INTEGRATING CHAT GPT IN ANESTHESIA

Implementation of Large Language Models in Anesthesia to Answer Patient's Questions During Pre-Anesthesia Visits: A Prospective, Observational Study

CLINICAL RESEARCH PROTOCOL

v.1.0:03-Oct-2024

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Document History

Version	Version Date	Changes

Protocol Synopsis

Study Title:	Implementation of Large Language Models in Anesthesia to Answer Patient's Questions During Pre-Anesthesia Visits: A Prospective, Observational Study
Protocol Short Title:	Integrating ChatGPT in Anesthesia
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Verbal Consent in Minimal Risk Research

For additional information on a verbal consenting process, please see the **Guidance on Verbal Consenting Process for Minimal Risk Studies** document posted on the OHSN-REB website.

Verbal consent is acceptable in certain minimal risk research. TCPS 2 defines "minimal risk" research as research *"in which the probability and magnitude of possible harms implied by participation in the research are no greater than those encountered by participants in those aspects of their everyday life that relate to the research."*

What is verbal consent?

Verbal consent means a participant states their consent to participate orally but does not sign any written form.

Verbal consent is generally obtained over the phone, and it is not generally acceptable to use when obtaining consent in person. Consent over the phone may be considered when the study is minimal risk and it is the only feasible method of obtaining consent from participants (e.g., completing surveys/questionnaires over the phone). Under particular circumstances, verbal consent may be obtained in person, subject to approval by the REB.

Verbal consent involves reading an REB approved Verbal Consent Script (which includes all elements of consent) or an REB approved Informed Consent Form to the participant. The participant's verbal consent to participate is then documented in writing in Epic and/or the study file by the person obtaining consent.

A witness is generally not required for a verbal consenting process for minimal risk studies; however, under discretion of the REB, a witness may be required.

My minimal risk study is going to use verbal consent; what documents do I need to submit to the REB?

1. An explanation in the initial REB application or Amendment Form as to why verbal consent is appropriate.
2. The written Information Sheet (or Informed Consent Form)
3. The Verbal Consent Script

Instructions for the Verbal Consent Script Template

This Verbal Consent Script template may only be used for minimal risk research when stand-alone verbal consent is being obtained (i.e. written consent will not be obtained).

Note, if your study design allows for written consent to be obtained, it is unlikely that the REB will accept verbal consent.

Note: Permission to contact is required. This script should only be used when permission to contact for research purposes is documented in Epic (i.e. patient is flagged as "OK to contact" **or** permission to contact was obtained and documented in a clinic note by a member of the circle of care) **or** alternatively, when initial contact is made by someone in the potential participant's circle of care.

TIPS FOR WRITING THE VERBAL CONSENT SCRIPT

- Delete the guidance page as well as this instructional page prior to REB submission.
- Only use the header logos that are applicable to your study.
- Use plain (lay) language that is easy for a non-medical person to understand:
  - Use short sentences and sections and simple words; avoid scientific or technical explanations;
  - Ensure that the final form is properly formatted and free of spelling or grammar errors;
  - Aim for grade 8 reading level, ideally no more than grade 10.
- Define all acronyms and abbreviations when they first appear.

HOW TO USE THIS TEMPLATE

- *GREY highlighted text*: General instructions.
- **BLUE text:** To be deleted/modified as needed, prior to REB submission.
- **PURPLE text:** Different scenarios.
- **BLACK text:** OHSN-REB approved template wording and/or examples that should not be altered without justification.
- This template is intended to serve as a **GUIDE**. Depending on the details of your study, you may need to provide different information and details than those stated in the template.

Verbal Consent Script

Study Title: [Study Title]
Principal Investigator: [Name and contact information]
OHSN-REB Number: [#]

Participant name:	**Person calling:**
Date Called:	**Time Called:**

Hello, may I please speak with [name of the potential participant].

***If respondent asks who the caller is:**
If speaking to someone other than the potential participant or SDM, limited information about the study should be provided as information about the study could reveal personal health information.
My name is [name of caller] and I am calling from [The Ottawa Hospital or The University of Ottawa Heart Institute] about a research study.

***If potential participant is unavailable:**
Do not leave a message regarding call back information as this may reveal personal health information.
Is there a better time to call back? Date/time:

***If potential participant indicates they are not interested:**
Thank you for your time. Goodbye.

***If potential participant is respondent:**
Continue with script below

This is [name of caller] calling from [The Ottawa Hospital or The University of Ottawa Heart Institute].

