Informed Consent Process Checklist

- Person who obtained consent has been assigned this responsibility on the DOA
- Most recently CIRB-approved and stamped consent document used
- Patient or LAR personally signed and dated document, in all the correct spots
- If the patient lacked cognitive capacity to consent for him or herself, the appropriate LAR was used
- If an LAR was used, the reason for using an LAR was documented in the subject's medical or research record (as per local procedures) and on the informed consent CRF in WebDCU
- An impartial witness (of consent process and signature) was used, and documented appropriately, if any of the following situations apply:
    - Short form consent used
    - Patient physically incapable of signature
    - Patient is illiterate
    - Patient is visually impaired
- Assent obtained if appropriate
- If patient/LAR is not English-speaking, then the following were performed:
    - the consent conversation was conducted in the patient/LAR's primary language (either the person obtaining consent was fluent or a formal interpreter was used), **AND**
    - a fully translated ICF (CIRB-approved) was used, **OR**
    - a translated CIRB-approved short form was used, the process was witnessed (translator may perform), and a fully translated consent was provided within 30 days
- If faxed consent procedure was available locally and used, a signed and dated ICF was returned to the site prior to performing any study procedure
- Copy of signed/dated consent given to patient/LAR for his/her records
- Consent process documented per institutional process
- Re-consent performed if a change in consent capacity occurred during the study