**Supplement L**

**REQUEST FOR WAIVER OF CONSENT AND/OR DOCUMENTATION OF CONSENT (INCLUDING RESEARCH INVOLVING DECEPTION)**

Indicate your responses below and explain your selections in the protocol. Do not provide details in this document.1

1. **Request for waiver of documentation of consent (45 CFR.46.117(c))**

## **Please select one of the following:**

\_\_The research involves no more than minimal risk; and involves only procedures that do not require written consent outside of research.

# \_\_ The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.

## Please explain in the protocol, in the absence of written informed consent, how consent will be documented, e.g. tape recordings, videos, chart notes, etc...

# Request for waiver of informed consent

## **In order to waive the requirement for informed consent, ALL of the following criteria must be met:**

\_\_ The research involves no more than minimal risk.

\_\_ The waiver or alteration will not adversely affect the rights and welfare of the subjects.

\_\_ The research could not be carried out without the waiver or alteration.

\_\_ Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

# Deception

APA Code of Ethics 6.15 (<http://www.apa.org/ethics/code/index.aspx?item=11>)

**a. Will deception, including withholding of information, be used in this research?**\_\_ Yes \_\_ No

1. If yes, provide the following information in the protocol:

### Describe the deception being used in this study

### Explain why deception is necessary in this research.

See SOP 15 for FDA-regulated research

### Are the risks to subjects in this research greater than minimal?

\_\_ Yes (If yes, then deception cannot be used in this research.)

\_\_ No

### Describe what information is being provided to subjects when they decide to participate.

### Describe the how the subjects will be provided with additional pertinent information after participation (debriefing).