This form is to be completed by the person observing consent (POC).

Protocol ID:\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Name and Title of the observer:
2. Study name:
3. Name and Title of the Person Obtaining Consent (POC):
4. Description of Participant, e.g., does participant fit the age/gender profile per the protocol?
5. The observer considers the following key elements when observing consenting of a potential study participant (other issues may also be considered by the observer:

Is the consent form the most recent IRB-approved version?....................................**Yes** **[ ]  No** [ ]

Does the POC mention that the study involves “research?”……………………….**Yes [ ]  No** [ ]

Does the POC describe the study procedures (following the

consent descriptions)?...................................................................................... …... **Yes [ ]  No** [ ]

If study involves an unapproved agent (i.e., not FDA approved),

does POC explain this? …………………………………………………………….**Yes [ ]  No** [ ]

Does the POC solicit and sufficiently answer questions?......................................... **Yes [ ]  No** [ ]

1. Does the POC avoid using medical terms and scientific jargon that the participant clearly does not understand, and does the POC communicate using understandable language?.,,,,,,,,**Yes [ ]  No [ ]**
2. If participant agrees to enroll, are the consent form and HIPAA Authorization properly signed and dated? ………………………………………………………………………**N/A[ ]  Yes [ ]  No** [ ]
3. Is a copy of the signed consent form with HIPAA Authorization given

to the participant?.......................................................................................... **N/A[ ]  Yes [ ]  No** [ ]

1. Is the consenting “environment” suitable (E.g., private, reasonably comfortable)? **Yes [ ]  No** [ ]
2. Did the POC spend sufficient time obtaining informed consent? If possible, also enter a start and stop time of the consent interaction…………………………………………………**Yes [ ]  No** [ ]

Other: