Checklist How to write a Low Literacy Informed Consent Form	
Recommendations to lower the reading level of consent forms	**Check**
Words	
Use words familiar to the non-medical reader	
If possible, keep words to 2- 3 syllables or fewer	
Use common, familiar words	
Sentences/Paragraphs/Print Size & Type	
Write short, simple, and direct sentences	
Keep paragraphs short and limited to one idea	
Use active verbs	
Use the second person (you) not third person (the participant) to increase personal identification	
Avoid contractions	
Use page numbers	
Use at least 12-point font and consider a larger font based on your audience	
Check the text to see if each idea is clear and logically sequential	
Avoid large blocks of printed text	
Avoid Complex Medical Terminology	
Avoid medical terminology. If a medical term must be used, define/explain it	
Be consistent with use of all terminology, such as drug names and abbreviations	
Use the appropriate abbreviation the first time a drug name is used in the consent	
Abbreviations	
Spell out abbreviated terms the first time you use them	
Abbreviated terms such as DNA, HIV and AIDS that have come to be accepted as standard by your proposed study population need not be spelled out	
Do not use e.g. or etc., use instead, "for example," "so forth."	
Spell out acronyms when first used	
Pictures	
Use photos, graphics, tables, illustrations or diagrams if they will help clarify procedures	
Numbers	
Use numerals rather than words for numbers, e.g., “10” instead of “ten,” “1 out of 4” instead of “one out of four.”	
Tips to Describe Study Procedures	
Consent forms for projects that involve collection of blood or other fluids should include the amount(s) to be taken. Do not use ml. or cc. as a volume measure; give a volume equivalent in teaspoons or tablespoons. Rather than abbreviating such words as teaspoon and tablespoon, please spell them out.	

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Tips to Describe Study Procedures	**Check**
Do not use symbols such as ">"; use "greater than."	
Describe study design procedures such as "double blind," "randomized," and "placebo/controlled" when the concept(s) is/are 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” to describe an investigational drug, device or procedure. Use the term "study drug" not "study medication" when the drug is investigational. The word "medication" or "medicine" should only be used if the drug is commercially available for that particular condition	
Do not use the term "treatment” or “therapy”" if one of the study arms will be a placebo. Instead, use words like: “study product”, “study drug or placebo”	
Do not describe investigational drugs, devices or procedures as “new.” For investigational drugs or devices, state they are investigational or “experimental” and describe that term (e.g., 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 in using “investigational” throughout the consent form.	
Use "research study," instead of "trial."	
Use the word "participant" in the consent form instead of “patient” since this is research. However, you may use “patient” when referring to the person prior to his/her entering the study.	
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."	
To check the grade level of a consent document, the investigator can implement the following steps	
For Microsoft Word: 1. *on the “File” tab, click the “Options” button;* 2. *on the “Proofing” tab, under “When correcting spelling and grammar in Word”, make sure “Check grammar with spelling” is selected;* 3. *under “When correcting spelling and grammar in Word”, select the “Show readability statistics” check box. Click on OK* 4. *Click on the “Review Tab”* 5. *Click on “Spelling & Grammar”* *After the grammar check is complete, Word displays a message box showing you the readability grade-level.*	