Documentation of the Informed Consent Process for Subject File

IRB#:

Study Title:

PI:

Subject ID:

Consent obtained by:

Date of Consent:

|  |  |
| --- | --- |
| **Check all that apply** | |
|  | Subject meets all eligibility requirements as documented on the I/E checklist, with applicable source documents copied for the research record. |
|  | Subject’s comprehension was assessed to ensure that the subject understands the research and the risks and benefits involved in the study. |
|  | Discussed, explained and reviewed the **IRB approved/stamped** consent form with subject   * Written consent was obtained (per IRB approved consent process) * Surrogate consent was obtained (per IRB approved consent process) |
|  | Subject’s questions were answered/concerns addressed. (document multiple subject contacts below)   * Subject did not have any questions/concerns |
|  | Subject was given time to review the consent form and to discuss participation in this study with family members/others. |
|  | Subject agreed to participate in the study and signed/dated the most current valid **stamped** IRB approved consent form *prior to the start of any study procedures*. |
|  | A copy of the signed and dated consent form was given to the subject. |
|  | The original signed and dated consent form was placed in the research record or separate binder. |
|  | A note was made in the subject’s medical record documenting their participation in the study. |
|  | Comments: |

|  |  |
| --- | --- |
| Signature/initials: | Date: |