THE GEORGE WASHINGTON UNIVERSITY
WASHINGTON, DC

CHECKLIST: Waiver or Alteration of Consent

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Protocol #: PI: Reviewer: Date:

This checklist is used to determine and document whether a WAIVER OR ALTERATION OF THE CONSENT PROCESS/PARENTAL PERMISSION can be waived for non-exempt <Human Research>. The research must meet the following criteria.

1 Waiver or Alteration of the Consent Process involving <Minimal Risk> to subjects. *(45 CFR 46.116(d))* (All criteria must be met)

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- The research is not FDA-regulated.
- The research presents no more than <Minimal Risk> to subjects.
- The waiver or alteration will NOT adversely affect the rights and welfare of the subjects.
- The research could NOT practicably be carried out without the waiver or alteration
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- The research does NOT involve non-viable neonates.

- The informed consent requirements are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.
- Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

Comments:

2 Waiver or Alteration of the Consent Process involving research or demonstration projects. *(45 CFR 46.116(c))* (All criteria must be met

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- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
  (i) public benefit or service programs;
  (ii) procedures for obtaining benefits or services under those programs;
  (iii) possible changes in or alternatives to those programs or procedures; or
  (iv) possible changes in methods or levels of payment for benefits or services under those programs;
- The research could not practicably be carried out without the waiver or alteration.

Comments: