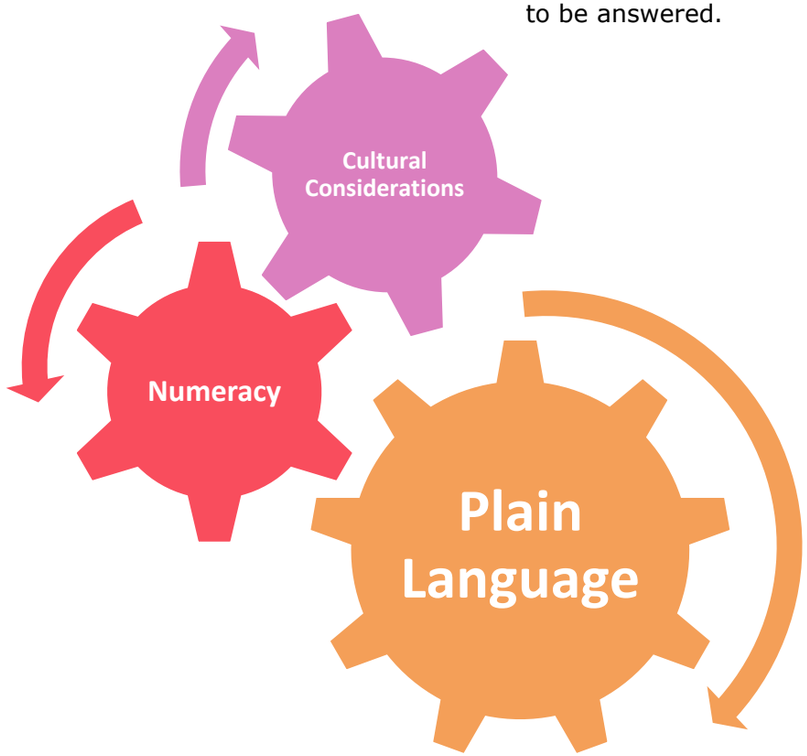
"Informed Consent" is a process, not just a one-time event. There are three elements to consider when creating informed consent documents: **Plain Language**, **Numeracy**, and **Cultural Considerations**. These elements, like gears, work together to ensure patient understanding and comprehension during the consent process. When creating a consent form, you are creating documentation of the consent process; therefore, it is critically important that information that could impact a person's decision to continue in a study be provided in a timely manner and in a clear and transparent way. This document provides guidelines for writing a consent form that best supports patient understanding and comprehension.

Numeracy:

Numeric concepts can be challenging to explain and hard to understand, especially when presented with other technical information; therefore, ensuring a patient understands numeric concepts may require extra attention during the consent process.

- If courses or cycles of treatment are used, please define them. For example, "You will receive four courses of treatment for the study. Each course of treatment occurs once every four weeks."
- Consider creating a visual representation of the study visit schedule to increase the likelihood that a potential participant has enough information to decide whether they can commit to being in a study that may impact their day-to-day routine.
- Keep in mind that the best approach to an understandable schedule of events might be to include information on 'what's typical' for a study visit and then highlight 'the special procedures to be aware of' (Corneli et al, 2017).
- If your study involves drawing blood, identify how much blood will be taken from the participant in tablespoons or teaspoons. Include how much blood will be drawn at each blood draw as well as the total amount of blood to be taken over the course of the study. (Conversions: 5ml = 1 teaspoon; 15 ml= 1 tablespoon).



Cultural Considerations:

Understanding how the study population typically approaches decision making and the role of community or other authorities is important.

- For example:
  - A patient may defer to their physician during a clinical encounter if that physician is the one explaining the research and obtaining consent.
  - The patient may be uncomfortable asking important and relevant questions or want to avoid "disappointing" their doctor.
  - A young adult may defer to his father, or a woman to her husband, for permission to enroll.
  - Consent of the community 'elder' may be required in some communities.
- Consider techniques that involve the participant to engage in active listening, such as "teach back" techniques.
- Ensure enough time is left for a one-on-one conversation to occur, and all questions to be answered.

Plain language:

The consent process is a teaching opportunity for the communicator that allows for a more thoughtful approach to conveying research information to promote participant understanding. The communicator should strive to simplify complex terms, concepts and procedures using *plain language*.

- 6th to 8th grade reading level
- Present only the most necessary information.
- Use the Active Voice.
- Use understandable, non-technical, common, everyday words.
- Scientific or medical terminology should be explained or defined in lay language.
- If you use an abbreviation, use it in its full form at its first use with the abbreviation following it in parentheses. Thereafter, the abbreviation can be used without further definition. Do not use symbols.
- Several drugs have more than one name. Use only one drug name throughout the consent form and present it consistently throughout.
- Use the same words throughout the consent form. For example, if you use the phrase "radiation therapy" at the beginning of the consent form, do not use "radiotherapy" or "irradiation" later.

Use the Prisma Health Informed Consent Template document when creating your ICF. Use the above guidelines to ensure comprehension and understanding among potential participants, as well as IRB approval of your proposed ICF.