JOHNS HOPKINS SCHOOL of MEDICINE eIRB2

Date: Friday, January 15, 2021 11:07:42 AM

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Application
IRB00265294
Elliott Haut

1 - General Information

ID: IRB00265294

1. * **Principal Investigator:**
*Click **Select** to choose PI:*
Elliott Haut

2. * **Will the PI obtain consent for this study ?**
○ Yes ● **No**

3. * **Is the PI a JHHS RN?**
○ Yes ● **No**

4. * **Indicate the PI's primary affiliation:**
(Select "Other (Affiliation Not Listed)" if the PI's primary affiliation is not listed):
Surgery - Broadway

5. * **Title of Study:**
Implementing Best-Practice, Patient-Centered Venous Thromboembolism (VTE) Prevention in Trauma Center

6. * **Provide a BRIEF statement of your research question and plan:**
This project focuses on implementing findings from a completed PCORI study (IRB00057117), which showed that a single, web-based nurse education module can have a dramatic effect on missed doses of VTE prophylaxis administration (blood clot prevention) in hospitalized patients. It also showed that a patient-centered education bundle delivered to hospitalized patients reduces missed doses by nearly 50%. The program showed similar benefits in medical and surgical floors at a university-affiliated hospital and are equally effective at a smaller, community non-teaching hospital.

CLOTT, is a 3-year prospective project involving 17 level 1 and level 2 trauma centers that looking at missed doses of VTE prophylaxis and risk factors associated with VTE. Because of the connection that has been built between these trauma centers, we sought the opportunity to expand our already effective education module to other trauma centers within the country. 10 of the 17 trauma centers involved in CLOTT (IRB00160626) have agreed to implement our nurse education module and patient-centered education bundle. The primary objective of this new study is to help nurses and patients make informed decisions regarding VTE prevention and reduce the occurrence of blood clots in injured patients. Our aims are: • To implement the validated nurse education module, and patient-centered education tool at 10 trauma centers in an existing research hospital network (CLOTT) • To examine data on missed and refused doses of VTE prophylaxis and study the intervention's impact on VTE outcomes in trauma patients at high-risk for VTE events • To conduct a qualitative study to tailor the intervention to the different health care settings and computer systems so that it can be implemented nationally.

this application will be for the research data repository for trauma patient data from 10 trauma centers to support the evaluation of the planned intervention.

7. * **Select the type of review requested:**
Expedited

8. * **Will an external IRB act as the IRB of record for this study?**
○ Yes ● **No**

9. **What kind of study is this?**
Multi-site study

   * **WIll Hopkins/Affiliates serve as the lead/coordinating center for this multicenter study?:**
   ● **Yes** ○ No

10. * **Will your [JHM] IRB act as the single IRB of record for other participating sites?**
○ Yes ● **No**

12. * **Does this project ONLY involve review of records?**
Select "Yes" if this project will **ONLY** involve review of charts/medical records.
○ Yes ● **No**

13. * **Is this a quality improvement project?**
○ Yes ● **No**

14. * **Is the purpose of this protocol to create a research resource (eg clinical data, biospecimen, or recruitment registry) that will be maintained by the study team?**
● **Yes** ○ No

You have indicated that the purpose of this project is to create a research resource. The e-Form R must be used as the Protocol type for this project. Please upload the e-form R in Section 6. Additionally, if your research resource involves Johns Hopkins Medicine clinical data/specimens, the resource must adhere to the JHM Guidelines and Technical Requirements for Registries**.**

15. **Is there a component of your proposed project that is a public health surveillance activity?**
○ Yes ● **No**

17. * **Is this a resubmission of an expired, terminated, withdrawn or disapproved application?**
○ Yes ● **No**

19. * **Is this a conversion of an active study already approved by a Hopkins/Affiliates IRB (including the JHM All Children's Hospital IRB)?**
○ Yes ● **No**

23. * **Estimated time to complete this study:**
5 years

24. * **Does the institutional policy on physician consent require that a physician-investigator or mid-level provider obtain informed consent for this research?**
○ Yes ● **No**

25. **Study Team Members:**

*Click **Add** to add new Study Team members. Click **Update** to modify existing Study Team member information.*

