

Protocol Title: Gaining foundational knowledge of stakeholders' perceptions and concerns about LLM-mediated conversational agents to improve informed consent.

DF/HCC Principal Investigator(s) / Institution(s):

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INTRODUCTION AND KEY INFORMATION

For purposes of this research, you will be referred to as a "participant."

1. Why am I being invited to take part in a research study?

You are invited to take part in this research study because you expressed interest in learning more about our study.

Mass General Brigham and Dana-Farber Cancer Institute are conducting a research project to explore how artificial intelligence (AI) chatbots may be used as a part of informed consent for clinical trials, with a goal of making clinical trial information clearer and more informative for patients.

We are inviting adult cancer patients who are ≥ 18 years old, current or prior cancer diagnosis, English-speaking, and able to provide informed consent)

2. Why is this research being done?

The purpose of this study is to understand stakeholders' experiences, perceptions, and concerns about using AI chatbots to explain cancer clinical trial consent information. The results will help researchers design chatbot tools that are accurate, trustworthy, and useful for patients and trial staff.

3. Who is supporting this research?

The Principal Investigators of this study and PIs' home institution - Brigham and Women's Hospital and Dana-Farber Cancer Institute - are initiating and taking responsibility for the research project. This research is funded by a research award from the Patient-Centered Outcomes Research Institute.

4. What does this research study involve and how long will it last?

This research study involves taking part in a one-time, virtual focus group discussion using the HIPAA-compliant Dana-Farber Cancer Institute Zoom platform. The whole session will last about 60 to 90 minutes.

During the session, you will:

- *Hear a short introduction to the study and the discussion guidelines.*
- *Share your experiences and opinions about clinical trial recruitment and informed consent*
- *View and discuss an example of an artificial intelligence (AI) chatbot that could be used to explain trial consent information*

The session will be audio-recorded so that we can review the discussion in detail. Your name will not appear in any transcripts or reports.

5. What are the risks to participating in this study?

This is a minimal risk study. This means that the risks involved in participating are no greater than those you encounter in daily life.

Possible risks include:

- A small risk to your privacy and confidentiality if personal information is accidentally disclosed
- Possible emotional discomfort when talking about your experiences with cancer or clinical trials

We will take steps to reduce these risks, such as using first names only during the session, removing identifying details from transcripts, and storing recordings securely so that only the study team can access them

6. Will being in this study benefit me in any way?

There is no direct benefit to you from participating. Your feedback may help improve how clinical trial information is communicated so that patients can make more informed decisions about their care, which could benefit future cancer patients and research teams.

7. What are my options?

Instead of being in this research study, you have other options which may include the following:

- Decide not to participate in this research study.
- Withdraw from the study at any time, without penalty and without affecting your care.

8. Do I have to take part in this research?

All research is voluntary. It is your choice whether you take part in this research or not. If you decide to participate, please sign and date at the end of this form. We will give you a copy and you can refer to this information sheet at any time.

If you choose not to participate, are not eligible to participate, or withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

We encourage you to take some time to think this over, to discuss it with other people and your primary doctor, and to ask questions at any time.

9. Who should I contact if I have questions about this research?

If you have any questions about the study, you may contact the Principal Investigator, Dr. Danielle Bitterman at 617-278-0165 or bwhtrialchatbotstudy@mgb.org.