STANFORD CONSENT FORM
For MINIMAL RISK Medical Human Subject Research

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FOR QUESTIONS ABOUT THE STUDY, CONTACT: Jessy Jia Song

DESCRIPTION: You are invited to participate in a research study on a voice-based symptom and recovery check-in app ("Ossyn") for adult outpatients after allogeneic hematopoietic cell transplant (allo-HCT). The purpose of this research is to understand whether daily voice check-ins are feasible and helpful for capturing between-visit health updates and generating organized summaries and insights of symptoms and concerns.

You will be asked to enroll in the Ossyn app and provide at least one update each day for 30 days. Your updates may include symptoms or side effects, home-measured vitals (e.g., temperature), medication updates, activity level, and questions you want to remember for your care team.

The app will record your voice notes, create a transcript, and generate structured fields and brief summaries from what you report. Study staff may contact you for brief check-ins to support app use and collect feedback. Audio recordings will be stored for up to 30 days and then deleted according to the study procedures; transcripts and structured data may be retained for research analysis and reporting in accordance with institutional requirements.

This research study is looking for up to 20 patients to be enrolled. Enrollment will occur at Stanford only. Stanford University expects to enroll all the research study participants.

You give consent for your audio recordings to be used for the purposes of this research study, including creating transcripts and generating structured summaries of your reported symptoms and concerns, and for study quality review by authorized study staff.

Your audio recordings will be stored for up to *30 days* and then deleted; study results may be presented or published, but your identity will not be included.

Please initial your choice: ___Yes ___No

<u>Future use of Private Information and/or Specimens</u>

This study does **not** involve collecting any biological specimens.

The study data you provide include private information such as symptom updates, transcripts, and structured summaries.

Identifiers might be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

RISKS AND BENEFITS:

The risks associated with this study are primarily related to confidentiality. Because the study involves collecting identifiable health information and voice recordings, there is a small risk of unintended disclosure or unauthorized access despite reasonable safeguards. Some participants may also find daily logging mildly inconvenient or uncomfortable; you may contact the study staff to stop at any time.

The benefits which may reasonably be expected to result from this study are that you may find it helpful to keep track of symptoms and questions over time and to organize information you want to share with your care team. The study may also help improve future outpatient monitoring tools. We cannot and do not guarantee or promise that you will receive any benefits from this study. Your decision whether or not to participate in this study will not affect your medical care.

TIME INVOLVEMENT: Your participation in this experiment will take approximately **30 days**, with **at least one brief daily check-in**. Daily entries are expected to take about **1–3 minutes per day**, plus optional brief study team check-ins (if needed) and an optional end-of-study interview (about **10–20 minutes**).

PAYMENTS:
You will not be paid to participate in this research study.

REIMBURSEMENTS:
Participants will not be reimbursed for expenses related to participation in this study. Participation does not require additional travel beyond routine clinical care.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed**.**

You have the right to refuse to answer particular questions.

Authorization To Use Your Personal Health Information For Research Purposes

Information about you and your health is personal and private. We need your permission to use and share it for this study. If you sign this form, it will provide that permission. The form tells you how your health information will be used or shared for the study. Please read it carefully before signing it.

What information will be used for this study?

We will include and use the information below in our research records:

- Demographic information like
    - name
    - age and birthdate
    - race and ethnicity
    - gender and sex
    - contact information (phone number, address, email)
- Audio recordings
- Relevant information from your medical record like
    - medical history and diagnoses
    - current and past medications or treatments

- Information from all tests and procedures that will be done for this study

Who may use, share, or receive my information?

The research records may be used and shared with others who are working with us on this research. This includes:

- Members of the research team and those at Stanford University who are performing their jobs to support research
- Others at Stanford who oversee the research
- Your health care team or organization who may receive it for treatment purposes
- Others who are required by law to review the quality and safety of the research, including but not limited to:

    - State, federal, and international government agencies or committees, such as the Food and Drug Administration or the Office for Human Research Protections
    - The study sponsor and/or their representatives

- Researchers and/or those responsible for research with whom collaboration may be required (e.g. other hospitals or academic centers)

If we share your information with groups outside of Stanford University, they may not be required to follow the same federal privacy laws. They may also share your information with others not described in this form.

Do I have to sign this permission form?
You do not have to sign this permission form. You can still receive medical care at a Stanford Medicine affiliated organization if you don’t sign this form. If you do not sign this form, you will not be able to participate in this research study.

If I sign, can I change my mind later?
You can cancel your permission at any time. If you change your mind, we will not collect new information from you for the study and you will be withdrawn from the study. But we can continue to use information we have already collected and started to use in our research, to maintain the integrity of the research.

If you wish to cancel your permission, you must write a letter or email to the Protocol Director using the contact information provided in this form.

When will my permission expire?
Your permission to use and share your health information will end when the research and all required study monitoring is over.

Will access to my information in my Stanford medical record be limited during the study?
You have a right to use information about you to make decisions about your health care. However, your information from this research will not be available during the study. It will be available after the study is finished.

___________________________________ ______________

Signature of Adult Participant Date

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Print Name of Adult Participant

WITHDRAWAL FROM STUDY:

You may stop participating in this study at any time by contacting the study team or by stopping use of the Ossyn app. The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- If you are unable to follow study procedures (for example, you stop using the app or do not complete required study activities).
- If the Protocol Director determines that continued participation is not in your best interest (for example, if participation becomes burdensome or raises safety or privacy concerns).
- If the study is cancelled, paused, or closed.
- For other administrative reasons or unanticipated circumstances.

If you withdraw, the study team will stop collecting new information from you. Data collected up to the point of withdrawal may still be used for research analysis, consistent with the consent form and institutional requirements.

CONTACT INFORMATION:

If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Jessy Jia Song at 415-688-0886. You should also contact them at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at 650-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB at irbeducation@stanford.edu.

EXPERIMENTAL SUBJECTS BILL OF RIGHTS: As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- 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.

May we contact you about future studies that may be of interest to you?
____ Yes ____ No

The extra copy of this signed and dated consent form is for you to keep.

______________________________ ________________
Signature of Adult Participant Date

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Print Name of Adult Participant