ELEMENTS OF INFORMED CONSENT:

Consider the following as you prepare your submission.

Will informed consent be sought and appropriately documented? Do proposed alterations or waivers of informed consent meet the criteria for approval? The IRB reviews each consent form for:

- *Purpose* of the research
- *Procedures* involved in the research
- *Length of time* the subject is expected to participate
- *Alternatives* available should a subject decide not to participate in the research
- All *foreseeable risks and discomforts* to the subject. These include not only physical injury but also possible psychological, social, or economic harm, discomfort, or inconvenience.
- *Benefits* of the research to society and possibly to the individual human subject
- *Payment or inducement* for participation (if applicable)
- *Person to contact* for answers to questions or in the event of a research-related injury or emergency
- Statement that *participation is voluntary* and that refusal to participate will not result in any consequences or any loss of benefits that the person is otherwise entitled to receive*
- Subjects' *right to confidentiality and right to withdraw* from the study at any time without any consequences*

*Instructions on questionnaires should also remind respondents of elements

See: *Collaborative Institutional Training Initiative* program – https://www.citiprogram.org/default.asp?language=english (based on U.S. Department of Health and Human Services regulations at 45 CFR part 46)