UIC CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

CONSENT CHECKLISTS: REGULATORY CRITERIA

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

WAIVERS

WAIVER OF DOCUMENTATION OF CONSENT

Consent to participate is obtained BUT signature is NOT obtained.

- **If the information presented to participants (written or verbal) also omits some of the DHHS consent requirements, an Alteration of Consent must also be requested**
- **This waiver could apply to the entire research project, or for a specific component such as initial screening.**
- **The initial review application form or the protocol should provide sufficient information regarding the recruitment and consent process so that the IRB can verify all applicable waiver criteria have been met.**

At least one of the criteria below must apply

☐ Signature is the only identifier collected: the only record linking the subject to the study is the signed informed consent and the principal risk is harm resulting from breach of confidentiality.

☐ Signature not required outside of research: the study presents no more than minimal risk of harm to subjects and involve no procedures for which written consent is normally required outside of the research context

☐ Cultural norms: the subjects are members of a distinct cultural group or community in which signing forms is not the norm, that the study presents no more than minimal risk of harm to subjects and provided there is an appropriate mechanism for documenting that informed consent was obtained

WAIVER OF CONSENT / ALTERATION OF CONSENT

- **A waiver is requested when consent is not obtained from participants.**
- **An alteration is requested when an abbreviated consent (missing some of the DHHS consent requirements) is obtained.**
- **A waiver / alteration can apply to the entire research project, or for a specific component such as recruitment or screening**
- **The initial review application form or the protocol should provide sufficient information regarding the recruitment and consent process so that the IRB can verify all applicable waiver/alteration criteria have been met.**

One of the criteria below must apply

☐ 116(f) criteria: research (or applicable component) meets the following:

a) minimal risk; b) could not practicably be carried out without waiver / alteration; c) if using identifiable data/specimens, the research could not practicably be carried out without the identifiers; d) does not affect subject's rights or welfare; e) if appropriate, additional information will be provided to subject; and f) not subject to FDA regulations.
☐ 116(g) criteria: for screening, recruiting, or determining eligibility only. The following criteria must be met: a) information obtained through oral or written communication with the subject (or their representative); or b) identifiable data / samples obtained from records or stored specimens (for example, medical records or biorepositories)
☐ Waiver of consent for testing FDA regulated in-vitro devices using leftover tissue samples: must meet the following criteria: a) device is exempt from IDE b) uses leftover tissue from medical procedure or research, or tissue from biorepository; c) specimens and any accompanying medical information are not individually identifiable; d) individuals caring for the patient are different from and do not share information about the patient with those conducting the investigation; and e) specimens provided without identifiers, and the supplier has established policies and procedures to prevent release of personal information.

GUIDANCE ON WAIVER REQUIREMENTS FOR SPECIFIC SITUATIONS
Research involves deception: Must meet criteria for Alteration of Consent (consent form does not fully disclose research purpose, other aspects of research) under 116(f) criteria
Research involves pre-screening medical records for recruitment: Must meet criteria for a Waiver of Consent under 116(g) criteria, HIPAA Preparatory to Research for the recruitment component
Research involves an initial screening before full written consent will be obtained (for example, individuals responding to a recruitment flyer are screened through phone or email): May need to request Alteration of Consent under 116(g) criteria (generally used for a brief consent script in conjunction with a screener document), Waiver of Documentation of Consent (agreement to screening process)
Medical Chart Review Study: Must meet criteria for Waiver of Consent under 116(f) criteria, and either Waiver of HIPAA authorization or HIPAA Preparatory to Research criteria