EDC User Access Agreement

Study: MISTIE-III (Minimally-invasive thrombolysis in ICH)

Sponsor: Dr. Daniel Hanley (Investigator IND) of Johns Hopkins University

My PRINTED Name: _____

My Email Address: _____

PRIMARY role on this study:
❑ Investigator ❑ Coordinator ❑ Site Data Entry ❑ Site Documentation
❑ Site Monitor ❑ Statistician/Medical Writer ❑ Protocol Coordinator
❑ Study Chairman ❑ Sponsor Project Manager
❑ Central CT Reviewer ❑ Medical Monitor ❑ ICU Medical Monitor
❑ Surgical Reviewer ❑ Safety Coordinator ❑ Safety Committee Member
❑ Trial Pharmacist ❑ Trial Accountant ❑ Outcomes Reviewer
❑ Other: _____

This document memorializes my agreement to the terms and conditions specified herein as is required for me to receive and retain access to the EDC for the above study and the patient data therein.

I hereby acknowledge that my signature below and my use of the EDC obligate me to protect certain proprietary rights and to maintain confidentiality of certain information. I also hereby agree to and acknowledge my obligation to comply with certain laws and regulations in the U.S. and other countries regarding 1) electronic signatures and electronic systems used in clinical research and 2) the protection of personal health information. This includes, but is not limited to, 21-CFR Part 11 regulations of the U.S. FDA, the HIPAA Privacy Rules of the U.S. HHS, the Data Protection Directive of the EU, and similar rules in other countries. I understand that this document may be provided to domestic or international government agencies and my compliance with these obligations may be enforced by these agencies.

An *Electronic Data Capture System* is a database and associated rules-based collection of online forms for reporting and managing clinical trial data. The EDC system for this trial is owned and provided by Prelude Dynamics, Inc. of Austin Texas (Prelude). Emissary International LLC of Austin, Texas (Emissary) and/or Prelude developed the study-specific programming specifications, concepts, and designs used in this study on behalf of the Sponsor under a work-for-hire arrangement. Other certain designs, layouts, and content (such as the eTMF) are owned by Emissary and/or Prelude exclusively and have been licensed to the Sponsor. Emissary, Prelude and Sponsor hold certain singular or joint proprietary rights, including copyright, trademark, and other intellectual property rights, to the EDC including but not limited to the programming code, content, form layouts, logos, and proprietary methods and processes. By signature below, I acknowledge these intellectual property rights and agree to maintain confidentiality of said proprietary information. I will take reasonable precautions to protect this intellectual property and will not show the EDC to anyone that is not a participant in this study or

otherwise authorized (such as a regulatory auditor) to view the EDC and the information contained therein.

Electronic Signature means a digital representation of a personal signature based upon cryptographic methods of originator authentication, computed by using a set of rules and parameters such that the identity of the signer and the integrity of the data can be verified. For this study, my electronic signature will be executed in the EDC by entering a unique username and password combination. My electronic signature carries the same significance as my handwritten one.

My username will be assigned to me along with an initial password. I will be required to immediately change this initial password upon login. I will not write down my password. I will not select a password that could be easily guessed (such as a family member or pet's name or my phone number, SSN or DOB) by an individual having extensive knowledge of me. I will immediately report any forgotten, lost, stolen, or suspected-stolen passwords. I WILL NOT DISCLOSE MY PASSWORD TO ANYONE, including members of my staff, my family, my employer, Emissary, Prelude or Sponsor staff, regulatory agency or legal authority (except under court order and only after prior notification to the companies above).

I understand that the EDC and printed reports, emails or faxes generated by the system may potentially contain confidential personal health information (PHI) of study participants, including patient and family names & contact information, patient signatures, insurance records, procedure dates & reports, confidential drug screens, disease information, patient chart scans, photos, videos and radiographic images. I acknowledge that I may, in the course of my involvement in this study, possibly gain access to PHI that has not been blinded by removal of any personally identifiable information, or which could not be blinded due to the specific requirements of this study, even though I may not be directly involved in providing care to that individual. I acknowledge that said PHI is collected under a HIPAA release and/or Informed Consent which obligates me to maintain this PHI in compliance with applicable laws and regulations across multiple jurisdictions both in the U.S. and internationally.

I understand that all PHI must be maintained in the strictest confidence. As a condition of my involvement, I hereby agree that, unless pursuant to my authorized role as the patient's caregiver or as may be required by law, I will not at any time during or after my involvement with this study disclose any PHI or permit any person whomsoever to examine or make copies of or use any computer screens, EDC reports or downloads, communications or other study documents prepared by me or coming into my possession or under my control containing PHI other than as necessary and appropriate in the course of my involvement in this study. When patient information must be discussed verbally with other authorized individuals in the course of my work, I will use discretion to ensure that others who are not involved in patient's care cannot overhear my conversations. I further acknowledge and agree to comply with all requirements stated in the Informed Consent and/or Personal Health Information Disclosure Agreements executed between the study patients and the clinical investigators and institutions in this study relating to protecting the PHI of patients participating in this study.

By signature below, I acknowledge my understanding, agreement and acceptance of the obligations and requirements herein. I also agree to be held personally accountable and responsible for actions initiated in the EDC system under my Electronic Signature. I understand that violation of this agreement may result in civil, regulatory and/or legal action against me.

Signed by: _____