**Obtaining informed consent**

* The informed consent process begins prior to study participation and continues throughout the duration of the study. Informed consent must be obtained from the study participant prior to conducting any study procedures.
* Know if the participant has a Legally Authorized Representative (LAR) and if so, confirm identity of the LAR.
* Prior to consenting, incorporate a “time out” period to ensure the current IRB approved version of the main consent form, sub-study consent form, optional consent form(s), and assent are being used. If consenting for a pediatric study, ensure the correct age-appropriate assent form is being used (if applicable).
* Allow participants sufficient time to consider study participation prior to obtaining consent. A good rule of thumb is to provide the participant with a copy of the consent form at least a day before the informed consent discussion is to take place. The waiting period may be omitted only if the IRB has issued a waiver.
* Know if you have been delegated to obtain consent. Ensure this is documented on the delegation of authority log. Also know if the IRB or sponsor requires consenting only by the PI or credentialed clinician.
* Ensure the principal investigator is available to answer the participant’s questions (if needed) prior to the participant signing the consent form.
* Assess if the participant can read by having him/her read a few sentences aloud.
* Use an unbiased witness if a witness is required.
* Give the participant uninterrupted time to read the consent form, in a quiet and private area. Ensure the participant has not taken medications that may alter his/her decision-making skills.
* While reviewing the consent form with the patient, pause to assess understanding. Ask the participant to explain major points in his/her own words.
* Continue to assess understanding and ongoing consent at each visit.
* Do not coerce or pressure the patient to participate in the study.
* Implement the full informed consent process when reconsenting.
* Understand the withdrawal process in case a participant decides to withdraw their consent.

**Documenting informed consent**

* Use black or blue ink only.
* Identify each signature block and ensure the participant signs all applicable areas on the consent form.
* Explain that the participant’s signature means they have read and understood the consent form and that their questions have been answered to their satisfaction.
* Document the consent process on an Informed Consent Checklist or narrative note. Documentation should include the consent version, IRB approval date, date of consent, name of person conducting the informed consent discussion, whether or not a copy was provided to the participant, and other elements covered in ICH GCP E6 4.8

* Keep original signed ICF in study files and give the participant a copy of the signed ICF (unless waived by the IRB). A copy should also be placed in the medical record when required by the IRB and institution.
* If mistakes are made, a single line should be drawn through the error and initials/date entered next to it. This should be completed by the person who made the mistake. Do not obscure the original entry.

Example:

