

Special Procedures and Populations

1. Does the study involve any of the following special procedures or considerations? N/A – none listed below

The study team may enroll subjects with impaired decision-making capacity.

If selected, describe below how the study team will verify someone is qualified to be the potential subject's Legally Authorized Representative.

The study team may enroll wards of the state (e.g., foster children).

The study team may enroll prisoners.

If selected, describe below how the study team will verify someone is qualified to be the potential subject's Legally Authorized Representative.

For studies that involve a drug, biologic, and/or device,

Describe:

- a) the specific location where study drugs/devices/biologics will be stored
- b) how storage location will be secured
- c) who is responsible for study drug or biologic preparation
- d) who will dispense subject drug or biologic to the subject

Medical Records

1. Will medical records be accessed prior to written consent, or with a waiver of consent?

Yes No N/A – no medical records will be accessed for this study

If the study does not involve medical records, please skip to the next section.

2. Describe how the PI will gain access to the records.

Data Handling and Storage

1. How and where will data (e.g., electronic, paper, audio) be stored at your site?

2. Who will have access to the data?

3. How is subject confidentiality protected?