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