

RESEARCH ADVISORY COUNCIL

REQUEST FOR MODIFICATION OF INFORMED CONSENT

(Waiver of Informed Consent)

Under specific circumstances, an investigator may request approval of a modification in the requirements for informed consent (waiver of informed consent). To request a waiver of informed consent, complete both Parts A and B.

Note: The Research Ethics Committee (REC) may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent (ie, a waiver of informed consent) if four very specific criteria are met. Your request will be considered on a case-by-case basis at a convened meeting of the REC.

A To determine if your request meets **ALL FOUR** of these criteria, you must answer the following questions:

- 1) does the research present more than minimal risk of harm to the subject? (Minimal risk is defined as the probability and magnitude of harm or discomfort not greater than those ordinarily encountered in daily life, or during the performance of routine physical or psychological tests). Yes No
- 2) will the waiver adversely affect the rights and welfare of the subjects? Yes No
- 3) can the research be practicably carried out without the waiver? Yes No
- 4) will the subjects be provided with additional pertinent information after participation, whenever appropriate? Yes No

B Indicate below why the research could not practicably be carried out without the waiver.

<p>_____</p> <p>Name of Principal Investigator (print/type)</p> <p>Signature: _____</p> <p style="text-align: right;">Date: _____</p>	
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