Is this an ok time to talk?

☐ No ***If no →** Is there a better time? Date/time:
☐ Yes ***If yes →** *Continue with script below*

***When permission to contact for research purposes is documented in Epic (i.e. patient is flagged as "OK to contact"):**

- I'm calling because your medical record indicates that you have agreed to be contacted about research and we have a research study that you might be interested in.

***When permission to contact for research was obtained and documented in a clinic note by a member of the circle of care:**

- We've been informed by a member of your circle of care that you have agreed to be contacted for research.

***When the caller is a part of the circle of care and is also a research team member:**

- I'm calling on behalf of [name of circle of care physician/team - etc.] regarding a research study they are running.

If the phone call is being recorded: Please note that this phone call is being audio recorded for [explain why the phone call is being recorded].

The study is being conducted by Dr. [name of the PI or lead researcher] at [The Ottawa Hospital or The University of Ottawa Heart Institute].

You are a candidate for this research because [state main inclusion criteria/why the participant is being considered for the study].

The goal of the research study is to [state main study objectives in lay language],
Are you willing to hear more about the study?

☐ No ***If no** → Thank you for your time. Goodbye
☐ Yes ***If yes** → *Continue with script below*

All aspects of consent must be included. You don't have to read the headings below aloud, they are included as a guide. These sections may be written in a conversational tone.

Conflicts of Interest:

Describe any conflict of interest that exists or may appear to exist as it relates to any of the investigators, study staff or member of their immediate family. A conflict of interest exists if there is a potential benefit to the investigator(s), study staff or member of their immediate family beyond the professional benefit from academic achievement or presentation of the results. Examples include, but are not limited to, speaker's fees, travel assistance, consultant fees, honoraria, gifts, and intellectual property rights such as patents. A declaration of conflict of interest should include the identity of the person with the conflict of interest, the type of incentive or inducement, and its source. See examples below.

The [identify individual e.g., study doctor/researcher], [insert name], is receiving personal financial payment from [identify source of funds e.g., the study Sponsor] for [include reason for

payment e.g., providing advice on the design of the study]. You may request details about this payment.

or

There are no conflicts of interest to declare related to this study.

or

The [insert recipient of funding e.g., hospital] is receiving financial payment from the [sponsor/funder name] to cover the cost of conducting this study.

Research Activities:

All research activities must be described. What each activity entails, how long it will take, and the timing of the activities should be described. Descriptions may be brief and conversational in nature.

Your participation in the study would involve: [describe research activities, including what the participant will have to do, how many visits it will take, how the visits will be carried out i.e. in person or over the phone or via MS Teams/Zoom HC video conference, and how long each visit will be - see examples below].

- *For Focus Groups:*
  Completion of [number of] focus group(s). *If more than one focus group, provide information about timing e.g., every X weeks/months.* A focus group is a small group of representative people who are asked to speak about their opinions as part of the research. A moderator will organize the focus group(s). Each focus group discussion will be about [specify length in minutes or hours] in length and will take place [specify location]. You will be asked to speak about [explain topics of discussion e.g., your experiences with condition/intervention].

- *For interviews:*
  Completion of [number of] interview(s). *If more than one interview, provide information about timing e.g., every X weeks/months.* During the interview, you will meet with [a member/members] of the research team [and specify others if applicable]. Each interview will be about [specify length in minutes or hours] in length and will take place [specify location]. You will be asked to speak about [explain topics of discussion e.g., your experiences with condition/intervention].

- *For surveys/questionnaires:*
  Completion of [number of] survey(s)/questionnaire(s). *Provide information about the timing of questionnaires e.g., once only, now and then every two weeks for a year, etc.*
  The purpose of the survey/questionnaire is [include description of purpose e.g., to understand how the illness affects your quality of life]. Each survey/questionnaire will take about [indicate estimated time to complete in minutes] to complete.

The survey/questionnaire is administered [explain how it will be administered; e.g., over the phone, online via a link that will be sent to their email address, in paper via mail that will be sent to their home address with a postage paid return envelope].

The information you provide is for research purposes only. Some of the questions are personal. You can choose not to answer questions if you wish.

- *For review of medical records:*
  Review of your health record at [The Ottawa Hospital or The University of Ottawa Heart Institute]. Information about [list types of information that will be collected from health records] will be collected from your health record. *Provide information about how often their health record will be accessed e.g., once only, now and then every two weeks for a year, etc.*

If audio/video recordings will be used:
You will be [audio/video] recorded during the [interview(s)/focus group(s)].

