

The general regulations 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.
- Consent must be documented

Section A indicates that the following elements of consent are REQUIRED:

- ◆ A statement that the study involves research
- ◆ An explanation of the purposes of the research
- ◆ Contact information for questions about the study, research subject's rights and who to call if injury occurs
- ◆ A statement that participation is voluntary

These top 4 elements are required for all research regardless of risk level.

The elements below are additional required elements for research that is greater than minimal

- ◆ 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
- ◆ 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)
- ◆ A statement that the subject may refuse to participate/withdraw without penalty or loss of benefits

Section B provides elements of consent which are OPTIONAL

- ❖ 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.

Comment [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 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.

Comment [A2]: If you as the reviewer are requesting that optional elements be added to an ICF, please be sure to clarify whether each change is required for approval or is only recommended/optional.