

# RESEARCH ADVISORY COUNCIL

## REQUEST FOR MODIFICATION IN DOCUMENTATION OF INFORMED CONSENT (Waiver of Signed Consent)

Under specific circumstances, an investigator may request a waiver of the usual requirement for research subjects to sign a consent form to document that informed consent has been given (waiver of signed consent). To request a waiver of signed consent, complete the following questionnaire.

**Note:** The Research Ethics Committee (REC) may consider the possibility of approving a consent procedure which does not require a subject's signature when at least one of two specific criteria are met. Your request will be considered on a case-by-case basis at a convened meeting of the REC.

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

- 1) would the consent document be the **ONLY** identifiable link between the subject and the research, **AND** would there be potential harm to the subject if the confidentiality of the consent form was breached?

Yes  No

Indicate below how a breach of confidentiality would be harmful to the subject:

- 2) a) does the research present more than minimal risk?  
(Minimal risk is defined as the probability and magnitude of harm or discomfort are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological tests).

Yes  No

- 2) b) AND, does the research involve any procedures for which written consent is normally required outside of the research context?

Yes  No

\_\_\_\_\_  
Name of Principal Investigator (print/type)

\_\_\_\_\_  
Signature:

\_\_\_\_\_  
Date: