

Checklist for Elements of Consent Disclosure

A consent disclosure statement must address each of the elements described in the first list below. In addition, a consent disclosure must address any elements described in the second list if they are applicable to the proposed research project. (Adapted from Tufts University IRB review documents.)

LIST 1 (required for all proposals)

- The study involves research
- The purposes of the research
- An overview of why prospective subjects might want to participate in the study
- The procedures to be followed
- The expected duration of the subject's participation
- Any anticipated risks or potential discomforts to the subject
- Any anticipated benefits to the subject or to others from the research
- The extent to which confidentiality of any records identifying the subject will be maintained
- A statement of whether or not information/specimens might be used for future studies, and an indication of how consent will be obtained in the event of future use of the information
- Participation is voluntary
- Refusal to participate will involve no penalty
- The subject may withdraw from participation at any time without penalty
- How to contact the research team with any questions, concerns, or complaints about the research
- How to contact someone outside the research team with any questions, concerns, complaints, or other input about the research

LIST 2 (required as applicable to the proposal)

- Whom to contact in the event of a research-related injury to or adverse effect on the subject
- Disclosure of whether/how clinically-relevant research results (including individual results) will be provided to the subjects
- Identification of any procedures which are experimental
- Disclosure of any alternative procedures/treatments
- A statement that a procedure might involve unforeseeable risks
- Disclosure of any potential costs to the subject as a result of participation
- Disclosure of withdrawal procedure and consequences of withdrawal by the subject
- Disclosure of potential circumstances in which the researcher might terminate a subject's participation
- A statement that any new findings that might influence a subject's continued participation will be disclosed to the subject

- The approximate size of the study
- Disclosure of whether a subject's biospecimens might be used for profit and whether or not this profit will be shared with the subject
- Disclosure of whether research on biospecimens will or might involve whole genome sequencing