**Informed Consent Requirements** – This guidance on the contents of good informed consent begins with items that address the presentation for consent. Remember consent is more than an informational form with a signature. It is a process. All the elements presented below will not be necessary in every consent form. It depends on the type of research. 45CFR46.116

**Required elements**

1. Investigator must obtain informed consent from the subject or their legally authorized representative, unless there is IRB approval for waiver or alteration.
2. Time for discussion and consideration is provided and coercion or undue influence is minimized.
3. Information is provided in a language understandable by the subject or legally authorized representative.
4. The information provided must meet the expectations of a reasonable person to make an informed decision.
5. At the top of the consent form, concise key information should be provided that explains why a person would or would not want to participate.
6. The consent form cannot take away any rights from the subject or any responsibility for the subject’s safety and privacy from the researcher or the institution.

**Basic elements that should be present unless waived or altered via IRB approval**

* 1. A statement declaring that the study is research,
  2. The purpose of the research,
  3. An explanation of the subject’s expected duration of participation and time commitment,
  4. A description of the procedures. Experimental medical procedures must be declared as experimental, i.e. procedures never used in humans before,
  5. A description of expected risks or discomforts,
  6. A description of expected benefits to the subject or others,
  7. A disclosure of any alternative procedures or treatments (usually applies to medical research),
  8. A statement about the expectation of confidentiality,
  9. If more than minimal risk, a description of any compensation and/or any support services, including mental health counseling if psychological distress/trauma, or medical treatment if physical injury occurs,
  10. A statement explaining how to contact the researcher with questions about the research, use of their data or to report an injury due to participation,
  11. A statement similar to:If you have questions about your rights as a participant in the study, contact the IRB Chair via [irb@louisiana.edu](mailto:irb@louisiana.edu) or 337-482-5811,
  12. A statement that participation is voluntary, refusing to participate will not result in penalty or loss of benefits and withdrawal may happen at any time without penalty or loss of benefits,
  13. When identifiable information or biological specimens are collected, a statement similar to one of the following statements:
      1. Your identifying information might be removed from the data (and/or specimens) so that future or additional research can be performed without obtaining your consent for new study. This research may be performed by other researchers.
      2. Your data (and/or specimens) will not be used or distributed for use in future research even if your identifying information is removed.

**Additional elements of informed consent may be needed** in the informed consent document, depending on the circumstances of the study

* 1. A statement that the treatment or procedure may involve unforeseeable risks to the participant or fetus, if appropriate.
  2. A statement indicating the circumstances that the investigator would end a subject’s participation.
  3. A statement about any costs for participating
  4. The consequences of withdrawing and procedures for termination. This is usually a concern with new medical treatments where a doctor may have to schedule a procedure to remove a medical device or the patient may need to wean off a medication in order to avoid adverse physiological consequences.
  5. A statement that new findings that would affect a participant’s willingness to continue will be shared.
  6. A statement about the approximate number of participants in a study.
  7. When appropriate, a statement that specimens will be used for commercial profit and whether the subject will or will not share in the profits.
  8. A statement indicating whether clinically relevant results will be shared with the participant and how that information will be provided.
  9. When biospecimens are taken, a statement indicating whether whole genome sequencing will be performed.

**Broad Consent** may be used only for storage, maintenance and secondary research of identifiable private information or biological specimens. This type of consent is generally used with tissue banks, etc, where there is no primary research project.

1. The Broad Consent Form must contain (these cannot be waived or altered)
2. A description of expected risks or discomforts,
3. A description of expected benefits to the subject or others
4. A statement about the expectation of confidentiality
5. A statement that participation is voluntary, refusing to participate will not result in penalty or loss of benefits and withdrawal may happen at any time without penalty or loss of benefits
6. When appropriate, a statement that specimens will be used for commercial profit and whether the subject will or will not share in the profits.
7. When biospecimens are taken, a statement indicating whether whole genome sequencing will be performed.
8. A general description of the types of research that may be conducted with the identifiable information or biological specimens.
9. A description of the identifiable data or specimens that might be used, how it might be shared, what type of institutions or researchers might conduct research with the information or specimen.
10. An explanation of how long the information or specimens will be stored for future use.
11. If the participant will not be informed about the future use of their data or specimen, there should be a statement explaining this.
12. There should also be a statement that clinically relevant results will not be shared with them, unless there is a plan to do so.
13. There should be a statement about who the participant can contact with questions about their rights as participants. Refer to the IRB chair.
14. There should be a statement about who the participant can contact with questions about the storage and use of their private identifiable information or specimens and who to contact in the event of a research-related harm.

**Waiver or alteration of consent for research on public benefits or service programs. 45CFR46.116(e)**

**NOTE –** When a participant has been offered an opportunity to provide broad consent and declined, the IRB cannot waive consent. 45CFR46.116(e)(1)

**The IRB must determine and document the following:**

1. The project is conducted by or subject to approval of state or local government officials and designed to study:
   1. Public benefits or service programs
   2. Procedures for obtaining benefits or services
   3. Possible changes in programs or procedures
   4. Possible changes in methods or levels of payment for benefits or services
2. The research could not happen without the waiver or alteration of consent.

**General waiver or alteration of informed consent. 45CFR46.116(f)**

**NOTE –** When a participant has been offered an opportunity to provide broad consent and declined, the IRB cannot waive consent. 45CFR46.116(f)(1)

**The IRB must determine and document the following:**

1. The research is no more than minimal risk
2. The research could not happen without the waiver or alteration of consent.
3. If the research involves identifiable information or specimens, it could not happen without alteration or waiver
4. Waiver or alteration does not adversely affect the rights and welfare of the participants.
5. When appropriate, participants or their representatives will be provided additional pertinent information after participation.

**Screening without consent**

An IRB can approve gathering information or specimens from potential participants without Informed Consent if either of the following is true:

1. Information is received via oral or written communication
2. Identifiable information or specimens are received by accessing records or stored specimens.