OKLAHOMA STATE UNIVERSITY INSTITUTIONAL REVIEW BOARD

**Informed Consent Checklist**

# Concise & focused presentation (45 CFR 46.116(a))

*If the informed consent is longer than 4 pages, the informed consent document must begin with a summary of the following key information. Please use the language and format provided in the informed consent template, customizing the language carefully for your study.*

* Purpose
* Duration of Study
* Procedures Summary
* Risks and/or discomforts
* Benefits
* Compensation

# Required elements (45 CFR 46.116(b))

*The following elements must be included in the informed consent statement. The informed consent statement template provides a guideline for language, which might be acceptable; however, language should be customized carefully for your study. Sections which are starred (\*) may require use of the mandatory language provided in the informed consent template, unless otherwise approved by the IRB.*

* Statement that the study involves research
* Explanation of the purposes of the research
* Description of the procedures, and identification of any procedures which are experimental
* Disclosure of appropriate alternative procedures or courses of treatment, if any
* Expected duration of participation
* Description of reasonably foreseeable risks or discomforts
* Description of any benefits that may be reasonably expected
* Statement describing the extent to which confidentiality of records identifying the subject will be maintained\*
* Description of any compensation to be given for participation in the research project
* For research involving more than minimal risk, an explanation as to whether any medical treatments are available if injury occurs\*
* Explanation of whom to contact for questions about the research and research subjects’ rights, and in the event of a research-related injury\*
* Statement that participation is voluntary, refusal to participate will not result in penalty or loss of benefits, and subjects may withdraw without penalty
* Statement that identifiers might be removed and deidentified information and/or biospecimens used for future research studies or distributed to another investigator for future research studies without additional consent OR statement that subject’s information and/or biospecimens will not be used or distributed for future research

# Additional elements, if applicable (45 CFR 46.116(c))

*The following elements should be included when applicable. The informed consent template provides a guideline for language, which might be acceptable; however, language should be customized carefully for your study.*

* Statement that treatment may involve risks to the subject or fetus that are currently unforeseeable
* Anticipated circumstances in which subjects’ participation may be terminated
* Any additional costs to the subjects
* Consequences of the subject’s decision to withdraw
* Statement that significant new findings that may relate to the subject’s willingness to participate will be provided
* Approximate number of subjects
* Statement that the subject’s biospecimens may be used for commercial profit and whether the subject will/will not share in those profits
* Statement regarding whether clinically relevant research results will be disclosed to subjects and, if so, under what conditions
* For research involving biospecimens, whether the research will involve whole genome sequencing

# Additional requirements, if applicable

*The following elements should be included when applicable. You must use the mandatory language provided in the informed consent statement template for these sections, unless otherwise approved by the IRB.*

* ClinicalTrials.gov (21 CFR 50.25(c))
* Certificate of Confidentiality, if NIH-funded or a Certificate has been granted (NIH Certificate of Confidentiality policy and FAQs)
* Genetic Information Nondiscrimination Act (GINA) notification (OHRP Guidance on Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards)
* Financial interest disclosure, if an investigator on the protocol has a related financial interest (OHRP Guidance on Financial Conflict of Interest, FDA Guidance: Informed Consent Information Sheet)
* Radiation risk language, if radiation/radioactive materials are used for research purposes.

*Required language will be provided by Radiation Safety Office as part of review.*

**If in person procedures are being used during the COVID-19 pandemic include a section describing steps that will be taken to reduce the risk of spread of COVID-19**