The general regulations (§46.116) state these broad points:

- The prospective subject must have sufficient opportunity to consider whether or not to participate
- The possibility of coercion or undue influence must be minimized
- The information that is given must be in language that is understandable to the subject.
- No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive legal rights or the researchers from liability. For examples, see: www.hhs.gov/ohrp/regulations-and-policy/guidance/exculpatory-language-in-informed-consent-documents/index.html.
- Consent must be documented, unless otherwise waived by the IRB.
- ★ **NEW as of 2019**: Informed consent must present information in sufficient detail and must be organized and presented in a way that facilitates understanding of why one may or may not want to participate.

The following are the REQUIRED basic elements of consent:

- ★ **NEW as of 2019**: **Consent Summary**—Informed consent must begin with a concise, organized, and focused presentation of the key information that is most likely to assist a prospective subject in understanding why one might or might not want to participate.
- A statement that the study involves research
- An explanation of the purposes of the research
- The expected duration of the subject's participation
- A description of the procedures to be followed (experimental procedures must be identified)
- A description of any reasonably foreseeable risks or discomforts
- A description of any benefits to the subject or to others
- Contact information for questions about the study, research subject's rights and who to call if injury occurs
- A statement that participation is voluntary
- A statement that the subject may refuse to participate/withdraw without penalty or loss of benefits
- A disclosure of alternative procedures
- A description of how confidentiality will be maintained
- An explanation of any compensation/medical treatment available if injury occurs (required for greater than minimal risk research)
- ★ **NEW as of 2019**: **Future Use**—A statement about whether the research involves any plans for the future use of the private information and/or specimens collected. Only one of the following should be included:
  - ★ A statement that data and, if applicable, specimens will not be stored or distributed for future research studies.
  - ★ A statement that data and, if applicable, specimens will be de-identified, and could be stored and distributed for future research studies without additional informed consent.
  - ★ A statement that identifiable data and, if applicable, specimens will be stored and distributed for future research studies without additional informed consent. Additionally, the following elements are required if **identifiable** data and/or specimens may be stored and shared for future use:

Commented [A1]: If you as the reviewer noticed any of these elements are missing or insufficient, your edits should be incorporated into a draft of the ICF with these comment bubbles providing instruction on location and preferred language for each change.

Remember: the IRB staff who communicate your requests to the study team after the meeting have not performed a thorough review of the documents as you have and may not be able to develop appropriate language for your changes without your assistance.

- ★ A statement about which identifiers will be retained and shared with data/specimens.
- ★ The types of institutions or researchers that might conduct research with the data/specimens.
- ★ A description of the period of time that the data/ biospecimens may be stored, maintained, and used for research purposes. If indefinite, this should be stated.
- ★ A general description of the types of research that may be conducted with the data/ specimens.
- ★ A statement regarding whether subjects will or will not be informed of the details of any subsequent research, and that they may not have chosen to consent to the future research.
- ★ A statement regarding whether clinically relevant research results, will be disclosed to subjects, and if so, under what conditions.
- ★ Specifically related to the future use: A description of: how confidentiality will be maintained during storage/ sharing, reasonably foreseeable risks and benefits of future research use, and who to contact with any questions about future use/storage and research related harms.

The following elements of consent should be included when appropriate:

- ♦ A statement that there may be unforeseeable risks
- ♦ The circumstances when subject participation may be terminated by the investigator
- ♦ Any additional costs to the subject
- ♦ The consequences of a subject's decision to withdraw/explanation of how to withdraw
- ♦ A statement that significant new findings which may affect willingness to continue participation will be provided to the subject
- ♦ The approximate number of subjects involved in the study.

★ **NEW as of 2019**: **Returning Research Results—**A statement regarding whether *clinically relevant* research results, will be disclosed to subjects, and if so, under what conditions. NOTE: This may apply to research with biospecimens as well as research with any diagnostic devices.

★ **NEW as of 2019**: **Collection of Identifiable Biospecimens—**When the study involves the collection of identifiable biospecimens, the following elements of consent are required:

- ★ A statement that the biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this profit
- ★ A statement regarding whether the research will or might include whole genome sequencing.