

WAIVER OF INFORMED CONSENT*

THESE CRITERIA DO NOT APPLY IF THE STUDY IS FDA REGULATED**

THE INSTITUTIONAL REVIEW BOARD (IRB) MAY CONSIDER WAIVING THE REQUIREMENT FOR OBTAINING INFORMED CONSENT IF ALL OF THE FOLLOWING CONDITIONS ARE MET. To request a waiver, the research description should address each of the criteria listed below.

1. THE RESEARCH INVOLVES MINIMAL RISK TO SUBJECTS

This condition is satisfied if either the likelihood or the magnitude of harm/discomfort is no greater than what the subjects would ordinarily encounter in daily life or during routine clinical care.

2. THE WAIVER OR ALTERATION WILL NOT ADVERSELY AFFECT THE RIGHTS AND WELFARE OF THE SUBJECTS

The IRB will assess whether subjects' rights, such as the "right to privacy", would be violated if the consent were waived. For example, in the case of "right to privacy", the IRB will consider the safeguards for minimizing the potential invasion of privacy and will consider the potential benefits of participation.

3. THE RESEARCH COULD NOT PRACTICABLY BE CARRIED OUT WITHOUT THE WAIVER; AND

For example, obtaining informed consent would not be practicable if the investigator will have no direct contact with subjects and will not know their identities.

4. WHENEVER APPROPRIATE, THE SUBJECTS WILL BE PROVIDED WITH ADDITIONAL PERTINENT INFORMATION AFTER THEY HAVE PARTICIPATED IN THE STUDY

In social science research involving deception, it is common practice to debrief the subjects at the conclusion of the study. In other studies, however, it would not be appropriate to require debriefing. For example, if the research proposed collection of tissue without identifiers, it would not be possible for the investigator to provide additional information since the identities of the subjects would be unknown.

* TO CONDUCT RESEARCH INVOLVING DECEPTION OR PASSIVE CONSENT PROCEDURES, THESE CRITERIA MUST BE MET.

**WAIVER OF CONSENT IN FDA REGULATED STUDIES IS PERMISSIBLE ONLY IN LIFE-THREATENING SITUATIONS OR ACUTE CARE RESEARCH IF SPECIFIC FDA MANDATED REQUIREMENTS ARE MET.

EVEN IF ALL OF THE ABOVE CONDITIONS ARE MET, THE IRB IS AUTHORIZED TO REQUIRE AN INVESTIGATOR TO OBTAIN INFORMED CONSENT. For example, the IRB may determine that the knowledge being sought is not important enough to justify the use of unaware subjects.

PLEASE CONTACT BEVERLY RAISOR AT 859-257-8315, OR E-MAIL HER AT BRAISOR@UKY.EDU FOR FURTHER INFORMATION OR FOR COPIES OF THE FDA REQUIREMENTS.