LONG ISLAND UNIVERSITY

RESEARCH INVOLVING DECEPTION OR CONCEALMENT POLICY

PURPOSE

The purpose of this policy is to establish guidelines for conducting research that involves deception or concealment.

STATEMENT OF POLICY

Research may require that subjects not be fully informed in advance of the intent or procedures of a study.

Investigators should utilize an informed consent form/waiver even if the research activities include deception, but should exclude information that could compromise the research.

DEFINITIONS

“Concealment” is involved when the researcher intentionally does not reveal initially to the participant all the relevant details of the protocol (not the whole truth / incomplete disclosure).

“Deception” is involved when participants intentionally are told something untrue (not the truth).

Deception or concealment can only be permitted when a waiver of the usual informed consent requirement is justified under the criteria present in 45 CFR 46.116(d). Specifically, all four below criteria must be satisfied:

- The research involves no more than minimal risk to subjects.
- The waiver will not adversely affect the rights and welfare of the subjects.
- The research could not be carried out practicably without the waiver.
- Whenever appropriate, the subjects will be provided with additional pertinent information after they have participated in the study.

In order for the IRB to adequately review the research, investigators should justify, in detail, on the application form, the reasons for deception or concealment, including:

- The necessity for deception or concealment, including why there are no effective alternative procedures that do not involve deception or concealment.
- How the potential benefits of the research justify the use of deception or concealment.
- Whether the investigator will provide additional pertinent information to the subjects.
  - ·If subjects will *not* be given additional pertinent information, why not (e.g., an explanation of why providing additional pertinent information would do more harm than good).
  - ·If subjects will be given additional pertinent information, how the investigator will provide additional pertinent information and inclusion of a script or statement that indicates the information participants will receive.

An Additional Information / Permission to Use Information Collected in a Research Study form, which can be

found on the IRB website http://liu/edu/irb/forms), is used to inform participants about the deception or concealment, the exact nature of the deception or concealment, and the reasons for the deception or concealment. As part of this process and after being fully informed about the deception or concealment, participants must be provided with the opportunity to not have their data used in the study. Specifically, after full disclosure, participants must be provided with the following or other comparable wording that has the same intent, unless waived by the IRB:*

Please initial your choice:
_____ I give permission to have my information used in this research project.
_____ I DO NOT give permission to have my information used in this research project. Please destroy all information collected from me immediately.

* Participants in exempt studies are not required to initial their choice, but they must be given the choice of removing their data from use in the research study, unless waived by the IRB.

POLICY TYPE: ACADEMIC AFFAIRS