	Last	First	Degrees	JHED Dept	Primary Affiliation	Role	Consenting Hopkins participants	Consenting Physician-Investigator/ Mid-Level Provider	Agree Consenting Physician-Investigator/ Mid-Level Provider	Receive Notifications	Agree To Participate
View	Canner	Joseph	n/a	SOM Sur Clinical Research Office	Surgery - Broadway	Co-Investigator	no		no	yes	yes
View	Kraus	Peggy	n/a	Adult Pharmacy	Pharmacy - Broadway	Co-Investigator	no		no	yes	yes
View	Lau	Brandyn	n/a	SOM Rad Diagnostic Imaging	Radiology - Broadway	Co-Investigator	no			yes	yes
View	Owodunni	Oluwafemi	n/a	Surgery-Acute Care Surgery and Adult Trauma Surgery	Surgery - Broadway	Co-Investigator	no		no	yes	yes
View	Streiff	Michael	M.D.	SOM DOM Hematology	Hematology - Broadway	Co-Investigator	no		no	yes	yes

	Last	First	Degrees	JHED Dept	Primary Affiliation	Role	Consenting Hopkins participants	Consenting Physician-Investigator/ Mid-Level Provider	Agree Consenting Physician-Investigator/ Mid-Level Provider	Receive Notifications	Agree To Participate
View	Varasteh Kia	Mujan	MPH	SOM Sur Clinical Research Office	Surgery - Broadway	Co-Investigator	no		no	yes	yes

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2 - Study Team Compliance Training

1.0 All Study Team Members listed below must complete indicated training requirements
*PIs of active IRB Protocols must complete the **REWards training (Research Ethics Workshops)** or equivalent. PIs have one year from the date of their first eIRB submission to complete the **REWards** requirement.*

For studies with a Prospective Reimbursement Analysis document (PRA), Clinical Research Billing Orientation (CRBO) training is required for study team members who have a role in the consenting process. Clinical Research Support Services will notify those members by email. The IRB cannot take final action until all training is complete.

Principal Investigator

Last Name	First Name	HSR Required	Date	H&R Required	Date	COI Required	Date	Date REWards Completed	CRBO Required	Date CRBO Completed
Haut	Elliott	Yes	2/12/2017	Yes	10/31/2004	Yes	2/17/2020	4/21/2006		

Local Site PI

Last Name	First Name	HSR Required	Date	H&R Required	Date	COI Required	Date	Date REWards Completed	CRBO Required	Date CRBO Completed

Study Team:

	Last Name	First Name	HSR Required	Date	H&R Required	Date	COI Required	Date	Date REWards Completed	CRBO Required	Date CRBO Completed
View	Canner	Joseph	yes	8/12/2019	yes	1/4/2013	yes	12/19/2016	7/18/2016		
View	Kraus	Peggy	yes	5/28/2019	yes	4/13/2009	yes	11/13/2018	1/27/2020		2/2/2016
View	Lau	Brandyn	yes	1/7/2020	yes	9/15/2010	yes	10/25/2019	10/19/2010		
View	Owodunni	Oluwafemi	yes	9/20/2019	yes	10/29/2016	yes	10/29/2016			
View	Streiff	Michael	yes	3/30/2020	yes	4/10/2003	yes	5/8/2017	6/1/2006		9/5/2008
View	Varasteh Kia	Mujan	yes	11/12/2019	yes	11/2/2016	yes	10/18/2016			

2.0 If the dates above are blank or incorrect, upload copies of training certificates or myLearning Report and the JHM IRB staff will enter the dates for you.

*Click **Add** to upload a new document. Click **Update** to upload a revised version of the existing document. (Click **History** to see all uploaded versions of an existing document.)*

Title	Date Modified	Version	Status
There are no items to display			

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6 – Protocol Information

1.0 * Type of protocol:

☑ **JHM-IRB eForm**

☐ **Outside Sponsor**

☐ **Investigator-Initiated**

2.0 * **Clean Protocol:**
*Click **Add** to upload a new clean document. Click **Update** to upload a clean revised version of the existing document. (Click **History** to see all uploaded versions of an existing document.)*

	Title	Date Modified	Version	Status
View	~~eformR Haut clean version 10-22-2020 revised #1 TRACKED CHANGES 12-9-2020.docx~~(0.01)	12/9/2020 8:39 PM	0.01	Deleted
View	eformR Haut clean version 10-22-2020 revised #1 CLEAN 12-9-2020.docx(0.02)	12/9/2020 8:39 PM	0.02	Submitted

3.0 **Track Changes Protocol or Summary of Changes**
*Click **Add** to upload a new track change document. Click **Update** to upload a track change revised version of the existing document. (Click **History** to see all uploaded versions of an existing document.)*

	Title	Date Modified	Version	Status
View	eformR Haut clean version 10-22-2020 revised #1 TRACKED CHANGES 12-9-2020.docx(0.01)	12/16/2020 12:13 AM	0.01	Submitted

5.0 **Appendices/Sub-study protocol/Letter of Amendment**
*Click **Add** to upload a new document. Click **Update** to upload a revised version of the existing document. (Click **History** to see all uploaded versions of an existing document.)*

Title	Date Modified	Version	Status
There are no items to display			

6.0 * **Did this study receive a non-IRB scientific review?**
○ Yes ● **No**

9.0 **Additional pilot data or relevant publications**
Click **Add** to upload a new document. Click **Update** to upload a revised version of the existing document. (Click **History** to see all uploaded versions of an existing document.)

	Title	Date Modified	Version	Status
View	Haut_2018_oi_180207 Effect of Real-time Patient-Centered Education Bundle on Administration of Venous Thromboembolism Prevention in Hospitalized Patients.pdf(0.01)	10/22/2020 10:30 PM	0.01	Submitted
View	Effectiveness of two distinct web-based education tools for bedside nurses on medication administration practice for venous thromboembolism prevention RCT.pdf(0.01)	10/22/2020 10:30 PM	0.01	Submitted
View	Patient Preferences for Receiving Education on Venous Thromboembolism Prevention _ A Survey of Stakeholder Organizations PLOS One 2016.pdf(0.02)	10/23/2020 9:08 AM	0.02	Submitted

10.0 * **If your study is occurring at JHH or JHBMC, check all of the below that apply:**

☐ **There are research activities or drugs administered in this protocol that are intended to induce symptoms in research participants, such as: procedures to provoke an allergic reaction (pulmonary, nasal, or GI), induced sputum, or exercise stress test.**

☐ **Research participants will undergo high risk, invasive procedures that are NOT part of prescribed routine clinical care for the participant. Examples include bronchoscopy, cardiac catheterization, use of a glucose clamp, or insertion of an arterial line. (Lumbar puncture is not considered high risk.)**

☐ **There are drugs administered as part of the protocol that have a likelihood of causing an allergic reaction, or side effects, which could require the use of rescue medications.**

☐ **This is the first time you have been listed as PI on a more than minimal risk application.**

☑ **None of the above**

11.0 * **Does your study involve organ transplantation from an HIV positive donor (living or deceased) to an HIV positive recipient?**
○ Yes ● **No**

13.0 * **Does this study involve HIV testing in the State of Maryland?**
○ Yes ● **No**

14.0 **Will any photographic images or recordings (audio or video) of participants be taken solely for research purposes?**
○ Yes ● **No**

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7 - Clinical Trials Information

1. * **Is this a clinical trial?**
○ Yes ● **No**

Registration on ClinicalTrials.gov is strongly encouraged or required for many studies that may not meet the definition of a “clinical trial” (i.e., medical journal guidelines, in the terms and conditions of Foundation or other sponsored research). If your protocol is registered at ClinicalTrials.gov, please enter the National Clinical Trials (NCT) number below

9. * **ClinicalTrials.gov identifier (NCT Number):**
Please enter only the eight digits of the registration number (without "NCT").

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8 - Conflict of Interest

1.0 * **Does the PI or any study team member (or their spouse, domestic partner, or dependent children) have a financial interest or fiduciary relationship that**

1) could be affected by the research, or
2) is in an entity that could be affected by the research?

* **This applies to current interests/relationships and those within the past 12 months.**
○ Yes ● **No**

All conflicted individuals must disclose potential conflicts of interest to the Office of Policy Coordination (OPC) before this application can be approved.

5.0 * **To the best of your knowledge, does Johns Hopkins have a financial interest that 1) could be affected by the research or 2) is in an entity whose financial interest could be affected by the research?**
○ Yes ● **No**

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9 - Support Information

1.0 * **Check all sources of support (pending or awarded):**
☑ Monetary
☐ Material
☐ None

2.0 **Does the sponsor require the IRB review process to comply with International Conference on Harmonization / Good Clinical Practice Standards (ICH GCP)?**
○ Yes ● **No**

3.0 * **Will data from this study be submitted to a federal genomic database or repository (e.g., dbGaP)?**
○ Yes ● **No**

4.0 * **MONETARY SUPPORT:**

Click **Add/Update** to select monetary support source:

	Source	Status	Grant Number
View	Patient-Centered Outcomes Research Institution	Awarded	

5.0 * **Will Johns Hopkins receive funds through a sub-contract or sub-award?**
● **Yes** ○ No

6.0 * **Name the institution/entity through which you will directly receive funds:**
Coalition for National Trauma Research (CNTR)

7.0 * **Does this research have COMMERCIAL FUNDING?**
○ Yes ● **No**

9.0 * **Will you apply to the Bayview Institute for Clinical and Translational Research - Clinical Research Unit (ICTR-CRU) (formerly GCRC) or JHH ICTR-CRU (includes NBRU) for funding or use of facilities?**
○ Yes ● **No**

10.0 **If ORA has requested IRB review of your grant or you have funding from the Maryland Stem Cell Research Fund, submit a copy of the complete grant, including the face page but excluding the appendices:**
Click Add to upload a new document. Click Update to upload a revised version of the existing document. (Click History to see all uploaded versions of an existing document.)

Title	Date Modified	Version	Status
There are no items to display			

11.0 **Do you have or do you anticipate receiving federal funding for this study?**
● **Yes** ○ No

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10 - Study Location

1.0 **Johns Hopkins Primary Sites:**

	Location	PI Name	PI Email	PI Phone	Notes
View	Johns Hopkins Hospital	Elliott R. Haut	ehaut1@jhmi.edu	410-502-3122	

Johns Hopkins ICTR-CRU Sites:

Location	PI Name	PI Email	PI Phone	Notes
There are no items to display				

Other Johns Hopkins Sites:

Location	PI Name	PI Email	PI Phone	Notes
There are no items to display				

Other Non-Hopkins Sites:

Location	PI Name	PI Email	PI Phone	Notes
There are no items to display				

If using a JHCP location click on the help link for guidance and to complete the JHCP Research Application.

2.0 **Is this study using a Johns Hopkins Clinical Research Network site?**
○ Yes ● **No**

3.0 **Is this study using a PCORI-Path site?**
○ Yes ● **No**

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11 - Sample Size

1.0 * **Will this research involve intervention/interaction with participants?**
○ Yes ● **No**

4.0 * **How many participants will be accrued at Hopkins/Affiliates?**
0

5.0 * **For multi-center studies, how many participants will be accrued at all sites (including Hopkins/Affiliates)?**
2000000

8.0 * **Will you need JHHS nursing staff for any research-related activities (e.g., as participants, blood draws, drug administration, device use, specimen collection, increased monitoring, survey administration)?**
This question does not apply to research conducted only on the ICTR-CRU units using ICTR-CRU nursing staff. If you will only be using ICTR-CRU nursing staff question 8.0 should be answered "no."
○ Yes ● **No**

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12 – Participant Information

1.0 * **Will you obtain identifiable data, records, specimens, or samples, or have access to codes, links or identifiers?**
● **Yes** ○ No

2.0 * **Age ranges of participants (e.g., 0-17, ≥ 18 years):**
all ages

3.0 * **Study population - check all that apply:**
- ☑ **Male adults (18+)**
- ☑ **Female Adults (18+)**
- ☑ **Male children (<18) [Who cannot consent for themselves]**
- ☑ **Female children (<18) [Who cannot consent for themselves]**
- ☐ **Males (<18) [Who can consent for themselves as permitted by law]**
- ☐ **Females (<18) [Who can consent for themselves as permitted by law]**

4.0 **Special Study Populations - check all populations that may be enrolled:**
- ☐ **Adults lacking capacity to consent**
- ☐ **Pregnant Women**
- ☐ **Non-viable neonates/neonates of uncertain viability**
- ☐ **Prisoners**
- ☐ **Non-English speakers**
- ☐ **Children who are in foster care or wards of the state**

