this study is to assess the use of an exercise program in people with pancreatic cancer. We will be monitoring attendance to exercise sessions as well as impacts on healthcare utilization, muscle mass, quality of life, physical activity, and post-operative outcomes when applicable.

- **Procedures:** The main things that will happen in this study are: you will participate in a supervised, in-person exercise program 3 times per week for 6 weeks in a Cedars-Sinai gym facility (250N. Robertson Blvd, Beverly Hills). You will also receive a Fitbit to be worn continuously during the study and to complete surveys and exercise tests at specified timepoints.

- **Duration:** Taking part in this study will last about 6 months.

- **Risks:** All research studies involve some risks. Risks or discomforts from this study may be: discomfort or fatigue while participating in exercise and risk of fall during exercise or assessments.

- **Benefits:** The possible benefits of taking part in this study are improved energy levels, maintenance of muscle mass, improved quality of life, improved bone health, improved mood, improved sleep, and improved physical function.

- **Alternatives:** You can choose not to take part. There may be other choices for you.

Please take time to read this entire form. You should ask questions before deciding whether to take part in this study. You can talk with family, friends and/or healthcare providers before you decide.

During the study, we may find out new information about this research study. We will tell you about any important changes or new findings that may impact whether you want to continue taking part in the study.

2. Purpose of the Study

We are doing this study to see the effects of a prehabilitation exercise program in people with pancreatic cancer. Prehabilitation, or exercise prior to undergoing surgery or while concurrently undergoing treatment for cancer, has been shown to have beneficial effects for patients with cancer. In this study, we would like to see if patients are regularly able to participate in an exercise program and see the impact on healthcare utilization, muscle mass, quality of life, physical activity, sleep and post-operative outcomes when applicable.

You are being asked to take part in this research study because you have recently been diagnosed with pancreatic cancer and have been cleared to participate in this exercise program by a physician.

The study will include up to 16 people in total.

3. Study Procedures

This section talks about what will happen in this study.

When you read this section, also read the flowchart of procedures. The flowchart is given with this consent form. The flowchart of procedures shows a timeline of the study. It shows which study procedures are research-related and which are standard of care (routine).

Research-related procedures are procedures done only for the research study. They would not be performed for your routine care outside of the study. **Standard of care (routine) procedures** would be performed as part of your routine care even if you did not take part in this study.

The procedures in this study are often part of routine care for a person with your condition. They are not experimental procedures. The procedures and their risks are research related.

This means they are being done only for research purposes. These common procedures and their risks should be the same as when performed outside this study.

Description of research procedures:
As a participant of this study, you will undergo a 6-week PREHAB exercise program.
In addition to this program, you will have three research study visits.

- **Visit 1: Baseline Visit**: Before starting the PREHAB exercise program, you will have a baseline visit to assess your baseline physical function.

- **Visit 2: Post-Intervention Visit**: Following the 6-week program you will have a post intervention visit to assess your physical function following the exercise program. This visit may take place on the same day as your last PREHAB session.

- **Visit 3: 3-Month Follow Up Visit**: You will also come back 3 months after the end of your program to assess your physical function.

At the baseline visit we will give you a Fitbit to wear for the entirety of the study. You will be asked to complete questionnaires at each of these visits.
The research team will also review your standard of care blood test results and your CT scans to make sure you are healthy enough to continue in the PREHAB exercise program.

- **Physical Exercise:** The exercise program will include 3 in-person supervised exercise sessions per week for 6 weeks. Sessions will be 1 hour in length and will be held at the Cedars-Sinai gym at 250N. Robertson Blvd, Beverly Hills with a qualified exercise physiologist or personal trainer. Each session will start with a 5-minute warm-up period on a stationary bike followed by 15-minutes of cycling at a brisk rate. This biking session will be followed by six different resistance exercises including chest press, lateral pull downs, shoulder press, squats, leg press and leg extensions. Following these exercises there will be a 10-minute cool down period on the stationary bike.

