Supplement K

**RESEARCH INVOLVING ADULTS WHO ARE OR MAY BE UNABLE TO CONSENT**

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

# For research involving adults who are or may be unable to consent, provide the following information in the protocol (SOP 14.E):

## Provide the justification for the inclusion of this population.

## Explain why these subjects need to be included in this research.

## Are any of these subjects institutionalized? *(if applicable, complete Supplement H)*.

### If yes, describe the setting. (*Provide documentation of permission from the institution.)*

# Risk/Benefit Assessment

## Are the risks to subjects in this research no more than minimal? \_\_ Yes \_\_ No

### If no, and the research involves greater than minimal risk to subjects, are there direct benefits to the individual subjects? \_\_ Yes \_\_ No

# Consent and Assent

The decision-making capacity of individual subjects should not be assumed because of a condition or diagnosis. The decision-making capacity of individual subjects should be determined through the use of a standardized measure or by consultation with a qualified professional.

Describe in the protocol:

## the procedures to be used to determine the individual subject’s capacity to provide consent.

## For subjects where it has been determined that they lack the capacity to give consent, describe the provisions for obtaining consent from the subjects’ legally authorized representative.

## how the assent, if any, of the subjects will be obtained and documented.