Institute Ethics Committee – IIT Delhi

Informed Consent Guidance: How to Prepare a Readable Consent Form

The IEC-IIT Delhi recommends that informed consent documents be written at or below an **8th-grade reading level** to ensure clarity and accessibility for participants. However, for studies involving highly technical content, it may not always be possible to maintain this reading level. In such cases, investigators are encouraged to consult with relevant specialists to simplify the language while maintaining accuracy.

Tips for Ensuring Readability:

To assess the clarity and readability of the consent form, researchers should:

1. **Read the form aloud** to colleagues, staff, or a representative sample of the target audience to identify complex or unclear sections.
2. **Use built-in readability tools** in word processing software to check the reading level.

Drafting Tips for Preparing Consent Forms

General Writing Guidelines:

- Use **simple, familiar words** that a non-medical reader can easily understand.
- **Limit words to three syllables or fewer**, where possible.
- Write **short, direct sentences**; if a sentence is too long, split it into two.
- Keep **paragraphs short** and focused on a single idea.
- Use **active voice** for clarity.
- Use the **second person ("you")** rather than the third person ("the participant") for a more personal tone.
- **Avoid contractions** (e.g., use "do not" instead of "don’t").
- Number **all pages** in the protocol, consent form, and related documents.
- Use at least **12-point font** and consider a larger font for readability based on your audience.
- Ensure that **each idea is clear** and logically structured.
- **Highlight key points** using bold, underlines, or boxes—avoid italics or ALL CAPS.
- **Avoid repetition** and large blocks of text.
- Use **graphics, photos, or tables** if they help explain procedures.
- Maintain **consistent terminology**, especially for drug names and abbreviations.
- **Brand names** of drugs or devices should be **capitalized** and include the ™ or ® symbol upon first mention.
- **Generic names** should be in **lowercase**.
- When using a drug name for the first time, include the appropriate **abbreviation** in parentheses.
- Commonly recognized abbreviations (e.g., DNA, HIV, AIDS) do not need to be spelled out.
- Spell out acronyms the **first time** they appear in the document.
- **Avoid symbols** like ">" or "<"; use words instead (e.g., "greater than").
- **Do not use** "e.g." or "etc."; instead, write **"for example"** or **"and so forth."**

Describing Study Procedures:

- For studies involving **blood or fluid collection**, specify the amount in **teaspoons or tablespoons** instead of milliliters (ml) or cubic centimeters (cc).
- Clearly define technical terms like "double-blind," "randomized," and "placebo-controlled" when first introduced.
    - Example: *"A placebo is an inactive substance that looks like the study drug but contains no medication."*
- Do **not** use the words **"treatment"** or **"therapy"** for investigational drugs, devices, or procedures. Instead, use:
    - *"study drug"* (instead of *"study medication"*) for investigational drugs.
    - *"study product," "study drug or placebo,"* or *"study regimen"* if one group receives a placebo.
- Do not describe investigational drugs, devices, or procedures as **"new"**. Instead, state they are **"investigational"** or **"experimental"** and explain the term.
    - Example: *"The word 'investigational' means that the study drug is not approved by the U.S. Food and Drug Administration (FDA) and is still being tested in research studies."*
- Use **"study doctor"** instead of "principal investigator" for clarity.
- Refer to the project as a **"research study"** rather than a "trial."
- Use **"participant"** instead of "patient," unless referring to the person **before** they joined the study.
- Avoid the word **"invite"** in consent text. Instead of *"You are invited to participate..."*, use:
    - *"You are being asked to participate in a research study because [insert reason]."*
- When describing **randomization**:
    - For **two groups**, say *"like the flip of a coin."*
    - For **more than two groups**, say *"like drawing numbers from a hat."*
- If the study drug might receive **FDA approval** during the research, specify whether participants will need to **pay for it** if it becomes available.
- For **optional** study components (e.g., future sample storage), include **checkboxes** or lines for initials to indicate consent.
- In **double-blind studies**, state that **the blind can be broken in an emergency**:
    - Example: *"In case of an emergency, the study doctor can quickly determine which study group you are assigned to."*

Additional Resources:

For further guidance, refer to these glossaries:

- **Glossary of medical terms (for children):** KidsHealth Medical Glossary
- **Clinical research glossary:** First Clinical Research Glossary
- **Layperson-friendly glossary:** Stanford Human Subjects Glossary

Participant Information sheet

(To be shared with the participant)
Institute Ethics Committee
Indian Institute of Technology, Delhi
Ph: 011- 26591221

Template

[TITLE OF THE STUDY]: *The title should be clear, self-explanatory and consistent across all documents referring to the study.*

I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

WHO I AM AND WHAT THIS STUDY IS ABOUT

Explain who you are and why you are doing this study. Explain the overall aim of the study. When describing the study take care to be as neutral as possible and avoid suggesting any bias about what you expect the outcomes from the research to be. If the research is being undertaken as part of a course of study state what qualification will result from the process.

WHAT WILL TAKING PART INVOLVE?

Explain what taking part in the research will involve including a list of topics that you will discuss and the expected location and duration of participation. If you plan to use audio-recording discuss that also.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

Explain why you have selected this particular individual to take part in your research and how you came to select them.

DO YOU HAVE TO TAKE PART?

Explain that participation is completely voluntary and that the person has the right to refuse participation, refuse any question and withdraw at any time without any consequence whatsoever.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

Give a frank and realistic assessment of the possible benefits of the research – do not oversell what the research will achieve. Consider any possible physical or psychological harm that may come to a participant as a result of participating in the research and what you will do should such a situation arise.

WILL TAKING PART BE CONFIDENTIAL?

Explain what steps you will take to ensure the confidentiality and anonymity of the participant and any individuals they talk about. Outline the situations in which you may have to break confidentiality: if the researcher has a strong belief that there is a serious risk of harm or danger to either the participant or another individual (e.g. physical, emotional or sexual abuse, concerns for child protection, rape, self-harm, suicidal intent or criminal activity) or if a serious crime has been committed. You should also make it clear that non-anonymised data in the form of signed consent forms and audio recordings are collected and retained as part of the research process.

HOW WILL INFORMATION YOU PROVIDE BE RECORDED, STORED AND PROTECTED?

Explain that the interview will be recorded and outline the arrangements for storing the research data (where it will be stored, security arrangements, who will have access). Also outline the relevant data retention policy. This will vary depending on the nature and needs of your project (see the Research Ethics Committee website for further

information). For students undertaking master's programmes who have no intention of subsequently publishing their research the relevant paragraph should read:

'Signed consent forms and original audio recordings will be retained in [*specify location, security arrangements and who has access to data*] until after my degree has been conferred. A transcript of interviews in which all identifying information has been removed will be retained for a further two years after this. Under freedom of information legalisation, you are entitled to access the information you have provided at any time.'

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

Outline fully and realistically your plans for the dissemination of the final research product including conferences, publications and teaching use. If your plans for the research only consist in submitting your dissertation then simply state this.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

Provide the name, affiliation and contact details of all researchers involved as well as supervisor details where relevant.

[THANK YOU]

INFORMED CONSENT FORM

(To be obtained from the study participants)

Institute Ethics Committee

Indian Institute of Technology, Delhi

Ph: 011- 26591221

Study Title / Project Title: _____

Study Reference Number: _____

Participant's Name: _____ **Date of Birth / Age:** _____

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[1] I _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ confirm that I have read and understood the Participant Information Sheet for the above study and have had the opportunity to ask questions.

[2] I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

[3] I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

[4] I understand that the information collected about me from my participation in this research and my health records may be looked at by responsible persons (Ethics Committee / regulatory authorities).

[5] I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.

[6] I agree to take part in the above study voluntarily. I am aware of the Audio-Visual recording of the Informed Consent (if applicable).

[7] I agree for my left over samples to be used for future research purposes

Name of the Research Participant	Signature / Thumb impression	Date
Name of the Legal Representative (in case of minor/vulnerable)	Signature / Thumb impression	Date
Name of the Impartial Witness	Signature / Thumb impression	Date
Name of the Person Administering Consent / Study Investigator	Signature	Date