Gym at 250 N Robertson

Pictures of some of the exercise that will be included in the PREHAB program

Pictures sourced from (www.hep2go.com)

- **Questionnaires:** You will be asked to complete a questionnaire. We will ask you questions to find out how you are feeling in regard to physical symptoms, your ability to complete everyday tasks, and how you feel the program is helping you. We think it should take about 10-15 minutes to complete the questionnaire.

- **Physical Exam:** We will measure your height, weight and calculate your BMI.

- **Demographic Information:** We will ask you about demographics, which may include your age, gender identity, race and ethnicity.

- **Medical History Review:** We will ask you about your medical and surgical history. We will also ask about your physical activity.

- **CT Scan:** A CT machine takes pictures of organs and structures in the body. It does this using radiation. These scans are a part of your routine care, and we will use your routine images to assess your muscle mass.

- **Six-Minute Walk Test (6MWT):** We will ask you to walk for 6 minutes. Study personnel will observe you before, during and after the 6-minute walk. Your heart rate and blood pressure may be taken before and after the test. We will measure the distance you walk during the 6 minutes. The entire test will take less than 30 minutes.

- **Hand Grip Strength:** We will measure your hand grip strength using a special measurement device called a dynamometer.

- **Physical Performance Metrics:** We will test your sense of balance by seeing how well you can stand on soft and firm surfaces. We will also test your strength by seeing how many repetitions you can do of various exercises.

- **Short Performance Physical Battery:** We will assess your overall functional ability through this test which consists of balance tests, assessing your walking speed, and assessing your ability to stand up from a sitting position.

- **Continuous Monitoring of Physical Activity and Sleep:** You will be asked to wear a Fitbit on your wrist continuously for the duration of the study observation period, beginning at your Baseline visit through to your 3 Month Follow Up visit. The Fitbit records real-time data relating to movement, altitude, heart rate, and sleep. Data from your Fitbit device are synced with the Fitbit App on your Smartphone or tablet. Only you and designated members of the study team have access to your Fitbit data, which is password protected. The study team will teach you how to sync your Fitbit as well as how to charge its battery.

At the end of study participation, your study account will be disconnected from the Fitbit platform, and you can keep it for personal use. No members of the study team will have access to your data or information upon disconnection of the study account.

How long will you be in the study?
We think you will be in this study for about 6 months. This will include a 4-week screening period, 6 weeks of exercise sessions, and a follow up 3 months after finishing the exercise program.

4. Possible Risks and Discomforts of the Research Procedures

This section talks about the possible risks and/or discomforts of the study procedures.

- **Physical Exercise:** Performing in these exercises may cause you to feel tired or out of breath. For some people, it may induce nausea and there may be a small risk of falling or possibly fainting during exercise.

- **Questionnaires:** Some questions may make you feel uncomfortable or embarrassed. The questionnaire will be labeled with a unique study number. This will link your identity so that only the research team can recognize you.

- **Physical Exam:** This does not have any physical risks.

- **Demographic Information:** This does not have any physical risks.

- **Medical History Review:** This does not have any physical risks.

- **CT Scan:** A CT machine uses radiation to take pictures of the inside of your body. Cumulative radiation exposure over time can increase the risk of cancer. We will not be obtaining any additional CT scans beyond what you will already be getting for your routine care. Some people may be uncomfortable laying down on the flat surface while the images are being taken.

- **Six-Minute Walk Test (6MWT):** You may feel tired or get out of breath. There is a rare chance of fainting while you do the 6-Minute Walk Test.

- **Hand Grip Strength:** Applying your strongest pressure during measurement may cause some discomfort in the hands.

- **Physical Performance Metrics:** Performing these metrics may cause fatigue or shortness of breath, there may also be a small risk of falling.

- **Short Performance Physical Battery:** Performing these metrics may cause fatigue or shortness of breath, there may also be a small risk of falling.

- **Continuous Monitoring of Physical Activity and Sleep:** The Fitbit will collect real-time data about your activity levels. FitBit Inc. is the manufacturer of this wearable biosensor. 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.

