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| **A green and white sign  Description automatically generated** | **INFORMED CONSENT PROCESS**  **DOCUMENTATION** | | | |
| **Subject ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | |
| ORA# | Study Title: | | | |
| Consent Version Date: |
| Approval Date of Consent: |
| Expiration Date of Consent: |
| Study Principal Investigator (PI): |
| Study and consent discussed with:  \_\_\_ Subject  \_\_\_ Legally Authorized Representative (LAR)  \_\_\_ Family Members  \_\_\_ Other (describe)  How was Consent obtained?  \_\_\_ In person  \_\_\_ Telephone call  \_\_\_ Online  \_\_\_ Other (describe) | If not in-person, how was the subject’s identity verified?  \_\_\_ Full Name (required) AND  **Two** additional identifiers (minimum)  \_\_\_ Date of birth  \_\_\_ Last four digits of SSN  \_\_\_ Address  \_\_\_ Emergency Contact name  \_\_\_ Other (describe) | | | |
| Key information presented to subject first? | | YES | | NO |
| Purpose of study discussed with subject? | | YES | | NO |
| Procedures discussed with subject? | | YES | | NO |
| Risks and Benefits discussed with subject? | | YES | | NO |
| All of subject’s or LAR’s questions were answered? | | YES | | NO |
| Subject or LAR verbalized understanding of consent? | | YES | | NO |
| Subject:  Agrees to Participate  Declined Participation  Wants to meet for further discussion | | | | |
| Consent signed prior to any study related procedures? | | YES | | NO |
| A copy of the executed study consent form was given to subject. (Describe how the copy was provided to them in “Comments”) | | YES | | NO |
| Is the subject currently enrolled in any other study? | | YES | | NO |
| Does the subject have any special needs? If Yes, describe in comments section below | | YES | | NO |
| Does the subject meet all Inclusion and no exclusion criteria at this time? | | YES | | NO |
| Comments: | | | | |
| Signature of Person Obtaining Consent: | | | Date and Time: | |