

RESEARCH ENROLLMENT NOTE GUIDELINES

ALWAYS document the consent process in the medical record. Include the following information:

- ❖ The study name (e.g., “EVOLVE Study Note”)
- ❖ That the subject meets inclusion criteria and no exclusion criteria
- ❖ That the subject/surrogate read the consent form and all elements of the study were discussed and all questions were answered
- ❖ Who the surrogate is and their relationship to subject (e.g., Wife, Power of Attorney, etc.) This must also be written on the consent form*
- ❖ That no protocol procedures were performed prior to obtaining consent
- ❖ The time and date that written consent was obtained
- ❖ That the subject/surrogate was given a signed copy of the consent form

NEVER sign, date or time the consent form for the subject/surrogate.

A copy of the signed consent form must be placed in the patient’s chart near the front with other consents and the original must be safeguarded.

* remember that the surrogate must be the legally authorized representative and that there is a hierarchy for surrogate consent that must be adhered to. Call Christina if you have questions about this (301) 643-5801 or 715-5257.