  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. The Fitbit account will be disconnected from the device and no further data will be synced or stored in the Fitbit dashboard after study completion or discontinuation. In order to protect your confidentiality, study staff do not recommend inputting other identifiable information into your Fitbit account, such as your first and last name. If you choose to disclose additional identifiable information, your information may not be protected. See the section, "How will my Private Information be Kept Confidential?" for more information.

  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.

  Possible Risk of Skin Irritation:
  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. Patients may experience an allergic reaction to the Fitbit. 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.

  Other possible skin irritations from the Fitbit include:
    - Bruising
    - Rash
    - Discomfort
    - Burning sensation

  These should be reported to the study team as soon as possible.

5. Benefits From Taking Part in the Study

Taking part in this research study may or may not have direct medical benefit to you. The possible benefits of taking part in the research study are improved energy levels, maintenance of muscle mass, improved quality of life, improved bone health, improved mood, improved sleep, and improved physical function. No benefit is guaranteed. It is possible that your condition may stay the same or even get worse.
We hope the information learned from this research study will be used to create other research studies that may improve quality of life and decrease healthcare utilization for people with cancer.

6. Reasons Participation May Be Stopped

Your participation in this study may be stopped at any time. The researcher or the sponsor can stop your participation without your consent for any reason. Some reasons for stopping your participation include:

- The study is stopped or suspended.
- Funding for the study is reduced, stopped or withdrawn.
- It is in your best interest.
- You do not follow the study procedures.

7. Choosing to Take Part and Other Options

Taking part in research is voluntary. You have the right to choose not to take part. You can stop taking part in this research study at any time. You can do this without any penalty or loss of benefits to which you would be entitled outside of the study. Your choice not to take part or to stop taking part will not affect the care you get at Cedars-Sinai.

If you decide to stop taking part, we will keep any data collected on you up to the time you choose to stop. Also, if you stop taking part, the study team may ask you whether you want to give further data from your routine medical care.

8. Confidentiality Protections

We will do our best to keep your personal information collected as part of this study private. But we cannot guarantee total privacy. We may put a copy of your research consent and authorization forms in your electronic medical record at Cedars-Sinai. Your personal information may be given out if required by law. Publications or presentations about this study at scientific meetings will not use your name and other identifiable personal information.

Organizations that may look at and/or copy your medical records for research oversight, quality assurance and data analysis include:

- Accrediting agencies (agencies that grant official certifications to educational institutions)
- Government and regulatory groups, such as the Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP)
- The Institutional Review Board (IRB), which reviews research to protect people taking part in studies
- Safety monitors, which monitor the safety of individual participants and the overall safety of the study
- Companies that sponsor the study and authorized representatives of the sponsor

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

We might share your information and/or research samples collected in this study. It might be shared 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.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

9. Research-Related Illness or Injury

We do not expect you will have any illness or injury from this research study. If you believe that you are ill or have been injured from this study, please contact the study team at the phone number listed on page 1 of this consent form.

10. Financial Considerations

Costs of Participation
You and your insurance company will not be charged for your participation in this research study.

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

Financial Interest in the Research
The principal investigator and institution have no potential financial conflict of interest with this study.

11. Contact for Questions or Problems

Please contact the investigator for questions, problems or concerns about the research. Their contact information is on page 1 of this form.

You might have feedback, questions, problems, concerns or want to obtain more information about this study. If so, you can talk with someone who is not part of this study by contacting:

Cedars-Sinai Human Research Protection Program (HRPP)
Phone: 310-423-3783
Email: ResearchConcerns@cshs.org
Website: cedars-sinai.org/research/administration/office-of-research-compliance/review-board.html

The Cedars-Sinai HRPP protects the rights and welfare of research participants.

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.

AUTHORIZATION FOR USE AND DISCLOSURE OF IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH

1. 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 "A Supervised Prehabilitation Program for Patients with Pancreatic Cancer" 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

☒ Demographics, which may include age, gender identity, race, ethnicity, and/or sexual orientation

☒ Other tests or other types of medical information: Questionnaires

2. 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, conduct of the research, data analysis, 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 takes steps to protect your private information when sharing it with the recipients described above. Though these steps and applicable law are meant to protect your private information, there is a risk that a recipient could share your private information without your permission.

