**Tilda Research Inc.**

**Case Study Assignment**

**Would you consider this study easy, moderate, or complex?**

I thought this clinical research case was moderately difficult. It was a matter of understanding the factors and components of the clinical trial, so I had to research the surgery procedures; the normal ranges of the laboratory test; and some of the medical terminology. The part I would say that was a little tedious was finding scientific literature that expounded my understanding for THB and TTH.

**What type** **of providers/clinicians would we pursue to maximize recruitment in the trial?**

If I had to recruit providers/clinicians for this study I would recruit: phlebotomist, medical assistant/nurses (to perform physical exams, draw blood, and take vital signs), clinical laboratory scientist/medical technologist (to analyze biochemical and biological specimens ), clinical psychologist, board certified surgeons, gastroenterologist (digestive organs an liver), anesthesiologist, orthopedic surgeon, cardiologist, physical therapist, surgical technicians, site monitors/CRA, and CRCs.

**The protocol is defined as single blind. Why is it considered single blind versus double blind?**

The protocol is a single-blind study because only the investigator knows the treatment group enrollment (STUDY PRODUCT or ACTIVE CONTROL AGENT) for each participant. In a double-blind study neither the investigator nor participants would know the assignment of each subject.

**Clinical Correlation: Why is the study targeting** **spinal surgery, hepatic resection, vascular surgery, and soft tissue dissections only?**

This clinical trial targeted spinal surgery, hepatic resection, vascular surgery, and soft tissue dissections because these *minimally invasive* surgeries benefit form topical adjusts that aid the TBS to return to hemostasis, this ultimately aids in the adhering and healing of localized tissue.

**Please describe what is meant in the protocol by TBS and TTH?**

The target bleeding site (TBS) is the surgical site where mild to moderate bleeding at the arterial graft/patch suture line/anastomosis continues due to the surgical techniques employed; hemostasis needs to be meet at the TBS. The time to hemostasis (TTH) is the time it requires for hemostasis to be achieved after the time the treatment was initially applied, to the site (the start time). The mean time is the average time for the TBS to reach hemostasis between 3 to 5 minutes.

**Ms. Smith Case:**

The report for Ms. Smith fails to provide information on whether she has full decisional- making capacity to voluntary make an informed consent. Because she is a widow, she may be dealing with grief, or depression. Furthermore, she may be stricken with Alzheimer’s disease, anxiety, or experiencing loneliness. I would like to know if she spoke with a clinical psychologist before enrolling. These factors could hinder her ability to understand the reason of the research, as well as its risks and benefits. If she did not have the mental capacity to sign the consent form, I would need to know if she had a surrogate (legal representative) present during her pre-clinical meeting with the investigator.

I would also want to verify the physical exam and vital signs of the subject(during the pre-screening visit)- as elderly patients decline with physical health (i.e, mobility, increased sensitivity to pain, and lack of appetite). It is important to verify that the patient discussed the clinical trial with her primary healthcare provider, as she may have pre-exiting illness or surgery which would exclude her from participating in the research. As some conditions may cause severe or fatal injury to her health. For example, she may have a history of heparin-induced thrombocytopenia.

Although Ms. Smith’s ALT(13 U/L) and AST(23 U/L) lab results are within the normal range (7-55 U/L; 8-48 U/L), her INR (2.7) and aPTT (110) are greater than the baseline of 2.5 and 110, respectively. Her platelet count was not determined during her pre-screening visit. Notably, platelet count (< 100 x10^9 PLT/L) is a also pertinent exclusion criterion, of this clinical trial.

Her CRF and source documents need to be reviewed and compared to answer these quires. If results determine that she does not comply with any of the selection criteria, she will be discontinued from the study. These observations must be reported to the sponsor, investigator, CRC, and documented in the investigator’s study file and the patient’s CRF.

**Bonus :**Design a staffing plan based on the study visit schedule. You may assume you have the ability to call upon a Physician, CRC or RN.

The CRA should spend a few minutes with the investigator at the start of the visitation. This would be the appropriate time to update the investigator the trial progress, and to inform the investigator of new findings during the prior visit.

In terms of the actually monitoring of the clinical trial, the CRA must collaborate with CRC/Nurse. The CRA is responsible for SAE reviews. Inquire about any potential SAEs, occurring since the last visit. If so, it should be reported in a timely manner to the appropriate personnel. The informed consents should be reviewed for accuracy for each new participant. Review protocol adherence (i.e., participant eligibility, randomization, protocol activities, and visit schedule and windows); Review CRF and compare with source documents; perform queries and error correction; and review the study document file.

Finally, an exit meeting with the investigator will be needed to discuss the trial progress, identify corrective actions and check the inventory/supplies/budget needs for the clinical site.