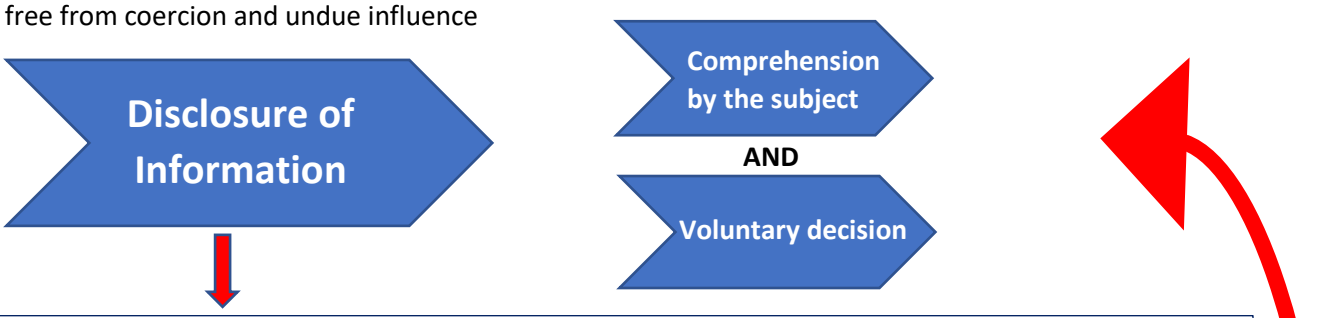
IRB Member's Role in Review of the Informed Consent Document

- The *Belmont Report* principle of respect for persons, as reflected in the consent process, contains three elements described below.
- When IRB members review consent forms, particularly at the time of initial review and when new consent language is being added because of a study modification, they have a responsibility to determine that the informed consent form (ICF) is written in a way that will help facilitate the key elements of this process.

THREE KEY ELEMENTS

1) **Disclosing information** to potential research subjects needed to make an informed decision
2) **Facilitating the understanding** of what has been disclosed
3) **Promoting the voluntariness of the decision** about whether to participate in the research under conditions that are free from coercion and undue influence



In reviewing the consent form, what can IRB members do to promote disclosure of information that will help facilitate subjects' understanding of the study and voluntariness of their subsequent decision to participate?

- Confirm inclusion of required basic elements of consent and any of the applicable additional elements. (See checklist on page 2 for 2018 Common Rule requirements.)
- Level and complexity of information in the ICF should be appropriate and culturally sensitive for the proposed study population. The consent should use understandable lay terms as much as possible.
  - While Board members should not rewrite the proposed ICF based on personal preferences, check to see if it is targeted at the recommended 6th-8th grade reading level using plain language to replace technical terms. Instructions to check readability statistics in Microsoft Word are here.
  - Use available resources to simplify complicated terms, risk, side effects, etc.*
- Key information section should communicate material most relevant from potential subjects' perspective.
- Required template language should be included appropriately.
- Risks are disclosed in a clear and understandable manner. (If the study is an interventional trial, does the risk section accurately reflect reasonably foreseeable risks included in the IB, package insert or device information?)
- Procedures should be accurately described in an understandable manner.
- Potential for direct benefit (if any) is realistically described.
- When enrolling minors, confirm there is an age-appropriate assent form, as applicable, with information conveyed in a meaningful manner. (Investigators should use the OHSRP assent template.)
- As applicable, the ICF should describe appropriate reward, compensation, or non-monetary incentive in such a way that undue influence is avoided.
- Consent form must be free of exculpatory language meaning it must not waive or appear to waive the rights of the subject or release or appear to release those conducting the study from liability for negligence.

* PRISM Alternative Wording Suggestions Appendix B
NCCN Informed Consent Language (ICL) Database
NCI Risk Terms Library MICROMEDEX Scientific Terms - Consent Terms Excel Spreadsheet-Risks AE Terminology
Resources for Assents: Children's Hospital of Philadelphia Glossary of Lay Terms; and Kids' Medical Dictionary (Nemours)

Basic elements that must be included in the consent form under the 2018 Common Rule (unless waived by the IRB)

- ☐ Statement that the study involves research (including purpose, duration of subject's participation, research procedures and identification of any experimental procedures)
- ☐ Description of reasonably foreseeable risks or discomforts
- ☐ Description of any benefits to the subject or to others that may reasonably be expected from the research
- ☐ Appropriate alternative procedures or treatment, if any, that might help the subject
- ☐ Description of how confidentiality of records identifying the subject will be maintained
- ☐ If the research is greater than minimal risk, include the following: a) explanation as to whether any compensation will be provided; and b) explanation as to whether medical treatments are available if injury occurs, what they consist of, and where further information may be obtained
- ☐ Information about who the subject should contact for research related questions and subjects' rights, and who to contact in the event the subject has a research-related injury
- ☐ Statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
- ☐ One of the following statements about any research involving collection of identifiable private information or identifiable biospecimens:
  - i) Statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or LAR, if this might be a possibility; or
  - (ii) Statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional elements of informed consent that must be included if applicable

- ☐ 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) that are currently unforeseeable
- ☐ Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or LAR's consent
- ☐ Any additional costs to the subject that may result from participation in the research
- ☐ Consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- ☐ Statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject
- ☐ Approximate number of subjects involved in the study
- ☐ Statement that subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
- ☐ A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
- ☐ For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)