5.0 * **Will you enroll healthy volunteers?**
○ Yes ● **No**

6.0 **Hopkins Study Populations - check all populations that you will target for recruitment or record review:**
- ☐ JHH/JHBMC adult emergency department patients/records
- ☐ Employees/records

- ☐ JHU School of Medicine residents/interns/records
- ☐ JHU School of Medicine students/records
- ☐ Other JHU students/records
- ☐ Hopkins/Affiliates inpatients
- ☐ Hopkins/Affiliates outpatients
- ☐ JHH obstetric patients

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13 - Recruitment Information

1. * **Check all sources of recruitment for this study:**

- ☑ **No intervention/interaction with participants (e.g., chart record review)**
- ☐ **Individuals who are clinical patients of the PI or co-investigators**
- ☐ **Review of clinical records of individuals who are not clinical patients of the PI or co-investigators prior to their consent**
- ☐ **Referral of individuals specifically for research purposes by treating clinicians not on the study team**
- ☐ **Prior Hopkins/Affiliates study participants**
- ☐ **Individuals who learn about the study through advertisements or peer/network recruiting**

8. **Data Sources [Check All that Apply]:**

- ☐ **JHM Clinical Data (including EPIC, Casemix, CCDA, Departmental databases)**
- ☐ **JHM Patient Experience Data**
- ☐ **JHM HERO or Safety Culture Assessment Data**
- ☐ **Check here if you are not sure what JHM data sources you will need**
- ☑ **Non-Hopkins/Affiliates clinical databases or medical charts/records**
- ☐ **JHM IRB approved studies or research databases**
- ☐ **Non-Hopkins IRB approved studies**
- ☐ **Public databases/registries/repositories**
- ☐ **Administrative/claims data from Johns Hopkins Healthcare LLC**
- ☐ **Cancer registry data elements**
- ☐ **Imaging Data collected for research**
- ☐ **Other Data Source [not listed above]**

11. **JHM-IRB waiver of privacy authorization (HIPAA Form 4)**

Required for:

• Chart/record review without participant consent/authorization
• Receiving PHI from a referring Clinician not on the study team
• Conducting telephone screening prior to obtaining written consent

Click **Add** to upload a new document. Click **Update** to upload a revised version of the existing document. (Click **History** to see all uploaded versions of an existing document.)

Title	Date Modified	Version	Status
There are no items to display			

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14 - Consent and Waivers

[For Adults and Individuals under 18 who can consent for themselves]

1. * **Check the type(s) of consent planned for this study:**

☐ **Written Consent**

☐ **Waiver of Documentation of Consent (including oral consent)**

☑ **Waiver of Consent**

* **Describe how each of the following criteria are met for this study:**

• Why the research involves no more than minimal risk to participants
• Why the research could not practicably be carried out without the waiver or alteration
• Why the waiver or alteration will not adversely affect the rights and welfare of the participants
• Whether the study is expected to generate information pertinent to provide participants after participation, and if so, the plan to provide this information

Please Note: If the research involves the use of identifiable private information or identifiable biospecimens, you must also describe the following:

• Why the research could not be practicably carried out without using such information or biospecimens in an identifiable format.

This intervention presents no more than minimal risk to participants. Patient data will only be accessible to trained study staff and only on password-protected computers. Paper data collection sheets will be stored under lock and key. Participants will not be administered a drug or device. 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 which pose no risk to patient's health.

The waiver will not adversely affect the rights and welfare of participants, as it will include all standard safeguards for ensuring confidentiality of patient information. All links between protected health information and personal identifiers will be destroyed after publication of study results.

The goal of this project is to improve patient outcomes. We will be educating all patients who are missing doses of medications that have been ordered by the physicians and/or authorized prescribers (i.e. nurse practitioners or physician assistants). Obtaining informed consent will be impractical and an unnecessary layer of complexity as there will be only a minimal risk for breach of confidentiality.

Providing participants with additional pertinent information is not appropriate for this study as we anticipate no more than minimal risk to participants.