Do you have questions about the activities this study involves?

☐ No ***If no →** *Continue with script below*
☐ Yes ***If yes →** *Answer questions and document all questions and answers before continuing with script below*

Questions: _____

Answers: _____

Other Comments: _____

Voluntary Participation and Withdrawal:

Taking part in this study is voluntary.

You have the option to not participate at all, or you may choose to leave the study at any time (this is called withdrawal), without having to provide a reason. *Specify any other potential areas where participants might be concerned about a potential penalty or discrimination, such as:* Your decision will not affect your [employment] or [any healthcare services you are entitled to] at [The Ottawa Hospital or The University of Ottawa Heart Institute.]

If the participant can withdraw information collected prior to withdrawal:
If you decide to leave the study, you can ask that the information that was collected about you not be used for the study.

If data is anonymized, explain the limits on withdrawal of information:

Since the information being collected for this study will be anonymized (meaning it won't be linked to your identity in any) you may withdraw permission for us to use the data while you are actively participating; however, once the data has been pooled with other participant's data, it won't be possible to withdraw it, but no further information will be collected.

Do you have questions about the voluntary nature and ability to withdraw from of this study?

☐ No ***If no →** *Continue with script below*

☐ Yes ***If yes →** *Answer questions and document all questions and answers before continuing with script below*

Questions: _____

Answers: _____

Other Comments: _____

Potential Risks, Harms, Discomforts:

All reasonably foreseeable risks, harms, discomforts or inconveniences must be described. Include both physical and psychological/emotional risks as applicable to the research. Suggestions provided below.

Taking part in this study may make you feel uncomfortable.

For focus groups/interviews: You may become uncomfortable while discussing your experiences. You may choose not to answer questions or leave the [group/interview] at any time if you experience any discomfort.

For focus groups:

While the study team will take precautions to protect your confidentiality, we cannot guarantee that other members of the focus group will respect your privacy or keep the discussions of the group confidential. For this reason, you should avoid using names of other people when describing scenarios or experiences.

Do you have questions about the potential risks this study involves?

☐ No ***If no →** *Continue with script below*

☐ Yes ***If yes →** *Answer questions and document all questions and answers before continuing with script below*

Questions: _____

Answers: _____

Other Comments: _____

Potential Benefits:

Inform participants of potential benefits to themselves and in general that may arise. If there is no known benefit (which is typically the case), ensure this is stated.

If there is no likely benefit to participation:
There are no benefits to you for taking part in this study.

If the benefit is known:
The expected benefit from taking part in this study is [specify].

If applicable:
You may not receive direct benefit from participating in this study. We hope the information learned from this study will help other people with [specify] in the future.

Do you have questions about the potential benefits this study involves?

☐ No ***If no →** *Continue with script below*
☐ Yes ***If yes →** *Answer questions and document all questions and answers before continuing with script below*

Questions: _____

Answers: _____

Other Comments: _____

Privacy/Confidentiality:

If you decide to participate in this study, we will only collect the information needed for this study.

Records identifying you at this centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) research [and medical] records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

Include only those organizations requiring permission for direct access to participant medical records or research records containing identifying information (e.g., permission to conduct on-site monitoring/auditing). Include a brief description of their role in the research. See suggestions below, or modify as applicable to the research:

- [Insert sponsor name], the Sponsor of this study
- The Ottawa Health Science Network Research Ethics Board who oversees the ethical conduct of this study.

- [Ottawa Hospital Research Institute or Ottawa Heart Institute Research Corporation], to oversee the conduct of research at this location.

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your [disclose applicable identifiers e.g., participant code, pseudo-initials, sex, and partial date of birth (month and year)].

The following organizations may also receive study data:
Include organizations with permission to receive study data only (organizations with direct access must be included in the list above). Include a brief description of their role in the research.

- [Identify any other organizations with permission to receive study data only]

If race/ethnicity information is collected as part of the study, identify this and provide a rationale. Suggested text:
This research study is collecting information on race and ethnicity as well as other characteristics of individuals because [specify reason e.g., these characteristics may influence how people respond]. Providing information on your race or ethnic origin is [voluntary/required] (If required, state why, e.g. because the main objective of the study is to determine how to better involve new Canadians in future research opportunities).

If email will be used for study purposes (e.g., distribution of questionnaires, etc.):
Communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.

If focus group/interview:
During the discussions, you will be encouraged to refrain from using names. If names or other identifying information is shared during the discussion, it will not be included in the written records.

