1. Concise and focused presentation of **key information** Assist in understanding they reason why one **may or MAY NOT** want to participate in research
    - The purpose and duration of the research (and that it is a RESEARCH study)
    - Top two or three risks that would be most important for a participant to know about
    - A description of procedures, identifying experimental procedures

2. **Organized** to facilitate comprehension

Body of Consent

3. **Statement** that the study involves **research**
4. An explanation of the **purpose** of the research
5. Expected **duration** of patient participation
6. Description of any **procedures** which will be followed
7. Identification of **experimental** procedures
8. A description of foreseeable **risks** and discomforts for the subject
9. A description of the foreseeable **benefits** for the patient or others
10. A disclosure of any appropriate **alternate procedures**
11. A description of how and to what extent **confidentiality** will be maintained
12. A statement that the **FDA may inspect** the project records *(if FDA regulated research)*
13. An explanation of compensation and the availability of medical treatments with **research-related injury** *(for research involving greater than minimal risk)*
14. An explanation of whom to **contact** if questions should arise about the research or the **patients' rights** should injury occur
15. A statement that participation is **voluntary**
16. A statement that the patient's **refusal to participate** shall involve **no penalty or loss of benefits** to which the patient is otherwise entitled
17. A statement that the patient **can discontinue participation** at any time **without penalty or loss of benefits** to which the patient is otherwise entitled

    **NEW REQUIREMENT
18. Research **collecting identifiable private information** and/or identifiable biospecimens must;
    - State that collected samples/data **may be de-identified and used** for future research or be given to another investigator for future research without additional Informed consent **OR**
    - State that collected samples/data **will not be used** or distributed for future research…even if de-identified

ADDITIONAL ELEMENTS OF INFORMED CONSENT—When appropriate, one or more of the following elements of information shall also be provided on each subject

*1. A statement that the procedure may involve **unforeseeable risk**
*2. A description of the circumstances under which **the patient's participation may be terminated by the investigator** without the patients consent
*3. A statement regarding any **additional costs** to the patient resulting in participating in the research.
*4. A statement regarding the **consequences of a patient's decision to withdraw from research.**
*5. A statement that significant **new findings** developed during research which may relate to the patient's **willingness to continue** participation will be communicated
*6. Approximate number of subjects anticipated to be involved in the study
*7. A statement that includes the **Covenant IRB Chairperson or designee** and telephone number as a contact for patients

*8. A statement that addresses investigator **conflict of interest,** or explanation why such a statement is not necessary for the protection of human subjects.
*9. Statement that **biospecimens**, even if de-identified, may be used for **commercial profit…**and whether/if that profit will be shared
*10. Statement regarding whether **clinically relevant research results** will be given to the subject, and under what conditions
*11. For research involving biospecimens, whether the research will or might include (specifically) **whole genome or exome sequencing**

Additional FDA requirements

1. If FDA Clinical Trial, must have the following statement; **" A description of this clinical trial will be available on http://www.ClinicalTrails.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."**