Why?

• The IRB is a nefarious organization bent on making your life as complicated as possible.

Or

• Informed consent is an integral (and legally mandated) part of ethical research.
45 CFR part 46 section 116

- §46.116 General requirements for informed consent.
- Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. **The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.** No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.
The consent is a teaching tool and dialogue

- Subject’s ability to comprehend
- Researcher’s ability to make comprehensible
Consent forms must assume ignorance

- Knowledgeable subjects
  - Staff/faculty/residents/etc.
  - The consent is a reference.

- Inexperienced subjects
  - New patients, subjects with low literacy skills
  - The consent is a guide.
How the IRB reviews your ICF

• Flesch-Kinkaid tool

• Section by section, paragraph by paragraph

• Looks at:
  ▫ Word choice
  ▫ Clarity
  ▫ Consistency
Keep Your Words Small

Use words and phrases found in common conversations, not legal documents.

- About vs. Approximately
- Take part/Be in vs. Participate
- End vs. Terminate
- Do vs. Perform
- Get/Have vs. Receive (a treatment)
Eliminate Unnecessary Words

Challenge each word – is it necessary?

• “Before” vs. “prior to”

• “It is required that you” vs. “You must”

• “conducting an investigation on” vs. “studying,” “testing,” or “examining”
Keep Your Sentences Short and Simple.

Say one thing per sentence and say it plainly. Don’t overwrite.

• Your participation in the main study will not be affected in any way if you choose to not allow your left-over samples to be used for research not specified in this protocol.
  ▫ 14.8 grade level, unclear language, excessive use of the word “not.

• You may continue to be in the main study even if you do not agree to future use of your samples.
  ▫ 8.3 grade level, one clear point.
Expected risks of study:
Psychological tests and interviews can sometimes bring up painful emotions. You are free not to answer any questions you wish. You may also feel temporarily anxious during the psychological assessment interviews and during the virtual reality task and the psychophysiological assessment. If needed, we can refer you to a clinician to help you cope with any feelings or problems that arise during the session. Scrubbing your skin with cleanser may cause skin irritation. The air blast will feel annoying but not painful. If it becomes too uncomfortable you can stop the test session. The noise level you will hear during the startle test session is about what you hear on a train. For most people, this sound level should not result in discomfort. If the sounds cause you discomfort, you can stop the test session at any time. Withdrawal from the study will not in any way affect your future care. There is no risk to you by chewing on a piece of cotton or spitting it into a tube.
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There is no risk to you by chewing on a piece of cotton or spitting it into a tube.
Keep Your Clauses Independent

Break down larger sentences and paragraphs into their component parts.

- The study drug will be given to you by intravenous infusion (IV), through a vein usually in your arm or a central venous catheter (catheter placed into a large vein), over a 1-2 hour period, depending on the dose you will receive.
  - 1 sentence, 19.2 grade level

- The study drug will be given to you by intravenous (IV) infusion (IV). We usually use a vein in your arm for the infusion. The drug may instead be given through a central venous catheter. A catheter is a tube placed into a large vein. Your study doctor will determine the best way to give you the drug. The infusion will take about 1-2 hours.
  - 6 sentences, 5.6 grade level
Use “You” and “We”

- Avoids passive sentences and circuitous language.

- None of the currently available treatments for advanced melanoma are certain to be curative, so new treatments or combinations of treatments need to be developed. vs.

- There are no certain cures for advanced cutaneous melanoma. We want to find new treatments or combinations of treatments. We hope these new treatments will work better than the current ones.
Define terms in sentences, not asides.

• Current treatment is largely based on using drugs such as pyridostigmine (which is used to help block some of the activity of this disease), and prednisone (a corticosteroid drug used to help control and improve disease symptoms)...

vs.

• Current treatment is largely based on using drugs such as pyridostigmine and prednisone. Pyridostigmine helps block some of the activity of this disease. Prednisone is a corticosteroid drug that helps control and improve disease symptoms.
Keep Parentheses Minimal (part 2)

Or use lay language first, then put the technical terms in parentheses.