If audio/video recording, describe confidentiality measures including, for example, who will have access, how long they will be kept, and whether they will be sent outside the institution. For example:
The audio/video recordings will be stored in a secure location and listened to/viewed only by members of the research team. The recordings will be kept until they have been transcribed (turned into written records), and then they will be destroyed.

If health information is being collected for other research/database:
In addition to the data that will be collected for this study, the researchers will also be collecting the following personal health information:

- [List all additional information being collected]

This additional data is being collected to [insert purpose e.g. to help researchers better understand common trends between your condition and other health problems]. This additional

information is not required for the purpose of this study, but for other future research interests at [insert organization name].

If identifiable data will be sent outside the institution:
This study requires the transfer of identifiable information to [insert name of institution/individual] for the purposes of [specify purpose]. The following information will be transferred:

- [Specify identifiable information to be transferred]

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be [include description of proposed uses of data, e.g., used in analyses and will be published/ presented to the scientific community at meetings and in journals].

Your de-identified data from this study may be used for other research purposes. If your study data is shared with other researchers, information that links your study data directly to you will not be shared.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

If data will be sent outside of Canada
Any information sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection of information may not be as strict as in Canada. However, all study data that are transferred outside of Canada will be coded (this means it will not contain your personal identifying information such as your name, address, medical health number or contact information). The information will be transferred in compliance with all relevant Canadian privacy laws. By consenting to participate, you are consenting to the disclosure of your coded information to organizations located outside of Canada.

For studies using smartphones, apps or applicable technology, describe any limits to the confidentiality. For example:
Data collected using the [insert app/tool/device name] resides on the [insert name e.g., Apple] servers and no assurance can be made about its confidentiality or that it will only be used for research purposes.

Do you have questions about the how your privacy will be protected?

☐ No ***If no →** *Continue with script below*
☐ Yes ***If yes →** *Answer questions and document all questions and answers before continuing with script below*

Questions: _____

Answers: _____

Other Comments: _____

Cost to participation:

If participation will result in additional costs for the participant:
Taking part in this study may result in added costs to you. For example:
- You may miss work as a result of participation in this study.

If participation will not result in any costs:
Participation in this study will not involve any additional costs to you.

Payment or Reimbursement:

If no payment or reimbursement:
You will not be paid for taking part in this study.

If paid:
If you decide to participate in this study, you will receive [$ specify amount of payment including payment interval if applicable e.g., every three months].

If gift card:
As a token of our appreciation, you will be given a [$ specify amount of gift card] gift card to [provide category of stores or specific store name] for your participation in this study. The gift card will be sent to you by mail after completion of the [questionnaire/interview/ focus group].

If there is re-imbursement of costs for participation:
If you decide to participate in this study, you will be reimbursed [$ enter actual or maximum dollar amount] for some study related expenses such as [list reimbursable expenses as applicable].

Do you have questions about the costs of participation or payment/reimbursement?

☐ No ***If no →** *Continue with script below*
☐ Yes ***If yes →** *Answer questions and document all questions and answers before continuing with script below*

Questions: _____

Answers: _____

Other Comments: _____

Participant Rights:

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. *Explain how the participant can obtain the results, for example*: If you would like to be informed of the results of this study, please contact the research team] *or* If you would like to be informed of the results of this study, please let the research team know.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

Questions:

In case you have any questions, here are some contact numbers that are good to have. Do you have a pen and paper ready?

For questions about your rights as a research participant or about ethical issues related to the study, you can contact The Ottawa Health Science Network Research Ethics Board at 613-798-5555, extension 16719, and speak to someone who isn't involved in the study at all.

I can answer any questions that you may have about the research study right now, but if you think of additional questions later on, you can contact me or the [role of contact] at [contact information].

Have all of your questions been answered?

☐ No ***If no →** *Answer questions and document all questions and answers before continuing with script below*

Questions: _____

Answers: _____

Other Comments: _____

☐ Yes ***If yes →** *Continue with script below*

Consent:

Based on the description of the study, would you like to participate? Or would you like some time to think about it?

☐ No ☐ Yes ☐ More time to think about it

***If they do <u>not</u> want to participate:** Thank you for your time. Goodbye.

***If they do want to participate:** *Continue with script below*

***If they would like more time:** *Continue with script below*

For your records and to help in making your decision, I can send you the Information Sheet via MyChart, mail or email. What is your preference?

☐ MyChart

☐ Mail

***If Mail**: Record and confirm address: _____

☐ Email (as a link [Microsoft 365 SharePoint/OneDrive, TOH Methods Centre Electronic Data Capture System, DocuSign, etc.] or password protected attachment)

***If Email:** Before I can initiate email contact with you, I'm required to inform you of the risks associated with use of email. I'm going to read a series of statements to you. Please stop me at any time if you have questions.

Read the 'Research Participant Consent to Communicate by Email'

Discussed on: _____/____/____ Time: _____ hours

Consenting Process completed by: _____ Date: _____/____/____

Record and confirm email address: _____

***If they wanted more time:** When would be a good time for me to call you back to answer any further questions you may have and obtain your decision? Date/time:

Wrap up with a reminder of the next steps and end the call.

Documentation of Verbal Consent

Study Title: [study title]
OHSN-REB Number: [number]

Name of Participant: _____

Date of Discussion: _____

Duration of Discussion: _____

SIGNATURES

- The participant's questions have been answered,
- The participant understands the information within this Verbal Consent Script,
- Each page of the Verbal Consent Script has been read to the participant.
- The participant will allow access to medical records as explained in this consent form,
- The participant agrees to take part in this study.

Investigator or Delegate Statement

I have carefully explained the study to the study participant. To the best of my knowledge, the participant understands the nature, demands, risks and benefits involved in taking part in this study.

_____	_____	_____
Signature of Person Conducting Consent Discussion	Printed Name and Role	Date

Physician Informed Consent Form for Participation in a Research Study

Study Title: Implementation of Large Language Models in Anesthesia to Answer Patient's Questions During Pre-Anesthesia Visits

OHSN-REB Number*:* 20240526-01H

Study Doctor: Arnaud Mbadjeu, Department of Anesthesiology & Pain Medicine, ambadjeu@toh.ca

INTRODUCTION

You are being invited to participate in a research study because you are a physician involved in pre-anesthesia care at The Ottawa Hospital or a member of the anesthesia department at The University of Ottawa. This consent form provides information to help you make an informed choice. Please read this document carefully and ask any questions you may have.

Taking part in this study is voluntary. Your participation will not affect your employment. You may choose to leave the study at any time.

IS THERE A CONFLICT OF INTEREST?

The researcher, Arnaud Mbadjeu, is receiving financial payment from the anesthesia department at The University of Ottawa to cover the cost of conducting this study.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to assess how well ChatGPT answers patient questions compared to responses provided by anesthesiologists during pre-anesthesia consultations. We will compare chatbot responses to anesthesiologist responses to determine if the chatbot responses meet the expectations of patients and expert anesthesiologists.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

We expect to enroll approximately 190 patients undergoing surgery at The Ottawa Hospital, along with 20 response generators and at least five anesthesiologist response raters from the Ottawa Department of Anesthesiology & Pain Medicine.
This study should take 6 months to complete, and the results should be known in about 3 months.

WHAT WILL HAPPEN DURING THIS STUDY?

If you agree to participate, you will be assigned one of two roles:

- **Anesthesiologist Response Generator:** Provide written responses to patient questions that we will obtain before the patient's pre-anesthesia consultation.

- **Anesthesiologist Response Rater:** Review and compare responses generated by the chatbot with those provided by Anesthesiologist Response Generators for the same patient questions.

A member of the study team can meet with you before you begin your role to explain the study procedures and evaluation criteria.

Data Collection:

A research assistant will collect basic demographic data from you, including age, gender, years of experience, and comfort with technology.

1. **Response Generation (for Response Generators)**:
    - If assigned as a response generator, you will receive a set of patient question regarding their anesthesia care.
    - You will be asked to provide concise, written responses to the questions based on your clinical expertise and brief patient medical history.
    - This process should take between 15 and 30 minutes, depending on the complexity of the questions.
    - Your participation will last approximately two months, during which you are expected to provide 1 to 2 answers to patient queries each week.

2. **Response Review (for Response Raters)**:
    - If assigned as a response rater, you will be provided with both the anesthesiologist responses and chatbot-generated responses for the same set of patient questions.
    - You will evaluate these responses based on criteria such as gain in knowledge, accuracy, completeness, and empathy.
    - You will be asked to rate each response on a Likert scale for each of these factors, helping to provide measurable data for analysis.
    - You will have one week to complete the evaluation and submit your feedback by completing a questionnaire, expected to last between 15 and 35 minutes.
    - A research assistant will be available to assist you with any questions during the evaluation, and paper versions of the questionnaires can be provided upon request.
    - Your participation will last approximately two months, during which you are expected to provide 3 to 4 reviews of the anesthesiologist response generator and ChatGPT answers each week

Optional Feedback:

At the end of the study, you may provide optional feedback on the process. This feedback will help improve future studies and the potential development of AI tools in anesthesia care.

Voluntary Participation and Withdrawal:

Participation in this study is entirely voluntary. You may choose to withdraw at any time without penalty or consequence.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you choose to participate in this study, you will be expected to:

- **Anesthesiologist Response Generators:** Provide written responses to patient questions.
- **Anesthesiologist Response Raters:** Review and compare responses.
- Keep study-related information confidential.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

1. **Anesthesiologist Response Generators**

Your participation will last approximately two months, during which you are expected to provide 1 to 2 answers to patient queries each week.

2. **Anesthesiologist Response Rater:**

Your participation will last approximately two months, during which you are expected to provide 3 to 4 reviews of the anesthesiologist response generator and ChatGPT answers each week

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the research team.

You may withdraw your permission to use information that was collected about you for this study at any time by letting the research team know. However, this would also mean that you withdraw from the study.

If you decide to leave the study, you may also request that any collected information not be used in the study. Let the research team know if you choose this.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?
Here are some potential risks for anesthesiologists participating in the study, although they are generally minimal:

- **Time Commitment**:
  Participation requires 15-35 minutes for response generation or evaluation. This could

potentially interfere with work or personal schedules, but you will have a week to complete the task at your convenience.

- **Emotional Discomfort**:
  You may feel uneasy about having your responses compared to AI-generated answers. However, the study focuses on AI evaluation, not individual performance, and all responses will remain confidential.
- **Privacy Concerns**:
  While your responses will be anonymized, there may be concerns about privacy. Strict confidentiality protocols will ensure no identifiable information is shared.
- **Reputation Concerns**:
  Some participants may worry that their responses could affect their professional reputation. However, participation is voluntary, confidential, and will not impact your employment or professional standing.
- **Comfort with Technology**:
  If you're less familiar with technology, there may be minor discomfort. However, the study does not require direct interaction with the chatbot, and assistance will be available if needed.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

You may not receive direct benefit from participating in this study. However, we hope the information learned will help improve perioperative education for future patients.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the research team will only collect the information they need for this study.

Records identifying you at this centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) research records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

- The Ottawa Health Science Network Research Ethics Board who oversees the ethical conduct of this study.
- Ottawa Hospital Research Institute, the Sponsor of this study and who oversees the conduct of research at this location.

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your participant code, , sex/gender, and age.

This research study is collecting information about race, ethnicity, and other characteristics of individuals. We know that AI can increase and continue existing inequalities related to sex and gender. By gathering this information, we aim to understand how this new AI solution works for different groups of people. Providing information on your race or ethnic origin is voluntary.

Communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.

If the results of this study are published, shared, or presented at scientific meetings, your identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published/presented to the scientific community at meetings and in journals. Even though the likelihood of someone identifying you from the study data is very small, it can never be completely eliminated.

Other Future Research

The data collected from this study may be used to inform and guide future research on the integration of AI technologies in clinical practice, particularly in improving patient communication and decision-making during pre-anesthesia consultations.

WHAT IS THE COST TO PARTICIPANTS?

There are no financial costs to participate in this study. The only cost is the time commitment required, which is expected to be 15-35 minutes for completing your assigned tasks (response generation or evaluation). Participation will not affect your employment or professional duties at The Ottawa Hospital.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

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

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results, please contact the research team.
Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form, you do not give up any of your legal rights against the researcher, sponsor, or involved institutions for compensation, nor does this form relieve the researcher, sponsor, or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, you can talk to the study researcher. That person is:
Arnaud Mbadjeu 437-227-0245, Principal Investigator

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. Please contact The Ottawa Health Science Network Research Ethics Board, Chairperson at 613-798-5555 extension 16719.

Study Title: Implementation of Large Language Models in Anesthesia to Answer Patient's Questions During Pre-Anesthesia Visits: A Prospective, Observational Study

SIGNATURES

- All my questions have been answered,
- I understand the information within this informed consent form,
- I allow access to personal information as explained in this consent form,
- I do not give up any of my legal rights by signing this consent form,
- I agree, to take part in this study.

Signature of Participant	Printed Name	Date

Signature of Person Conducting the Consent Discussion	Printed Name and Role	Date