Informed Consent 101:

Basic Elements of Informed Consent

In seeking informed consent, the following information must be provided to each subject:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any products which are experimental.

The statement that the study involves research is particularly important for clinical research because the relationship between patient-physician is different than that between subject-investigator.

Any procedures relating solely to research (e.g., randomization and placebo control) should be explained to the subjects. The procedures subjects will encounter also should be clearly outlined in the consent document.
Consent documents for studies of investigational articles (drugs, biologics or devices) should include a statement that a purpose of the study includes an evaluation of the safety of the test article. Statements that indicate test articles are safe or statements that the safety has been established in other studies are not appropriate when the purpose of the study includes the determination of safety. Studies that involve efficacy should also include the effectiveness of the test article, as a study purpose, but should not make claims of effectiveness.

2. **A description of any reasonably foreseeable risks or discomforts to the subject.**

The risks of procedures relating solely to research should be explained in the consent document. Risks and discomforts include physical, psychological, social and economic harm. The risks of the tests required in the study protocol should be explained, especially for tests that carry significant risk of morbidity/mortality themselves.

3. **A description of any benefits to the subject or to others which may reasonably be expected from the research.**

The description of benefits to the subject should be clear and not overstated. If no direct benefit is anticipated, that should be stated. Potential societal benefits should also be included. Also, when benefits may accrue to the investigator, the sponsor, or others, these benefits may be materially relevant to the subject's decision to participate, and they should be disclosed in the informed consent document.

4. **A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.**

To enable a rational choice to participate in the research study, subjects should be made aware of the full range of options available to them. Consent documents should briefly explain any pertinent alternatives to entering the study. As with other required elements, the consent document should contain sufficient information to ensure an informed decision.

5. **A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that external regulatory agencies, such as the Food and Drug Administration, may inspect the records.**

Study subjects should be informed of the extent to which the institution intends to maintain confidentiality of records identifying the subjects. In addition, they should be informed that external regulatory agencies, such as the FDA, may inspect study records (which include individual medical records). If any other
entity, such as the sponsor of the study, may gain access to the study records, the subjects should be so informed.

6. **For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.**

   An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

   This requirement contains three components, each of which should be specifically addressed. The consent document should provide the name of a specific office or person and the telephone number to contact for answers to questions about:

   1. the research subjects' rights;
   2. the research study itself.

7. **A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.**

**Additional Elements of Informed Consent**

*When appropriate, one or more of the following elements of information shall also be provided to each subject:*

1. **A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.**

   A statement that there may be unforeseen risks to the embryo or fetus may not be sufficient if animal data are not available to help predict the risk to a human fetus. Investigators should ensure that subjects who agree to enter a study fully understand the potential risks that the study poses. If measures (e.g., use of contraception) to prevent pregnancy should be taken while in the study, that should be explained.
2. **Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.**

When applicable, subjects should be informed of circumstances under which their participation may be terminated by the investigator without the subject's consent. An unexplained statement that the investigator and/or sponsor may withdraw subjects at any time, does not adequately inform the subjects of anticipated circumstances for such withdrawal.

A statement that the investigator may withdraw subjects if they do not "follow study procedures" is not appropriate. Subjects are not in a position to know all the study procedures. Subjects may be informed, however, that they may be withdrawn if they do not follow the instructions given to them by the investigator.

3. **Any additional costs to the subject that may result from participation in the research.**

If the subjects may incur an expense because they are participating in the research, the costs must be explained in sufficient detail as to prepare the potential subject for such a possibility.

4. **The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.**

When withdrawal from a research study may have deleterious effects on the subject's health or welfare, the informed consent should explain any withdrawal procedures that are necessary for the subject's safety and specifically state why they are important to the subject's welfare. An unexplained statement that the subject will be asked to submit to tests prior to withdrawal, does not adequately inform the subjects why the tests are necessary for the subject's welfare.

5. **A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.**

When it is anticipated that significant new findings that would be pertinent to subject's continued participation are likely, the IRB should determine that a system, or a reasonable plan, exists to make such notification to subjects.

6. **The approximate number of subjects involved in the study.**

If the numbers of subjects in a study is material to the subject's decision to participate, the subjects should be told not only the approximate number of subjects involved in the study, but also why the number of participants is important (e.g., a small number may compromise confidentiality).
In Conclusion:

Informed Consent is a tool used for the Protection of Human Subjects.