Additional Elements of Informed Consent

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Outline

- Additional Regulatory Elements of Informed Consent
- Additional Elements for FDA-Regulated Studies
- Additional Local/UCSD Elements of Informed Consent
- References

Additional Regulatory Elements of Informed Consent

To be included when appropriate:

- A statement that:
  - The research may involve unforeseeable risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant)
  - Significant new findings developed during the research that may affect the subject's willingness to participate will be provided to the subject
  - The subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in the profit
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without the subject's or LAR's consent
- Any costs from participating in the research
- Consequences of a decision to withdraw from the research and procedures for orderly termination of participation by the subject

Additional Regulatory Elements of Informed Consent

- Approximate number of subjects involved in the study
- A statement about whether clinically relevant research results, including individual results, will be disclosed to subjects, and if so, under what conditions
- If research involves biospecimens, whether the research will or might include whole genome sequencing
- When the research is required to be posted on clinicaltrials.gov, the following statement must be included:
  - "A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."
- When the research is funded by NIH or otherwise covered by a Certificate of Confidentiality, a statement about the protections afforded and their limitations

Additional Elements for FDA-Regulated Studies

- A statement that:
  - The FDA may inspect the records
  - The data collected on the subject to the point of withdrawal remains a part of the study and may not be removed
  - The study has received IRB approval
  - There is no intended clinical benefit, when this is the case
  - Monitors, auditors, the IRB, and regulatory authorities will be granted direct access to the subject's original medical records
  - Records identifying the subject will be kept confidential and will not be made publicly available to the extent permitted by law
  - If trial results are published, the subject's identity will remain confidential
- A description of the probability for random assignment to each study arm, when applicable
- When partial withdrawal is an option, a statement that the investigator will ask a subject who is withdrawing whether they wish to provide continued follow-up and data collection
- A description of the subject's responsibilities

Additional Local/UCSD Elements of Informed Consent

- If subjects will be compensated for participation and there are multiple study visits, a description of the prorated payment plan
- When using electronic consent, a clear statement of subject's rights with respect to electronic documents
- For research that meets California's definition of a medical experiment, the "Experimental Subject's Bill of Rights"
- For research conducted outside the U.S., disclosure of risks due to local context, as applicable
- No requirement that withdrawal of consent be delivered in writing
- No inclusion of HIPAA authorization language except to state that a separate document will be provided for signature
- Protocol-mandated regimens, experimental drugs, and experimental devices are not referred to as "treatment" without qualification (e.g. "study treatment")

References

- 21 CFR 50.25(b) & (c)
- 45 CFR 46.116(c)
- California Health and Safety Code Section 24172
  - Experimental Subject's Bill of Rights
- California Health and Safety Code Section 24174
  - Definition of a "medical experiment"
- OIA-314B