3. 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.

4. 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.

5. 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. Cedars-Sinai may not condition (withhold or refuse) the provision of standard of care treatment for 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.

Flowchart of Visits, Tests and Procedures

Legend
R = Research item/procedure done only for research purposes and their costs are covered by the study. You are not responsible for the costs of these procedures.
S = Standard of care item/procedure that is part of regular care and billed to the patient/insurance. You and your insurance company will be responsible for these costs.

Procedures	Screening	Visit 1: Baseline Visit	Week 1-Week 6[1]	Visit 2: Post-Intervention Visit	Visit 3: 3-Month Follow Up Visit
Informed Consent	R				
Confirm Eligibility	R				
Medical History	R				
Demographics	R				
Pregnancy status[2]	R				
Godin Leisure-Time Exercise Questionnaire	R				
Physical Activity Readiness Questionnaire (PAR-Q)	R				
Physical Activity Assessment	R				
Vitals (Height, Weight, BMI)[3]		S		S	S
Six Minute Walk Test		R		R	R
Hand Grip Strength		R		R	R
Physical Performance Metrics		R		R	R
Short Performance Physical Battery		R		R	R
Unanticipated Problem review		R		R	R
Patient-Reported Outcomes Measurement Information System (PROMIS-29) Questionnaire		R		R	R
Patient-Reported Outcomes Measurement Information System (PROMIS) Cancer Function Questionnaire		R		R	R
Data Review from Standard of Care (SOC) CT Scan[4]		R			R
SOC Lab Test Review		R	R[5]	R	R
Fitbit activity monitoring[6]		R	R	R	R
Dietitian referral[7]		R			
Online Pain platform[8] Training		R			

Online Pain platform use[8]			R		
Online Pain platform compliance			R[9]		
3 x Weekly 1HR PREHAB session			R		
Patient Global Impression of Change[10]				R	
Healthcare Utilization Assessment					R

Footnotes:

1. Up to 3 missed sessions will be made up in a 7th week
2. Pregnancy status confirmed with patient and via medical record review
3. Height will only be collected at Baseline
4. CT scans completed closest to baseline and 3-month follow-up will be used, even if they occurred outside of the relevant visit window.
5. SOC labs will be reviewed prior to each PREHAB session
6. Fitbit use is only required by those who met eligibility criteria 4.1.9 and do not meet exclusion criteria 4.2.3.
7. Only patients not previously referred to a Dietitian will be referred by the study team
8. Online Pain platform training and use is only required for those who met eligibility criteria 4.1.9 (First 8 participants only)
9. Online Pain platform compliance will be self-reported every 2 weeks (First 8 participants only)
10. Only completed by the participants who used the Online Pain Portal

Signature Page

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

If you agree to take part in this study, you should sign and date on the signature lines below. You will be given a signed and dated copy of this form. This includes the "Experimental Subject's Bill of Rights," "Authorization for Use and Disclosure of Identifiable Health Information (Research)" and any optional sub-study descriptions, when applicable.

Signature by the Participant
Main Research Study: *I agree to take part in the research study described to me during the informed consent process and described in this informed consent form. My questions have been answered to my satisfaction.*

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

Participant name (please print)	Signature	Date

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 the "Authorization for Use and Disclosure of Identifiable Health Information (Research)."*

Participant name (please print)	Signature	Date

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.

Investigator name (please print)	Signature	Date

Interpreter/Witness
(Signature of an interpreter is only required when enrolling a non-English-speaking subject with the assistance of an interpreter and IRB-approved "short form" consent processes. The

witness may be any person who is conversant in both English and the language of the non-English-speaking subject, such as a certified hospital interpreter, study staff, a family member or other person. The witness signs the consent forms to confirm that the oral interpretation occurred.

Signature of a witness is required when an English-speaking subject who has been determined to have capacity to consent is unable to read or physically sign the consent form but chooses to indicate via a "mark" or verbally that he/she agrees to participate. The witness signs the consent form to confirm that an oral consent process occurred and that the individual verbally consented to participate in the research.)

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Interpreter/Witness name (please print) Signature Date of signature