Informed Consent Resource Guide

At the heart of Informed Consent is the idea that participants should be provided the necessary information to be able to make a **free and informed decision** whether to participate in a research study. This concept is rooted in the principle of Respect for Persons, as outlined in the Belmont Report, and it is further elaborated in the code of federal regulations that oversee the ethical conduct of research with human subjects.[1]

The Informed Consent process should be an active process of sharing information between the investigator/research team and the prospective participant.

Be sure to provide ample opportunity for prospective participants to ask questions and seek clarification

At a minimum, an Informed Consent document should contain the following basic elements:

- Statement that the activity is research and a description of the purpose, expected duration, procedures to be followed, and declaration of any procedures that are experimental
- Statement that participation is entirely voluntary, that refusal or withdrawal will not involve penalty or loss of benefits, that consent can be withdrawn at any time, and, that participants may skip any question or study activity they are not comfortable completing
- Description of foreseeable risks/discomforts
- Description of benefits to subject and/or others
- Disclosure of appropriate alternative procedures or treatments, if any, that might be advantageous to the subject
- Statement about confidentiality of data
- If study presents more than minimal risk, an explanation of any compensation and medical treatments if injured

[1] Protection of Human Subjects, 45 CFR § 46.102(l). URL: https://www.ecfr.gov/cgi-bin/text-idx?SID=58d96a013d3e34979d7d98ede819e917&mc=true&node=pt45.1.46&rgn=div5

- Contact person and phone number for questions about the research, their rights or in case of injury (the PI of the study should be listed at a minimum)
- For studies involving experimental drugs/devices, the CA Experimental Research Subject's Bill of Rights may also be required

Additional Tips for Creating Consent Documents

- Use clear, accurate and understandable language
- Avoid medical and scientific jargon; instead, use common, everyday language that is appropriate for the target population
- For the general population the DPH IRB recommends an **8th-grade reading level or lower**
- Use the preferred language of the prospective participant
- Must include key information section plus a detailed section
- Spell out abbreviations or acronyms the first time they are used
- Use short sentences and short paragraphs
- Avoid details that do not help participants make a decision about being in the study
- Use active voice rather than passive voice whenever possible; for example, use "We will draw a blood sample", not "A sample of blood will be drawn"
- Use bullets for long lists of procedures or risks
- Use subheadings to break up large amounts of text
- If text messaging will be used for project activities, the consent form should state that standard messaging rates will apply

Additional Elements of Informed Consent (if applicable)

Depending on the nature of your project, some of the items listed below may need to be included in your consent form in addition to the basic elements listed previously.

- Statement that the procedure may involve unforeseeable risks to subject
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the LAR's consent
- Any additional costs to the subject that may result from participation in the research; for example, travel costs to and from research site

- Consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
    - How compensation will be affected if they choose not to complete an interview
    - Discussion of what happens to data already collected
- That the subject's biospecimens, even if identifiers removed, may be used for commercial profit and whether the subject will share in this profit
- Whether clinically relevant results, including individual research results, will be disclosed to subjects, and under what conditions
- Whether the research will or might include whole genome sequencing