**JHM IRB - eForm R – Development of a Research Resource**

**Protocol**

**This form is intended to describe the creation or set-up of a research resource. Common examples of research resources are a database, biospecimen repository and a recruitment database. Generally, the purpose of a research resource is to help support current and future research rather than to answer a particular research question.**

* **PLEASE NOTE: *If you intend to create a research resource, a separate IRB application is required for the creation of the resource itself. Use this form to describe the resource you are creating, how it will be managed and how it will be accessed for future research use.***
* **IRB protocols for registries and repositories that are designed to be used as a research resource should not also include specific hypotheses and planned analyses.**
* **Each research project utilizing your research resource must be submitted as a separate eIRB application.**
* **Investigators overseeing a research resource are required to track and report to the IRB annually a summary of any studies that have utilized the resource.**
* **Please provide complete information for each item below. If an item is inapplicable to your research resource, explain why.**
* **When submitting JHM IRB eForm R (new or revised), enter the date submitted, the name of the PI, and the eIRB application number in the header at the top of the form.**

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

1. **Objective & Rationale for the Resource**
2. **Explain the goal(s) of the resource.**

**Answer:** The aim of the research resource is to create a large repository of patient data from 10 trauma centers to examine venous thromboembolism (VTE) outcomes and associated factors in trauma patients. This registry will contain basic patient demographics, trauma specific injury information, outcomes (including VTE events), and VTE prevention practice (i.e. administration and non-administration of VTE prophylaxis doses).

1. **Provide a justification for the establishment of this research resource. Explain how this resource addresses an unmet need, [e.g. why is this new resource needed? What value will it provide?]**

**Answer:** Trauma is a well-known risk factor for hospital-associated VTE. VTE prophylaxis in this population has been a well-accepted standard of care for two decades. To address the dearth of knowledge regarding post-traumatic VTE pathophysiology and prevention after injury, national experts at 17 trauma centers formed the Consortium of Leaders in the study Of Traumatic Thromboembolism (CLOTT) team in 2013. Our proposed research repository will be used to support a newly funded project to disseminate best-practice VTE prevention at 10 trauma centers in the CLOTT network.

We have been funded by the Patient-Centered Outcomes Research Institute (PCORI) to

expand our already successful intervention for VTE prevention to these 10 trauma centers. We plan to use the four-step Translating Research into Practice (TRIP) framework to implement a combined nurse and patient-education approaches at 10 trauma centers, generating information about their VTE practices that will be used to populate the repository for missed doses. We will also be collecting core trauma registry data in line with the National Trauma Data Standard (NTDS) and the American College of Surgeons Trauma Quality Improvement Program (TQIP) data elements.

The clinically meaningful results from our previous studies have shown that missed doses of prescribed prophylaxis are a serious problem, with up to 15% of doses not given to patients. The main reason for missed doses is patient refusal, and the refusal rate of these injections is significantly higher than for other medicines. Importantly, missed doses of VTE prophylaxis are associated with VTE events, particularly in trauma and surgery patients. This repository will create the opportunity to understand and address the issue of missed doses across a different clinical setting. While trauma outcomes are commonly studied, this will be the first large-scale project to specifically link missed doses of VTE prophylaxis to trauma registry data.

1. **Description**
	1. **Identify the type of resource [biospecimen repository, data repository, recruitment registry, etc.]**

**Answer:** Our resource will be a data repository to include trauma registry data (i.e. NTDS, TQIP variables) and data about administration of VTE prophylaxis.

* 1. **Specify the data/material sources from which this research resource will be compiled.**

**Answer:** Trauma registry data from the 10 included trauma centers, supplemented by VTE prophylaxis dose-level data from the individual centers’ electronic health record systems. Trauma centers will provide a standardized data output from their trauma center registry using the same required format for which they already upload data to the ACS TQIP program. The VTE prophylaxis data will also come in standardized data format to include time/date of all prescribed VTE prophylaxis medication doses with data on administration (given vs. not given) and the reason for non-administration (patient refusal vs. other). Data will be shared from each trauma center to JHU via Safe Desktop.

