

## Common Consent Form Issues

- Use "study drug" not "study medication" when the drug is investigational and also when a placebo is used. The word "medication" or "medicine" should only be used if the drug is commercially available for that particular condition.
- Do not use "treatment" or "therapy" if a placebo is involved or if an investigational drug is involved. Words to use instead include: "study drug regimen" or "study procedure." (note: this is especially important in early phase studies such as phase I, II or first-in-human studies)
- State that the drug, device, combination of drugs, etc. are investigational if they are and define investigational. For example, "The word "investigational" means the study drug is not approved by the U. S. Food and Drug Administration (FDA) and is still being tested in research studies." Be consistent about using the word "investigational" and not switching between "investigational" and "experimental" throughout the consent form.
- Use "study doctor" (more understandable to a lay person) instead of "principal investigator."
- Do not capitalize "sponsor."
- Define the word "placebo" when first used. Examples of placebo definitions are: "sugar pill," "inactive substance," "inactive substance in the same form as the active drug," "pill that does not contain any drugs or medicines."
- Use "research study," instead of "trial."
- Use the word "subject" or "participant" throughout instead of "patient" since this is research. However, it is applicable to use "patient" if you are referring to the person prior to his/her entering the study.
- When a placebo and active drug are involved, clarify for the subject that when the consent refers to the study drug, the study drug means "placebo **or** active drug."
- Begin the consent form with, "You are being asked to take part in this research study because (insert condition here)" and then give information about what research is.
- Do not use the word "invite" (for example, "You are invited to participate in a research study.") Instead use, "You are being asked to participate in a research study because (insert condition here)."

- When describing randomization for **2 groups** use, “like the flip of a coin,” for **more than 2 groups**, use “like drawing numbers from a hat.”
- Include the re-disclosure statement in the confidentiality section of the consent form.
- Make sure to include whether or not DUHS, PI and research team are being paid to conduct the study.
- Use headers for sections - makes it more readable for the subject.
- Refrain from using Latin abbreviations such as i.e. or e.g. or etc. Use instead: “such as,” “for example.”
- Spell out acronyms when first used.
- Do not use CAPS or **bold items** unnecessarily. For example, **WE CANNOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.**
- If the FDA may approve the study drug while the research study is in process, let subjects know if they will be responsible for paying for the study drug if it is approved.
- Do not include the statement, “By signing this consent form, you will not waive any of your legal rights.”
- Use initial lines for optional portions of the study.
- Always use the MO345 form which is located on the IRB website:  
<https://irb.duhs.duke.edu/>
- Preference for use of bulleted lists instead of long strings of items, as they are easier to read.
- Use plain language – swallow a pill vs. oral administration.