☐ **Consent was previously obtained which accounts for the activity proposed in this new submission and no new consent is required.**

17 – Assent and Parental Permission for Research Involving Children

1.0 * **Check the type of assent planned for this study:**

☐ **Assent with a signature by the child (either in the parental permission form or a separate assent document)**

☐ **Assent without a signature by the child (including an assent statement in the parental permission form [without child signature] and oral assent)**

☑ **Waiver of assent**

☐ **No assent or waiver required**

2.0 * **Describe the process for obtaining assent, including:**

- Who will discuss the research
- Information that will be discussed
- Whether you will use different processes for children of varying ages or capacities

Waiver of assent. Same reply as reason for waiver of consent.

6.0 * **Waiver of Assent** *Check the most applicable justification for a waiver of the requirement to obtain assent:*

☐ **Ages, maturity, or psychological state of the children to be enrolled make them incapable of providing assent**

☐ **Intervention or procedure involved in research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the current context of the research**

☑ **Research involves no more than minimal risk to children and the research could not be practicably carried out without the waiver of assent**

7.0 Sponsor sample assent

Click **Add** to upload a new document. *Click **Update** to upload a revised version of the existing document. (Click **History** to see all uploaded versions of an existing document.)*

Title	Date Modified	Version	Status
There are no items to display			

8.0 Check the type of parental permission planned for this study:

- ☐ **Written permission**
- ☐ **Waiver of documentation of parental permission (including oral permission)**
- ☑ **Waiver of parental permission**
- ☐ **Parental permission not required**
- ☐ **Parental permission was previously obtained which accounts for the activity proposed in this new submission and no new parental permission is required**

12.0 Waiver of Parental Permission

There are two conditions when a waiver of parental permission may be granted. Please select the most appropriate option below:

☑ **Waiver of Parental Permission when the study is minimal risk**

Describe how each of the following criteria are met for this study:

Why the research involves no more than minimal risk to participants
Why the research could not practicably be carried out without the waiver
Why the waiver will not adversely affect the rights and welfare of the participants
Whether the study is expected to generate information pertinent to provide participants after participation, and if so, the plan to provide this information

Please Note: If the research involves the use of identifiable private information or identifiable biospecimens, you must include the following:

Why the research could not be practicably carried out without using such information or biospecimens in an identifiable format.

This intervention presents no more than minimal risk to participants. Patient data will only be accessible to trained study staff and only on password-protected computers. Paper data collection sheets will be stored under lock and key. Participants will not be administered a drug or device. 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 which pose no risk to patient's health.

The waiver will not adversely affect the rights and welfare of participants, as it will include all standard safeguards for ensuring confidentiality of patient information. All links between protected health information and personal identifiers will be destroyed after publication of study results.

The goal of this project is to improve patient outcomes. We will be educating all patients who are missing doses of medications that have been ordered by the physicians and/or authorized prescribers (i.e. nurse practitioners or physician assistants). Obtaining informed consent will be impractical and an unnecessary layer of complexity as there will be only a minimal risk for breach of confidentiality.

Providing participants with additional pertinent information is not appropriate for this study as we anticipate no more than minimal risk to participants.

☐ **Waiver when parental permission is not a reasonable requirement to protect subjects**

20 - Supplemental Study Documents

You are not required to submit standard and recognized questionnaires or tests if they have not been altered for specific use in this study.

1. **Upload supplemental study document(s) requiring a JHM IRB approval logo:**

Click Add to upload a new document. Click Update to upload a revised version of the existing document. (Click History to see all uploaded versions of an existing document)

Title	Date Modified	Version	Status
There are no items to display			

2. Upload supplemental study document(s) not requiring a JHM IRB approval logo:

Click Add to upload a new document. Click Update to upload a revised version of the existing document. (Click History to see all uploaded versions of an existing document)

	Title	Date Modified	Version	Status
View	Patient education sheet(0.01)	9/15/2020 6:48 PM	0.01	Submitted
View	Confirmation Questions for coordinating center IRB00265294.docx(0.01)	12/11/2020 5:10 PM	0.01	Submitted
View	IT Risk approval email for IRB.pdf(0.01)	12/16/2020 12:15 AM	0.01	Submitted
View	Data security approval (1)	12/17/2020 3:12 PM	1	Submitted

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22 - Devices

1. * Will any devices be studied in this research (including devices which are FDA-approved for marketing)?
○ Yes ● **No**

2. * Will any investigational devices (non-FDA-approved for marketing or used according to non-FDA-approved indications) be used in this research?
○ Yes ● **No**

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23 - Human Biological Samples

1.0 * Will human biological samples (e.g., blood, cells, tissue, urine) be used in this research?
○ Yes ● **No**

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24 - Institutional Biosafety Committee

1. * Will any of the following be used in this research?