* 1. **Describe the specific INCLUSION and EXCLUSION criteria for data/biospecimens to be included in the resource.**

**Answer:** All injured patients admitted to the 10 included trauma centers for whom data are collected in the trauma registry will be included in this data repository.

* 1. **Explain whether this resource will be static, comprised of only currently existing data/specimens or dynamic, prospectively adding new data/specimens. Explain whether you will be accumulating new data/specimens for patients already included in the database.**

**Answer:** Funding for the project at 10 trauma centers is available for 24 months from PCORI. We plan to aggregate previously existing data (before the 24 months) and prospectively collect data for future patients for the entire 24 month study period.

1. **Data Acquisition**
2. **Will the data/biospecimens to be included in this resource come from consented participants or are you requesting a waiver of consent? Provide a justification for a waiver of consent. If there is any intent to use the registry/resource for future patient contact, consent is required.**

**Answer:** We will require a waiver of informed consent.The data involving 10 trauma centers will be collected through an automated system once the main and the individual IRBs are approved. The interventions (nurse and patient education) to be implemented at these centers present no more than minimal risk to participants. Patient data will only be accessible to trained study staff and only on password-protected computers and approved servers. The intervention bundle includes a one-on-one discussion and education session with a nurse educator, a patient education sheet and a patient education video that pose no risk to patient's health. In addition, the trauma registry is a complex database of the demographics, injuries, care, and outcomes of trauma patients. The primary reason for the establishment of trauma registry has been to improve care management in trauma and to increase the survival rate of victims when trauma occurs. Data included in this registry are frequently used for improving care in a learning healthcare system. Participants will not be administered a drug or device.

1. **If participants will be consented, describe the method that will be used to recruit and consent participants. Upload these materials into the application.**

**Answer:** N/A

1. **If you will be including data/biospecimens from patients consented under other research studies, please list the IRB numbers for those studies.**

**Answer:** N/A

1. **If your study involves data/biospecimens from participants enrolled under other research studies with a written consent or under a waiver of consent, please list the IRB application numbers for those studies.  Please note:  Certificate of Confidentiality (CoC) protections applied to the data in source studies funded by NIH or CDC will extend to this new study if the funding was active in 2016.  If this situation applies, Section 36, question 4 in the application will need to be answered “Yes” and “Hopkins Faculty” should be selected in question 7. No other documents are required.**

**Answer:** N/A

1. **Will the data include new information provided by participants? If so, provide copies of forms/materials participants will complete. This includes any information gathered via apps.**

**Answer:** No. The resource will be populated using the individual trauma centers’ trauma registry and electronic health record systems. Thus, new information will not be provided by participants.

1. **If collecting data from medical records upload your data collection forms(s) and describe:**
	1. **The process for identifying patient records to be included,**

**Answer:** All injured patients admitted to the 10 included trauma centers for whom data is collected in the trauma registry will be included. These data will be joined with data for administration of prescribed VTE prophylaxis medication that will be provided by each site.

* 1. **The estimated number of patient records to be included,**

**Answer:** We estimate a total of 200,000 trauma patients will be included from all 10 trauma centers participating in this repository. However, we may have data for 2 million patient records as data for administration of prescribed VTE prophylaxis medication may be supplied to us for non-trauma patients. Individual trauma centers may not be able to join these data locally and if that is the case, we will join the EHR data (which may include all patients) with the trauma registry.

* 1. **The process for extracting the data (e.g. manual chart review, automated data extraction, CCDA, etc.),**

**Answer:** We will utilize automated extraction strategies from individual EHRs at each of the 10 trauma centers.

* 1. **The process for updating the resource: At what interval are you entering new cases or updating existing cases? How is this managed?**

**Answer:** We are planning to populate the resource with new data provided to us by the 10 centers involved in the study on a monthly basis. Joseph Canner at the Johns Hopkins Surgery Center for Outcomes Research (JSCOR) will be responsible to store and manage the data in SQL.