- grade 2 conduction block (a condition in which the electrical activity of the top of the heart is delayed in getting to the bottom of the heart)
- a condition in which the electrical activity of the top of the heart is delayed in getting to the bottom of the heart (grade 2 conduction block)

- changes in the cornea (the front part of the eye)
- changes in the front part of the eye (cornea)
Keep Formatting Simple (part 1)

Don’t do this:

In the event of an injury or illness resulting from your participation in this research study, your study doctor will TRY TO HELP YOU GET appropriate health care, including first aid, emergency treatment and follow-up care either at Emory University or another appropriate health care facility. If you experience an illness, adverse event, or injury that is the direct result of a medication, device, intervention, procedure, or test required for this study, THE SPONSOR will pay usual and customary medical fees for reasonable and necessary treatment. NEITHER the sponsor NOR EMORY UNIVERSITY PLAN TO PAY FOR expenses that COME FROM pre-existing medical conditions, underlying disease, or your FAILURE TO FOLLOW THE STUDY INSTRUCTIONS OR PROTOCOL. In addition, THE SPONSOR DOES NOT PLAN TO pay for expenses that result from Emory’s negligence OR WILLFUL misconduct. The study doctor and THE SPONSOR will determine if the adverse event or injury was a result of your participation in this study. If the cost of treating your research related injury was incorrectly billed to a government program by Emory University, the payment will be returned and THE SPONSOR will be billed. By signing this form you have not given up your legal rights. EMORY DOES NOT PLAN TO PAY ANY EXPENSES FOR STUDY RELATED ILLNESS OR INJURY UNLESS DIRECTLY CAUSED BY EMORY’S NEGLIGENCE OR WILLFUL MISCONDUCT.
Keep Formatting Simple (part 2)

- Be consistent in font choice and size throughout the consent.

- Use bold, italic, underline, and caps lock sparingly in body text, if at all.

- Use Left Aligned text, not Justified.
The Basics

• The document should be written at the eighth grade reading level.
• Use one or two syllable words whenever possible
• Write short sentences and paragraphs
• Define all medical or technical terms in lay language
• Organize information in sections with clear headings
• Print all headings in bold
• Use spacing to emphasize important concepts
• Avoid contractions such as ‘don’t’
• Address the consent document to the reader by using the active voice and the word “you” throughout
Other Tips

- Bulleted Lists are your friends, particularly in Risks/Side Effects sections.

- Older patients (and IRB members) appreciate larger fonts.

- Use subject initials instead of check-marks, especially for opt-in sections for future use of tissue for research.

- Use the current templates. We’re always updating and improving them!
If the Research Study involves medical treatment, then, in order to maintain the integrity of the research study, you generally will not have access to your personal health information related to this Research Study until the study is complete. When the study is complete, then, at your request, you may generally have access to any of your personal health information related to the research that makes up a part of the medical information and/or other records that your health care providers use to make decisions about you. If access to this information is needed before the end of the Research Study for your treatment, then the information may be provided to your physician.
New Emory HIPAA Template

During the study you will generally not have access to records related to the research study. This is to preserve the integrity of the research. You may have access to these records when the study is complete. These records may include research related PHI your health care providers use to make decisions about your care. If necessary for your care, this information may be available to your doctor before the end of the study.
Example 1 (Handout) Problems

- 13.2 average grade level
- Conflates the Introduction and the Purpose
- Puts the number of subjects in the voluntary participation study
- Inconsistent formatting of section titles
- Blue and italicized
Example 1 Solutions

- Independent Introduction section using the IRB template
- Move the number of patients to the introduction
- Include the number of local patients
- Edit the language in the purpose section
  - Now reads at an 8.8 grade level
- Simplify and standardize the voluntary participation title
- No more blue, no more italics
Example 2

If you are eligible for this study, you will be randomly assigned to one of the two study groups described below. There is a 50/50 chance (like flipping a coin) that the study medicine given to you will contain clopidogrel. This means that half of the patients in this study will receive treatment with clopidogrel and half of the patients will receive placebo (treatment that does not contain clopidogrel).
Example 2(revised)

There are two groups in this study. If you are eligible for this study, you will be randomly assigned to one of them. There is a 50/50 chance (like flipping a coin) to be in either group. One group will get clopidogrel. The other groups will receive a *placebo*. A placebo is a pill that contains no medicine. Placebos are regularly used in research to help make comparisons between two treatments. Neither you nor your study doctor will not which group you are in. This type of study design is called *double-blind*. The information about which group you are in will be available in case of an emergency.
NIH Sample Cancer Consent

- Some of our template sections must be used instead, but the remaining sections of this sample are useful
Resources

- [http://www.med.umich.edu/irbmed/guidance/guide.htm](http://www.med.umich.edu/irbmed/guidance/guide.htm)
- Emory IRB ICF staff reviewers:
  - Sarah Clark [skclar2@emory.edu](mailto:skclar2@emory.edu)
  - Sean Kiskel [skiskel@emory.edu](mailto:skiskel@emory.edu)
  - Madeline Peyton [mpeyto2@emory.edu](mailto:mpeyto2@emory.edu)
  - Rebecca Rousselle [rrous2@emory.edu](mailto:rrous2@emory.edu)
  - IRB Helpdesk, Fridays 11 am – 1 pm
    - Winship, Fridays 1 – 3 PM @ CTO Office