Standard Operating Procedures for use of the Phenotype Recording Instrument and the International Society on Thrombosis and Haemostasis Bleeding Assessment Tool Repository (ISTH-BATR)

1) Interested investigators will contact Ms. Yupu Liang (liangy@rockefeller.edu), whose contact information will be available in relevant publications and on the International Society on Thrombosis and Haemostasis Bleeding Assessment Tool (ISTH-BATR) website.

2) Ms. Liang will provide investigators with the url to the ISTH-BATR phenotype recording instrument (PRI, https://bh.rockefeller.edu/bat/ as well as a test login that will permit them to evaluate the instrument/questions. This test login will be flagged as unsuitable for inclusion in analyses by marking it with an ID indicating that it was completed under a test login.

3) If the investigator remains interested in participating in the ISTH-BATR after testing the instrument, she/he will supply Ms. Liang with:

- The number of Study IDs required and a name to associate with each Study ID. Study ID is a unique identifier used to identify different studies conducted at a single site.

- The number of User IDs required and a name to associate with each User ID. The User ID is a unique identifier used to identify different ISTH-BATR users and to define their level of access to the system.

- The number of Site IDs required and a name to associate with each Site ID. Site ID is a unique identifier used to identify different institutions and/or locations where the PRI is to be used.

- If the investigator subsequently requires further User, Study, and/or Site IDs, they will be supplied upon request.

The ISTH-BATR team will generate the requisite IDs and a password for each User ID and supply them to the investigator. Ms. Liang will maintain a log linking Sites, Protocols, and Users with their respective IDs and a duplicate log will be maintained by Suzanne Rivera in a password protected computer file.

4) All data collected will be tagged with User, Site, and Study IDs and maintained in the ISTH-BATR database with password-protected access for the investigator. Thus, if investigators prefer to retrieve only specific datasets, those specific records will be retrievable by filtering by User, Site, and/or Study ID. Similarly, datasets that are not relevant to specific investigations will be excludable.

5) After User ID, Site ID, and Study ID assignment are complete, Ms. Liang will supply the investigator with an electronic copy of the PRI User's Manual.

6) Investigators will have access to their data at any time via the PRI Reports suite of utilities. Data retrieval and representation utilities available from PRI Reports include:

- PRI Reports, which allows an investigator to query any subject as identified by the combination of UPIN, Site ID, and Study ID, and to generate a printable .pdf report of the retrieved record.

- PRI Aggregate Reports, which allows an investigator to query the entire ISTH-BATR for all collected data, to filter these data by Site ID, User ID, Study ID, and/or diagnosis, and to generate a downloadable Excel spreadsheet containing the retrieved records.

- PRI Graph, which allows an investigator to query the ISTH-BATR for all collected data, to filter these data by Site ID, User ID, Study ID, and/or question category, and to display the retrieved records in a graphical format.

- PRI Demographics, which allows an investigator to query the ISTH-BATR for all collected data, to filter these data by Site ID, User ID, and/or question category, and to display the gender, ethnicity, and race of retrieved records in a graphical format.

- PRI Score, which allows an investigator to automatically compute a participant's bleeding score(s) based on their responses to the questionnaire.

Access to PRI Reports will be restricted to investigators with a valid User ID and password.

7) Investigators can gain access to the system under 4 different conditions (see figure below). A. "Level 1" Access, which is defined as part of an ongoing protocol approved by the ISTH-BAT Standing Committee. B. "Level 2" Access, which is defined as access to the person's own data in a study that is not approved by the ISTH-BAT Study Committee, but not data collected by other investigators. C. "Level 3" Access, which is defined as part of a protocol approved by the ISTH-BAT Standing Committee, requiring access to data previously collected as part of a study approved by the ISTH-BAT Standing Committee. D. "Level 4" Access, which is defined as access to both the person's own data and the aggregate data set of studies that are not approved by the ISTH-BAT in exchange for depositing the investigator's own data.

If an investigator with Level 2 access prefers to keep her or his own data and does not want a copy of the data to be retained in a segregated dataset within the ISTH-BATR, individual arrangements need to be made to insure that the procedures for deleting the segregated databases are understood and mutually acceptable.