* 1. **Whether complete records will be copied and placed in this file (e.g. copies of image files, copies of medical notes, etc.) If so, please provide a justification. If the project will include storing copies of original documents from EPIC, you will need to identify an honest broker (contact the CCDA:** [**https://ictr.johnshopkins.edu/programs\_resources/programs-resources/i2c/center-for-clinical-data-analysis-ccda/**](https://ictr.johnshopkins.edu/programs_resources/programs-resources/i2c/center-for-clinical-data-analysis-ccda/)**)**

**Answer:** N/A.

* 1. **Identify the individual(s) who will be conducting the data extraction**

**Answer:** NA. Data extraction will occur at 10 other trauma center institutions; JHM will be the recipient of this data.

1. **Data Storage**
2. **Explain in what format the data/ will be stored (REDCap, SQL, etc.).**

**Answer:** Data will be stored in SQL.

1. **Provide specific details as to where the data/ will be housed.**

**Answer:** Data will be housed on Safe Desktop and managed by the Johns Hopkins Surgery Center for Outcomes Research (JSCOR).

1. **Identify the individual who will oversee data security and safe management of the resource.**

**Answer:** Access to the server requires a JSCOR data use agreement, current/active IRB training, and JHED authentication. Data will be stored in a restricted folder. Access to the restricted VTE folder will be granted/revoked by Joseph Canner, Program Administrator of JSCOR.

**Where will the working datasets be stored (The IRB prefers research data to be stored on a SAFE desktop. See here for details:** [**https://ictr.johnshopkins.edu/programs\_resources/programs-resources/i2c/secure-research-data-desktop/**](https://ictr.johnshopkins.edu/programs_resources/programs-resources/i2c/secure-research-data-desktop/)**)**

**Answer:** Datasets will be stored in SAFE Desktop to ensure data security.

**Where will any coding linkage data to reidentify data, if applicable, be stored**

**Answer:** N/A

**If any data is collected on portable devices via an app, will any PHI be stored locally on the app device?**

**Answer:** Data will not be collected on portable devices.

**For patient provided information via apps, will they use a study code number or their own personal identifiers?**

**Answer:** N/A. See 4f.

1. **Will communication to and from portable devices be encrypted?**

**Answer:** N/A. See 4f.

1. **Biospecimen Storage**
2. **Explain how/where biospecimens will be stored**

**Answer:** Biospecimens will not be collected.

1. **Data Management**
2. **Please identify who is going to manage access to the data/specimens contained in the resource.**

**Answer:** Access to the server requires a JSCOR data user agreement, current/active IRB training, and JHED authentication. Data will be stored in a restricted folder. Access to the restricted VTE folder will be granted/revoked by Joseph Canner in communication with the PI, Dr. Haut. Data joins include VTE prophylaxis prescription and VTE prophylaxis administration based on medical record number and/or encounter number. All data management will be done using SQL and analyses will be conducted using STATA on the institution’s SAFE desktop.

1. **Explain how individual researchers will request access to this resource.**

**Answer:** Requests for access to the resource will be reviewed by the core members of the Johns Hopkins VTE Collaborative (Haut, Streiff, Lau, Kraus, Shaffer) to determine appropriateness of request. If a request is appropriate, the researcher(s) will submit an IRB application for their proposed project before data may be accessed. Individual researchers will be provided with limited datasets or secure access to the full data on SAFE desktop upon meeting the data agreement requirements.

1. **What are the requirements for granting access to the resource?**

**Answer:** Researchers must have completed all required IRB training, have an approved IRB application for the scope of their project, and will be provided with a dataset that falls within the scope of their approved project.

1. **How will separate IRB approval for any use of the resource be verified before access is granted?**

**Answer:** The core members of the Johns Hopkins VTE Collaborative (Haut, Streiff, Lau, Kraus, Shaffer) will review the scope and determine appropriateness of the IRB approved project and will provide a limited dataset that falls within the scope of the approved project.

