

INFORMED CONSENT REQUIREMENTS

CHECKLIST OF BASIC ELEMENTS REQUIRED FOR INFORMED CONSENT

Statement that study involves research

Explanation of the purpose of the research and the expected duration of the subjects' participation

A description of the procedures to be followed, and identification of any procedures that are experimental

Description of any foreseeable risks or discomforts to the subject

Description of any benefits to the subject or to others that may reasonably be expected from the research

Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject

Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained

For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained

Explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject

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

Statement that identifiers might be removed from identifiable private information or identifiable biospecimens and that, after such 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 the legally authorized representative, if this might be a possibility **OR** 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 FOR INFORMED CONSENT (AS APPLICABLE TO RESEARCH)

- Statement that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable
- Anticipated circumstances under which the subjects's participation may be terminated by the investigator without regard to the subject'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 which 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 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 this commercial profit
- 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)

GENERAL REQUIREMENTS FOR INFORMED CONSENT (REVISED COMMON RULE)

- Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative
- An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence
- The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative
- The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information
- Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension
- Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate
- No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence

DISCLOSURE: Additional requirements may apply in certain circumstances (e.g., if the research is covered by a Certificate of Confidentiality, if there is a possibility of compensation being reportable to the IRS as taxable income, if the research will be registered on ClinicalTrials.gov, if the research will occur in a hospital or clinic, if the research is FDA-regulated, etc.). Please contact the IRB Chair at irb@cocc.edu if any of these are applicable for guidance.