



Documentation of Informed Consent: Checklist for Patient Record

- 1. Research Study Name:
- 2. IRB Number:
- 3. Study Subject Name:
- 4. Principal Investigator: Contact #
- 5. Informed Consent Form Version: Date:
- 6. Name of Person Obtaining Consent: Contact #
- 7. Date Consent was Signed by Subject: Time:
- 8. Person Signing the Consent: Subject Suitable LAR (Relationship to subject):
- 9. Language Version: English Spanish Other

- The subject met all of the inclusion and exclusion criteria for this study.
- The subject/LAR is competent to make medical decisions.
- No research related procedures were done prior to signing the consent.
- The subject/LAR was given ample time and opportunity to ask questions pertaining to the study and to have these questions answered by the study coordinator and/or principal investigator prior to signing the consent form.
- It was explained to the subject/LAR that if he/she decides to withdraw from the study, his/her medical care will not be affected.
- All visits and procedures associated with the study were explained to the subject/LAR.
- All risks and potential benefits of the study were explained to the subject/LAR.
- Any alternatives to participating in the study were explained to the subject/LAR.
- The subject/LAR consented freely to participation in the study.
- The subject/LAR was able to explain the study in his /her own words and what procedures will occur if he/she enrolls into this study.
- The subject/LAR received a copy of the signed research consent form with HIPAA information.
- A copy of the Drug/Device Data Sheet has been placed in the subject's medical record.
- The subject/LAR received the phone number and/or pager of the contact.
- Notification of Patient Enrollment was sent to the Office of Clinical Research.
- The subject/LAR was counseled on contraceptive use.
- All costs associated with the study were explained to the subject/LAR. It was explained which items may be billed to research and which items would be billed to the subject's insurance company.

Signature: _____

Date: _____