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Institutional Review Board for the
Protection of Human Subjects
Shuster Hall, Room 330
www.lehman.cuny.edu/provost/irb

Waiver of Informed Consent Waiver of Documentation of Consent

Waiver of Informed Consent (45 CFR46.116(d))

If you are requesting a waiver of informed consent you must document the responses to each of the following statements:

1. The research in its entirety involves no greater than minimal risk- yes/no
2. The waiver of informed consent will not adversely affect the rights and welfare of the subjects- yes/no
3. It is not practicable to conduct the research without the waiver/alteration- yes/no
4. Whenever appropriate, subjects will be provided with additional pertinent information after their participation- yes/no

If you answered yes, you must:

- Describe the reason(s) the waiver is necessary, *and*
- Explain whether entire informed consent is being waived or only certain required elements are being waived. If so, which ones.

Waiver of Documentation of Consent (45.CFR46.117(c))

The following items must be documented:

1. The entire consent (or elements thereof) was waived under 45 CFR46.116(d)- yes/no
2. The only record linking the subject and the research is the consent document, and the principle risk is potential harm resulting from a breach of confidentiality. Subjects are asked whether they want documentation linking them to research, and their wishes will govern- yes/no
3. The research involves no more than minimal risk of harm *and* involves no procedure for which written consent is normally required outside of the research- yes/no

If any of the three statements is yes describe the reason(s) the waiver is necessary.

