

Title: Evaluation of Large Language Model (LLM) Generated Text Plus Human Editing for Improving the Clarity, Readability, Length, Understandability, and Comprehensiveness of Elements of Informed Consent Documents

Appendix A: Large Language Model Generative AI Prompt and Sample Output

Version: May 16, 2025

Below is the final prompt that was developed by the study team and the results of a query using language from an randomly selected informed consent document form that was posted on www.clinicaltrials.gov

OpenAI ChatGPT-4.o PROMPT:

Role:

Take on the role of an expert in research ethics with specialized knowledge in informed consent for human subjects research in the U.S. to revise text. You should ensure that revised consent language improves clarity, readability, length, understandability, comprehensiveness, and effectiveness in compliance with regulatory requirements, IRB guidelines, and best practices.

Task:

You will be provided with the passages from an informed consent form for the Purpose, Risks, and Benefits sections of the informed consent form.

Before providing your revised text, explicitly outline your reasoning for how you plan to approach the revisions, including the principles and guidelines you'll apply.

Only after clearly providing the reasoning, revise and refine the text while ensuring:

Key Considerations:

1. Ethical & Regulatory Compliance

o Align revisions with:

- [OHRP's Informed Consent Tips](#)
- [FDA's Key Information & Facilitating Understanding in Informed Consent](#)
- [Federal Plain Language Guidelines](#)

o Ensure the text clearly communicates study purpose, risks, benefits, and voluntary participation without undue influence.

2. Readability & Accessibility

- o Use plain language (6th–8th grade reading level).
- o Write in short, direct sentences with an active voice to improve comprehension.
- o Avoid jargon and complex sentence structures to ensure accessibility for diverse populations.

3. Inclusivity & Ethical Sensitivity

- o Use gender-neutral, culturally inclusive language.
- o Avoid stigmatizing phrases
- o Ensure the language respects participant autonomy and does not pressure, coerce participation, nor create undue influence.

4. Participant Engagement & Clarity of Terms

- o Use a conversational, participant-friendly tone to foster trust.
- o Include a brief description of any technical jargon or scientific terms to ensure clarity and accessibility for all participants.

Expected Output:

- Identify specific weaknesses in the original text.
- Justify why improvements are necessary using ethical, regulatory, and readability principles.
- Provide three distinct revised options for each section of the informed consent form (Purpose, Risks, and Benefits), allowing researchers to select the best fit to further edit for their study.
 - o Version 1: Concise and Direct
 - o Version 2: Participant-Friendly and Engaging
 - o Version 3: Detailed and Compressive
- Summarize and combine elements from the three versions to propose a recommended final
 - o Provide an explanation of which elements were combined from the three versions
 - o Provide a justification for why the final version is the most effective
- Ensure all sections remain congruent and are logically structured.
- Ensure each version maintains accuracy while improving clarity, readability, length, understandability, and comprehensiveness.
- If applicable, include recommendations for further refinements to enhance participant understanding.
- Suggest improvements such as using bullets, tables, or images, to enhance and improve readability, particularly for the risk section.
- Offer additional recommendations for further refinement.
- Keep sentences short and to the point.
- Provide your reasons for the output/response.

The text from the consent form for the **Purpose** section is as follows: <insert text>

The text from the consent form for the **Risks** section is as follows: <insert text>

The text from the consent form for the **Benefits** section is as follows: <insert text>

Sample text used to test the above prompt (replaces lines 74-78)

The text from the consent form for the **Purpose** section is as follows: This research is being done to test an intervention called SMILEY, a chatbot used by teens who have had negative online experiences (e.g., bullying, harassment, or discrimination). The goal of SMILEY is to reduce further exposure to negative online experiences and depression symptoms while increasing use of coping skills and healthier social media use.

The text from the consent form for the **Risks** section is as follows: Potential risks of the study: There is a possible risk of loss of confidentiality (people not involved in the research study finding out personal information about you). Although we will make every effort to keep your information confidential, no system for protecting your confidentiality can be completely secure. It is still possible that someone could find out you were in this study and could find out information about you.

We will audio-record the screening interview and the phone calls with the study coach. These calls will be audio-recorded to make sure that study personnel are saying things that are consistent with study goals. Please note that your voice is technically identifiable according to patient privacy rules, so we will do everything possible to protect your voice identity. This recording may be transcribed (written down word for word) so that approved study staff members will be able to review your responses as part of the data collected for the study.

