Guide to Drafting & Editing ICF/Assent/HIPAA Authorization

How to use this tool: Designed for a quality check, researchers, IRB staff and IRB members may use this as a Read/Do checklist for drafting and editing (follow these points as you go along). Those with more experience may find it works better as a Do/Confirm checklist (compare it to the draft under review, then do what you missed). Questions? Ask the IRB Director or a Team Lead.

1. Required Elements, Tools & References

Website resources: http://www.irb.emory.edu/forms/index.html

- Current Emory templates must be used. IRB personnel may send back drafts not using them.
  - Follow instructions in the marginal comment balloons.
  - Delete anything that is not applicable.
- Required elements must be present or justifiably omitted (in which case, use a waiver of elements of consent worksheet). See website for Informed Consent Basic Elements and waiver worksheets.
- Spell check and grammar check.
- *The Elements of Style*, by Strunk & White, is our primary style guide.

2. Marginal Comments

- IRB personnel should use to explain edits that others might find confusing, to ask for confirmation that the original meaning has not been altered, or to ask others to edit further. Researchers should use as necessary to explain changes made (or not made).

3. Defining scientific/medical terms

- For a term used throughout the document, define in a stand-alone sentence, following the term at its first mention. Allow the use of the scientific/medical term thereafter.
- For a term used once or twice only (e.g., in a list of drug risks), use the lay definition first, then add the scientific/medical term in parentheses. Rationale: comprehension comes first, then fancy term can be referred to by those who are curious, or ignored by those who are not.

4. Reading level

- Must be at Flesch-Kincaid reading level grade 8.0 – 8.12 unless exceptions apply (see below).
- Note that the Word Readability Statistics include sentence length. Target is 15-21 words per sentence.
- Reading level grade > 8.12 may be OK if:
  - Subjects as a class have college or higher education (e.g., medical students).
  - Subjects are already familiar with terms used for the diagnosis or treatment of the condition of interest (e.g., patients and their families or caregivers).
  - Complex words cannot be replaced with simpler ones (e.g., study drug names, foreign words).

5. Style & Voice

- Avoid the passive voice. A good general rule is 80% active voice, 20% passive voice. (“We will then ask you some questions...” v. “you will then be asked some questions...”)
- Good reasons for allowing passive voice include: to add variety; to obscure the subject of the sentence; to shorten a sentence.
- Refer to the subject in the second person singular (“you” as an individual, not “I”).
- Researchers can describe themselves as “we,” or “he, she, they,” or, in rare cases where there is only one researcher doing all the work, “I.”
- SOLID CAPS, BOLDING AND UNDERLINING (except in headers) SUGGEST A LOUD VOICE, which can come across as inappropriately forceful. Avoid them.