UIC CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

CONSENT CHECKLISTS: REGULATORY CRITERIA

For consent documents on studies that fall under convened or expedited IRB review.

GENERAL REQUIREMENTS OF INFORMED CONSENT
Common Rule 2018 Requirements **Required for all consents**
☐ Legally effective informed consent or permission is obtained before enrolling a participant in the research
☐ The possibility of coercion is minimized
☐ Research is presented in a language and fashion understandable to the subject or their representative
☐ Key information is presented at the beginning of the consent document
☐ Information is presented in sufficient detail that a reasonable person would want to know in order to make an informed decision about whether to participate.*
☐ No exculpatory language is used [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]

* NOTE: If the consent fails to disclose this, and sufficient rationale is present for excluding information, this may be allowable as deception. Information on deception can be found on the OPRS website at: https://research.uic.edu/human-subjects-irbs/policies/guidance-for-investigators-informed-consent/

BASIC ELEMENTS OF INFORMED CONSENT
Common Rule 2018 Requirements Basic Elements ***If any of the basic elements of consent are missing (except for conditional items as noted below), you will need to request and meet the criteria for an "Alteration of Consent"***
☐ Includes a statement that the study involves research
☐ Includes an explanation of the purposes of the research*
☐ Includes expected duration of the subject's participation
☐ Describes the procedures to be followed and identifies any which are experimental*
☐ Describes reasonably foreseeable risks or discomforts to the subject
☐ Describes any reasonably expected benefits to the subject or to others
☐ Discloses appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject ☐ N/A – no alternative procedures are available
☐ Describes the extent, if any, to which confidentiality of records identifying the subject will be maintained
☐ Discloses persons and entities who may have access to the records, including, as applicable, the sponsor and funding agencies

☐ UIC-specific requirement: The consent must note the possibility that the representatives of the IRB and/or UIC OPRS; representatives of the State and University responsible for ethical, regulatory, or financial oversight of research; and Government Regulatory Agencies, such as the Office for Human Research Protections (OHRP) may have access to the consent form and research records

☐ Explains options available in the case of injury, including compensation, whether any medical treatments are available (and, if so, what they consist of), or where further information may be obtained.

☐ N/A – minimal risk research does not need to include this information in the consent

☐ Explains whom to contact for answers to:

- Pertinent questions about the research
- Questions on research subjects' rights
- Whom to contact in the event of a research related injury to the subject

☐ States 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 that involves the collection of identifiable private information or identifiable biospecimens:

a) A statement that identifiers might be removed from the 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

b) A 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

* NOTE: If the consent fails to disclose this, and sufficient rationale is present for excluding information, this may be allowable as deception. Information on deception can be found on the OPRS website at: https://research.uic.edu/human-subjects-irbs/policies/guidance-for-investigators-informed-consent/

ADDITIONAL ELEMENTS OF INFORMED CONSENT

Common Rule 2018 Requirements Additional Elements:
Consent language to be added as applicable to the research.
Note that if this information is deemed applicable, but is missing from the consent, then you will need to request and meet the criteria for an "Alteration of Consent".

☐ Includes 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) which are currently unforeseeable

☐ N/A

☐ Includes anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent

☐ N/A
☐ Describes any additional costs to the subject that may result from participation in the research ☐ N/A
☐ Describes consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject ☐ N/A
☐ Includes 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 ☐ N/A
☐ Includes approximate number of subjects involved in the research ☐ N/A
☐ Includes a 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 ☐ N/A
☐ Includes statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions ☐ N/A
☐ For research involving biospecimens, describes 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) ☐ N/A
☐ For research meeting the definition of a clinical trial, the consent must include a statement that the results of the research will be posted on clinicaltrials.gov ☐ N/A