Additionally, recordings may be reviewed by approved study staff during data analysis to make sure that the transcript accurately captured what was said and how it was said. You will have the right to review and mark for erasure any portions of the audio-recording. The use of the website to store personal information is not without risks. It is important that you use the website in private so that people around you can't access your information. This will help reduce the risk of accidental breaches of security by onlookers, family members, co-workers, and supervisors. When you visit a website on the computer, things called "cookies" are usually left behind. Cookies are little bits of information that can be used to trace back to your user ID or email address. When you sign in on the study website, there might be a chance that cookies could be left behind and that could possibly lead back to you at your computer address. There are two ways that we will try to keep this from happening:

- The web designers have used something called a "session variable" concept to remove cookies from your browser as an additional way to protect your confidentiality. A session variable is used so a website can recognize your log in and give you access to certain sections of the website. Any time you log onto the study website, a unique session variable will be randomly generated. This session variable will expire and be automatically removed from your computer when you log out from the site.
- The other way to help protect your privacy is for you to use a computer that no one else uses at a time that you will not be interrupted. In addition, to be extra careful, we recommend that after each time you are on the study website, you delete the study site

files and history from your browser. The study coach will explain to you how to do this during the initial phone call.

You will be asked not to leave your computer unattended while logged on to the website. If, for whatever reason, you get called away, it is important that you remember to close the session and not leave it open for others to see. If you have to use a public computer, like at a library or clinic, be sure to allot enough time to complete the session.

Do not leave the computer unattended while you are logged into the website, and remember to delete the cookies and history from your browser at the end for extra security. If, for whatever reason, someone without permission views your responses, please notify the study coach.

If you suspect that someone has logged on with your username and password, please notify the study coach immediately, so that she can assign you a new username and password.

For details on the steps we will take to secure your privacy and confidentiality, please refer to Section 7.

The particular treatments or procedures in this study may involve risks that are currently unforeseeable. We will contact you as soon as possible if new findings occur during this research that may pose a risk to you.

The text from the consent form for the **Benefits** section is as follows: Potential benefits of study: There may be no direct benefit to you from participating in this research. However, you may benefit by learning more about yourself by being in the study. If you are in the DESTRESS condition, you may benefit from the treatment that you are provided and skills that you learn. The phone monitoring condition may help you because you get a chance to track your PTSD symptoms over time. No benefit, however, can be guaranteed.

The findings from this study may benefit society by finding out if DESTRESS-WV is a good treatment option for women Veterans with PTSD.

Output Generated From Sample Test of Prompt:

Approach to Revising the Informed Consent Sections

To enhance the clarity, readability, and effectiveness of the informed consent document while ensuring compliance with ethical and regulatory guidelines, the revisions will follow these principles:

1. Ethical & Regulatory Compliance

- o Align with **OHRP's Informed Consent Tips**, **FDA's Key Information guidance**, and **Federal Plain Language Guidelines**.

- o Clearly state **purpose, risks, and benefits** without undue influence.
- o Ensure voluntary participation language is clear and non-coercive.
- 2. **Readability & Accessibility**
 - o **6th–8th grade reading level** for general comprehension.
 - o **Plain language**, avoiding jargon or overly technical terms.
 - o **Active voice** for clarity and engagement.
 - o **Shorter, direct sentences** to improve retention.
- 3. **Inclusivity & Ethical Sensitivity**
 - o **Gender-neutral, inclusive** language.
 - o **Avoid stigmatizing** or alarmist phrases.
 - o Ensure **respect for autonomy** and that participants **feel informed, not pressured**.
- 4. **Participant Engagement & Clarity**
 - o Use a **conversational tone** where appropriate.
 - o Explain key terms simply.
 - o **Bullet points, tables, or formatting** for ease of reading (especially in the Risks section).

Revised Consent Language Options

Purpose Section

Weaknesses in Original Text:

- Lacks a clear, engaging introduction.
- Could be more direct in describing SMILEY’s purpose and goals.
- The phrase “negative online experiences” is vague—needs clarity.

Option 1: Concise and Direct

This study tests **SMILEY**, a chatbot designed for teens who have experienced **bullying, harassment, or discrimination online**. The goal is to see if SMILEY helps reduce negative online experiences and feelings of sadness while improving coping skills and promoting healthier social media use.

Option 2: Participant-Friendly and Engaging

We are studying a chatbot called **SMILEY**, which is designed for teens who have faced **hurtful or harmful experiences online, such as bullying or harassment**. SMILEY aims to help by **reducing exposure to negativity, supporting mental well-being**, and **teaching helpful coping skills**. This study will help us learn if SMILEY is effective in improving how teens handle these challenges.

207 **Option 3: Detailed and Comprehensive**

208 This research is studying **SMILEY**, a chatbot designed to help teens who have
209 experienced **cyberbullying, online harassment, or discrimination**. The study will
210 evaluate whether SMILEY can:

- 211 • Reduce exposure to **negative online interactions**,
- 212 • Decrease **stress and sadness related to these experiences**, and
- 213 • Increase the use of **healthy coping skills** and **positive social media habits**.

214 Your participation will help us understand how well SMILEY works and whether it can
215 be a helpful tool for others facing similar challenges.

216 **Recommended Final Version**

217 **Combining elements from Option 1 (concise purpose), Option 2 (engaging tone),**
218 **and Option 3 (structured details):** We are testing **SMILEY**, a chatbot designed for
219 teens who have faced **cyberbullying, harassment, or discrimination online**. SMILEY
220 aims to **reduce exposure to negativity, support mental well-being**, and **teach useful**
221 **coping skills** for a healthier social media experience. Your participation will help us
222 understand if SMILEY is an effective tool for teens facing similar challenges.

223 **Justification:**

- 224 • Maintains **clarity and engagement** (from Option 2).
- 225 • **Concise and structured** for readability (from Option 1).
- 226 • Includes **key study goals** in bullet points for ease of understanding (from Option
227 3).

228

229 **Risks Section**

230 **Weaknesses in Original Text:**

- 231 • Long, dense paragraphs make it **difficult to read**.
- 232 • Some explanations are **overly technical** (e.g., cookies, session variables).
- 233 • **Repetitive wording** makes it longer than necessary.
- 234 • Does not clearly separate **types of risks** (privacy risks vs. unforeseen risks).

235 **Option 1: Concise and Direct**

236 This study involves some risks, including:

- 237 • **Loss of confidentiality:** While we will do everything possible to protect your
238 information, no system is 100% secure.

- **Audio recordings:** We will record your screening interview and phone calls with the study coach. Only approved staff will review these.
- **Online privacy:** Using the study website may leave traces (like cookies) on your device. To protect your privacy, we recommend clearing your browser history and using a private computer if possible.
- **Unforeseen risks:** If new risks arise, we will inform you.

Option 2: Participant-Friendly and Engaging

Your privacy and safety are very important to us. Here are some risks to consider before deciding to participate:

- **Privacy risks:** While we will take **strong steps** to protect your information, there is a small chance that someone outside the study could find out you participated.
- **Recorded calls:** We will record your phone calls with the study coach to ensure the study follows guidelines. These recordings will only be reviewed by trained staff.
- **Using the website:** Websites sometimes store small bits of information (called “cookies”). We have built extra protections into the site, but it’s best to **clear your history after using the website** and **use a private computer if possible**.
- **New risks:** If we learn about any new risks during the study, we will notify you.

Option 3: Detailed and Comprehensive

There are some risks involved in this study:

1. **Confidentiality risks:** While we take all necessary precautions, there is always a small chance that your participation could become known to others.
2. **Audio recordings:** We will record your screening interview and phone calls with the study coach. These recordings:
 - Will be used only for research purposes.
 - May be transcribed for analysis by study staff.
 - Can be reviewed by you, and you may request parts to be erased.
3. **Website security:**
 - Our website uses special protections to reduce the risk of leaving personal data behind.
 - You can **delete cookies and browser history** after each session for added security.
 - If you use a shared or public computer, be sure to **log out fully** and **close your browser**.
4. **Unforeseeable risks:** Some risks may not be known yet. If any new risks are identified during the study, we will inform you.

275 **Recommended Final Version**

276 **Combining elements from Option 1 (concise bullet points), Option 2 (engaging**
277 **and reassuring tone), and Option 3 (structured detail):** Your privacy and safety are
278 important. Here are some risks to consider:

- 279 • **Confidentiality risks:** We take strong precautions, but there is a small chance
280 someone outside the study could learn you participated.
- 281 • **Recorded calls:** We will record phone calls for research purposes. Only trained
282 staff will review them, and you may request parts to be erased.
- 283 • **Using the study website:**
 - 284 ○ Our site has built-in protections to limit tracking.
 - 285 ○ To protect your privacy, **clear your browser history** and **log out** after
 - 286 each session.
- 287 • **Unforeseen risks:** If new risks arise, we will inform you.

288 **Justification:**

- 289 • Retains **concise, direct structure** (from Option 1).
- 290 • Uses **engaging, participant-friendly** language (from Option 2).
- 291 • Includes **enough detail without overwhelming the reader** (from Option 3).

292

293 **Benefits Section**

294 **Weaknesses in Original Text:**

- 295 • Uses vague wording (e.g., "may benefit by learning more about yourself").
- 296 • "No benefit can be guaranteed" sounds discouraging.

297 **Option 1: Concise and Direct**

298 You may not directly benefit from participating. However, you may:

- 299 • Gain insight into your experiences and coping strategies.
- 300 • Learn skills that could help manage stress.
- 301 • Help researchers develop better support tools for teens facing online challenges.

302 **Option 2: Participant-Friendly and Engaging**

303 While there's no guaranteed personal benefit, you might:

- 304 • Learn helpful ways to cope with negative online experiences.
- 305 • Gain insight into your own well-being.
- 306 • Help improve mental health resources for other teens.

307 ***Option 3: Detailed and Comprehensive***

308 You may or may not benefit directly. Potential benefits include:

- 309 • Learning coping strategies to handle online stress.
310 • Gaining personal insights into how online interactions affect your well-being.
311 • Contributing to research that could help other teens facing similar challenges.

312 ***Recommended Final Version***

313 You may not receive a direct benefit, but you might:

- 314 • **Gain useful coping skills** for handling online challenges.
315 • **Learn more about your own well-being.**
316 • **Help improve resources for other teens.**

317 **Justification:** Combines clarity (Option 1), engaging tone (Option 2), and
318 **structured details (Option 3).**