**Summary of Informed Consent Process**

Study Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Site #: \_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Patient Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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On \_\_\_\_\_\_\_\_\_\_\_, the above patient was referred to me by Dr. \_\_\_\_\_\_\_\_\_\_\_\_ following /during his office visit on \_\_\_\_\_\_\_\_\_\_\_. We met in Exam Room \_\_\_\_ at the Vascular Surgery Office, 140 Canal View Blvd., Suite 103, Rochester, NY 14623. Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_had reviewed the \_\_Study Name)\_\_\_\_ with \_\_(pt name)\_\_\_\_\_\_\_\_\_\_ and ­­­­­­­­­­­­­­­­­­­­­­\_(family member names)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ who was/were also present. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ was interested in more information related to the study, so I met with him/her and \_\_\_\_\_\_\_\_\_\_\_\_ to briefly review the Informed Consent Form, give him a copy of the WIRB approved brochure, and my contact information. We briefly discussed and reviewed the intent / rationale, purpose, protocol requirements, procedures, potential risk / benefits of the \_\_\_\_\_\_\_\_\_\_\_ Study.

Initial questions from the patient and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ were addressed and discussed thoroughly.

He/She was given a blank copy of the consent form to take home and review at his leisure, and to also discuss with his family. He was also informed that he could review additional information available at the [www.clinicaltrials.gov](http://www.clinicaltrials.gov) website.

He/She agreed that I could contact him/her by phone on or after \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, to address any questions he had at that time after reviewing the Informed Consent Form (ICF).

I spoke with him/her on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to see if he/she had any further questions. He/She indicated he/she had read the Informed Consent Form, and had no questions (or had some questions which we discussed thoroughly). He/She also indicated that he wanted to participate in the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Study. We agreed to meet on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_at \_\_\_\_\_\_\_\_\_\_ to have him/her sign the consent.

On \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, we met in \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to review the ICF. \_\_\_\_\_\_\_\_\_\_is aware that participation in this study is completely voluntary. After answering all questions that he/she had, \_\_\_\_\_\_\_\_\_\_\_ agreed to be in the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Study. He signed and dated the Informed Consent Form; then Dr. \_\_\_\_\_\_\_\_\_\_\_ and I also signed the ICF. I then performed the Baseline Study Assessments (e.g. NIHSS, mRS, etc.) The Scores were as follows: NIHSS: \_\_\_\_, nRS\_\_\_\_.

A copy of the signed and dated Informed Consent Form and study contact information was given to \_\_\_(Pt name)\_\_\_\_ for his/her records. His/her surgery is planned for \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Cynthia Westfall, RN, CCRP Date:

Vascular Surgery Research Coordinator

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