- ☐ **Recombinant or synthetic nucleic acid molecules**
- ☐ **Potential infectious agents or viral-based vectors**
- ☐ **Biological toxins**
- ☑ **None of the above**

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34 - SKCCC CRO

1. * **Is this study cancer related (e.g., cancer prevention, screening, therapeutic, diagnostic, etc.), involving cancer patients, using cancer center facilities/resources?**
   ○ Yes ● **No**

   * **Does this study involve a drug that will be administered/dispensed in the Weinberg IDS?**
   ○ Yes ● **No**

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36 – Data Confidentiality

1.0 * **Please complete the** Risk Tiers Calculator**, upload a PDF copy of the completed worksheet, and select the resulting risk tier.**
Tier C

* **Risk Tiers Worksheet**

Click **Add** to upload the completed Risk Tier Worksheet. Click **Update** to upload a revised version of the existing document. (Click **History** to see all uploaded versions of an existing document.)

	Title	Date Modified	Version	Status
View	riskmatrixcalculator Haut.pdf(0.01)	10/23/2020 9:01 AM	0.01	Submitted

2.0 * **Will person-level data be sent outside of Johns Hopkins Health System or School of Medicine during the course of this study?**

Data in this context refers to any person-level information, including de-identified data, limited data set, or personally identifiable information or protected health information.
○ Yes ● **No**

4.0 * **Will you use one or more mobile apps in this research?**

* *A mobile app is defined as a software application that can be executed (run) on a mobile platform (i.e., a handheld commercial off-the-shelf computing platform, with or without wireless connectivity), or a web-based software application that is tailored to a mobile platform but is executed on a server.*
○ Yes ● **No**

6.0 * **Will a Certificate of Confidentiality be obtained for this study?**
○ Yes ● **No**

Study Team Information

1.0 * **Study Team member:**
Joseph Canner

2.0 * **Study Team role:**
Co-Investigator

3.0 * **Primary Affiliation:**
Surgery - Broadway

4.0 * **Will this study team member be consenting participants for this study?**
○ Yes ● **No**

6.0 **Will this person serve as a lead study coordinator?**
○ Yes ○ No

Study Team Information

1.0 * **Study Team member:**
Peggy Kraus

2.0 * **Study Team role:**
Co-Investigator

3.0 * **Primary Affiliation:**
Pharmacy - Broadway

4.0 * **Will this study team member be consenting participants for this study?**
○ Yes ● **No**

6.0 **Will this person serve as a lead study coordinator?**
○ Yes ○ No

Study Team Information

1.0 * **Study Team member:**
Brandyn Lau

2.0 * **Study Team role:**
Co-Investigator

3.0 * **Primary Affiliation:**
Radiology - Broadway

4.0 * **Will this study team member be consenting participants for this study?**
○ Yes ● **No**

6.0 **Will this person serve as a lead study coordinator?**
○ Yes ○ No

Study Team Information

1.0 * **Study Team member:**
Oluwafemi Owodunni

2.0 * **Study Team role:**
Co-Investigator

3.0 * **Primary Affiliation:**
Surgery - Broadway

4.0 * **Will this study team member be consenting participants for this study?**
○ Yes ● **No**

6.0 **Will this person serve as a lead study coordinator?**
○ Yes ○ No

Study Team Information

1.0 * **Study Team member:**
Michael Streiff

2.0 * **Study Team role:**
Co-Investigator

3.0 * **Primary Affiliation:**
Hematology - Broadway

4.0 * **Will this study team member be consenting participants for this study?**
○ Yes ● **No**

6.0 **Will this person serve as a lead study coordinator?**
○ Yes ○ No

Study Team Information

1.0 * **Study Team member:**
Mujan Varasteh Kia

2.0 * **Study Team role:**
Co-Investigator

3.0 * **Primary Affiliation:**
Surgery - Broadway

4.0 * **Will this study team member be consenting participants for this study?**
○ Yes ● **No**

6.0 **Will this person serve as a lead study coordinator?**
○ Yes ○ No