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.*