

INFORMED CONSENT GUIDANCE

WHAT IS INFORMED CONSENT?

***Informed Consent** – is both a form and a process by which a subject gains an understanding of the research and his or her rights, the procedures, as well as the potential risks and benefits of participation. Informed Consent must be obtained for all types of human subjects' research including; diagnostic, therapeutic, interventional, social and behavioral studies, and for research conducted domestically or abroad.*

The above definition applies to all study participants 18 years of age or older. The process begins with the recruitment or screening of a subject, and continues throughout the subject's involvement in the research. It is important that your informed consent include all the information necessary for the patient to make an educated decision as to whether or not they wish to participate in the study. If a person is under the age of 18 (or legal age of consent) an **Assent Form** must be used. Assent requires the same level of clarity but is often presented in an age appropriate means (See Assent Guidance). Below you will find a set of guidelines, and their descriptions, to assist you in writing a clear, comprehensive and concise **Informed Consent**.

INFORMED CONSENT GUIDELINES

INFORMED CONSENT LAYOUT

The informed consent document should be clearly labeled “Informed Consent” and the following should be easily identifiable:

- The Institution the research is affiliated with (as well as the department, if applicable), which may be done in the form of a seal or emblem.
- The Title of the research
- The Principal Investigator's name
- Each page should be numbered (e.g. 1 of 4; 2 of 4; 3 of...)

- There should be a place for the participant to initial on each page in addition to the authorization section and signature line on the final page of the form

INFORMED CONENT LANGUAGE

It is important to make sure that the informed consent is easily understandable. The following should be considered when writing your form:

- Write in second person
- Use simple language
 - Reading level should be 8th grade or lower
 - Do not use words that are over 3 syllables
 - Do not use sentences that are over 20 words
 - Do not use paragraphs that are over 10 sentences
 - **DO NOT USE MEDICAL TERMINOLOGY**
 - Do not go into excessive detail, only state vital information
- Make it visually appealing
 - Use large readable fonts, but not too large unless working with elders
 - Leave an effective amount of white space
 - Bullets, Tables, Timelines, Diagrams, etc. are always better
 - Avoid using too much **bold**, *italics*, underlining, and “quotes”
 - Use clear section headings
- Use exact language when appropriate
 - Examples where exact language is appropriate
 - Pharmaceutical companies
 - Standard statement for injury and compensations section
 - Total amount of blood drawn
 - Venipuncture risk statement
 - Exact amount of blood drawn for research purposes
 - Risks involving X-ray, CT, MRI, etc.
 - Include proper dose estimates for each procedure and total amounts in the radiation risks statement (a chart or table might serve best)
- Diagrams and study calendars may be included

- Adequately describe the study and its procedures

INTRODUCTORY SECTION

The introductory section should inform the participant that they are being asked to participate in a research study, then explain why, and provide inclusion and exclusion criteria. It should tell the participant that they are allowed to ask as many questions as they want at any time (before, during or after the study). The introduction should the PI and give a number for contacting them so the participant may contact them with further questions. If this is an adult study, a statement such as, *“You must be at least 18 years of age to participate in this study”* should also be included in the introduction.

PROJECT DESCRIPTION

Describe the nature, purpose and duration of the study/project. Make sure it is understandable. Be sure to include the total amount of participants and any future studies that will occur with their data.

WHAT WILL BE DONE

Explain what will happen to the participant, how long they will be involved in this study, and any incentives they will receive. Details describing which part(s) of the study are considered experimental need to be included and any alternative procedures should be explained.

RISK OR DISCOMFORT TO THE PATIENT

State any expected risks or discomforts for the participant. Note that it is near impossible to have a “no risk” study.

BENEFITS OF PARTICIPATING IN THIS STUDY

Explain the benefits that the participant or others will receive as a result of their participation. If there are no expected benefits for the participant, a sentence, such as the following may be included: *“Although there are no benefits to you directly, researchers will be able to learn more about weight loss.”*

DECISION TO QUIT AT ANY TIME

A sentence similar to the following may be used: *“The decision to take part in this study is up to you. You do not have to participate. If you decide to take part in this study, you may quit at any time. You will in no way be penalized for your decision. If you wish to quit, please contact ...”*

CONFIDENTIALITY

Explain how you will keep the information, as well as the participant’s identity, confidential, private or anonymous. Consider the following sentence: *“Your part in this study is confidential. None of the information will identify you by name. All records will be compiled into one report.”*

** If an investigational new drug or device is being used, the subject must be advised that the FDA has the privilege of inspecting records.

** If this study involves information that must legally be reported to government agencies, a statement similar to the following must be included: *“Your part in this study is confidential within legal limits. The researchers and the University of Amazing will protect your privacy, unless they are required by law to report information to city, state or federal authorities, or to give information to a court of law. Otherwise, none of the information will identify you by name. All records will be encrypted on a university protected server.”*

IN CASE OF INJURY TO THE SUBJECT (IF APPLICABLE)

This section should explain any medical treatments that are available if injuries occur and who the participant would need to contact. Consider the following: *“If this study causes you any injury, you should write or call [name of investigator, etc.] at the University of Amazing at 867-555-5309. You may also contact...”*

RIGHTS AND COMPLAINTS

Language such as the following should be included: *“If you are not satisfied with the way this study is performed, you may discuss your complaints with [PI’s name] or with the University of Amazing’s IRB anonymously, if you choose.”*

CONSENT

If the patient agrees to participate, this is the section that needs to be filled out by them. Consider the following: *“I have read the Informed Consent and my questions have been answered. My signature on this form means that I have no additional questions and I agree to participate in this study.”* Signatures as well as printed names and the date signed should be acquired from both the patient and the researcher.

** A copy of the consent form should be given to the patient for their records.