1. **Explain how other researchers will access the resource. Will they be granted access to the entire resource and able to extract any data they require, or will the overseers of the resource provide researchers with access only to data/specimens needed for their specific research plan?**

**Answer:** The core members of the Johns Hopkins VTE Collaborative will have access to the entire resource. They will review all requests for data, ensure that IRB approval for requested data has been granted, and will pull the relevant data from the resource defined by the scope of the approved project.

1. **If researchers are provided with a data file, will they be given an actual file or will they need to conduct their analysis within the same data framework that supports this resource?**

**Answer:** Researchers will be provided with a data file, and analyses conducted subsequently. They will be required to conduct their analysis within the same data framework.

1. **Will files include identifiable data or be a limited or de-identified data set?**

**Answer:** Files provided will be no more than a limited dataset, depending upon the scope of their approved proposal.

1. **What is the time period that researchers may use any data/specimens they are provided?**

**Answer:** The time period that researchers may use data is project dependent and according to their individual IRBs.

1. **What are the procedures once researchers have completed their analyses, i.e. do they return the data, is access terminated, is data deleted?**

**Answer:** The data will be deleted or access the SAFE desktop environment will be terminated.

1. **Is there a requirement that projects utilizing the resource contribute data/results back to the resource?**

**Answer:** Yes. The VTE Collaborative requires data/results be shared with the group.

1. **If this data source will also be a resource for research recruitment, please explain what the requirements are for researchers to receive patient contact information. Explain how this contact information would be shared and any time limit for its use.**

**Answer:** This data source will not be a resource for research recruitment.

1. **Explain your process for keeping records of access to this resource and for reporting the use of this resource yearly to the IRB.**

**Answer:** All access to the registry must be reviewed and approved by the VTE Collaborative. Joseph Canner will maintain a spreadsheet of all data requests, individuals who request data, IRB application numbers, and a brief description of the project. This spreadsheet will form the basis of the annual report provided to the IRB.

1. **For resources involving JHM clinical data and/or biospecimens collected at JHM, please confirm the registry adheres to the following institutional guidelines:** [**https://hpo.johnshopkins.edu/enterprise/policies/1099/39500/policy\_39500.pdf**](https://hpo.johnshopkins.edu/enterprise/policies/1099/39500/policy_39500.pdf)

**Answer:** The registry adheres to the institutional guidelines.

1. **Risks**
2. **Describe any risks related to this resource [including potential legal or financial risks].**

**Answer:** Collection of patient-level data presents a potential loss of confidentiality.

1. **Explain the steps taken to minimize the risks.**

**Answer:** Loss of confidentiality will be minimized by maintaining the data within the Johns Hopkins Medicine secure network (SAFE Desktop) and restricting data access to designated study team members via Hopkins JHED authentication.

1. **Describe your plan for reporting unanticipated problems and study deviations in accordance with the IRB’s** [**prompt reporting policy**](https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/prompt_reporting_policy.html)**.**

**Answer:** We do not anticipate any problems or deviations to occur. Should any non-compliance occur, we will report the issue to IRB promptly.

1. **Resources/Support**
2. **Provide information on the financial support for this data resource. (If this is departmental, please upload a letter of support).**

**Answer:** Financial support for this data resource will be provided by the Patient-Centered Outcomes Research Institute (PCORI) for the project titled “Implementing Best-Practice, Patient-Centered Venous Thromboembolism Prevention in Trauma Centers” via contract number DI-2019C3-17859.

1. **What resources exist to enable the study team to maintain/manage the resource as proposed [describe relevant resources including personnel, technology, etc.]?**

**Answer:** Financial support for this data resource will be provided by the Patient-Centered Outcomes Research Institute (PCORI) for the project titled “Implementing Best-Practice, Patient-Centered Venous Thromboembolism Prevention in Trauma Centers” via contract number DI-2019C3-17859.