Signed Informed Consent Form

Our study titled: “Superior Mesenteric Venous Thrombosis: Endovascular Management and Outcomes” was a retrospective study and not a clinical trial, therefore our Institutional Review Board (IRB) did not require signed informed consent from the patients studied. This can be seen in the note from our IRB below stating the reasons informed consent may not be required:

Waiver of Documentation of Consent

The IRB will review the research proposal to determine if waiver of documentation of informed consent is appropriate. The IRB may waive the requirement for an investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

- The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject or LAR will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context
- If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk or harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.
- When the IRB considers waiving the requirement to obtain written documentation of consent, the IRB reviews a written description of the information that will be provided to subjects via an oral consent script, contact letter, phone script or similar document.

If a waiver of written consent is granted by the IRB, the IRB will determine whether the investigator must document the oral consent in research study files and/or the subject's medical record