Institutional Review Board (IRB)
840 Walnut Street
Philadelphia, PA 19107
Phone: 215-440-3155
Email: IRB@willseye.org

Form-8: Substitute Consent for a Research Protocol

IRB Control #

Service/Department:

Principal Investigator:

Telephone:

Medical Title:

Lay Title:

Name of Subject:

Please provide answers to the following questions:

1. Is the subject able to give informed consent?

- ◯ Yes. *If yes, you may not obtain substitute consent. Use the IRB-approved consent document.*
- ◯ No.

2. Reason for subject's inability to give informed consent:

3. Is the risk of harm posed by the research reasonable in relation to the potential of direct benefit of the research to the subject?

- ◯ Yes.
- ◯ No. *If no, you may **NOT** obtain substituted consent for the subject's participation.* ***Only where the risk of harm is considered reasonable in relation to the potential direct benefit of the research subject can the investigator obtain substituted consent.***

4. Surrogate Information: Fill in the applicable description of subject's legal representative.

◯ COUR ORDER AUTHORIZING GARDIAN CONSENT

Date of Order: Name:

◯ POWER OF ATTORNEY Name:

◯ SPOUSE Name:

◯ PARENT Name:

◯ ADULT CHILD Name:

◯ ADULT BROTHER/SISTER Name:

◯ OTHER ADULT RELATIVE Name: Relationship:

6. Principal Investigator's Statement:

I certify that to the best of my knowledge, the information contained in this Substitute Consent Form is accurate and complete.

_____

Signature of Principal Investigator Date

Instructions: Complete this Form-8 for each subject for which you are obtaining substituted consent and place a copy in the subject's file. The subject's legal representative must read and sign the IRB-approved consent document for the research protocol in addition to the investigator's completion of this Form-8.

If at some time after the subject is enrolled in the study via the consent of a substitute, the subject's condition improves and he or she regains the capacity to provide informed consent, the investigator shall obtain the legally effective informed consent of the subject for continued participation in research.