PEPPER
Pulmonary Embolism Prevention after hiP and kneE Replacement

Patient Initials | Patient study ID

Adverse Event Reporting

Adverse Event Number (patient specific): ☐

Date of Completion (mm/dd/yy): ____/____/____

Date of Event (mm/dd/yy): ____/____/____

Date of Discovery (mm/dd/yy): ____/____/____

Note: *all documents and notes should correspond with the date of event listed above*

Patient's age at time of AE: _____

Date of Surgery (mm/dd/yy): ____/____/____

Type of Surgery: ☐ Knee ☐ Hip

Randomized to: ☐ Aspirin ☐ Coumadin ☐ Rivaroxaban

PLEASE COMPLETE ALL SECTIONS

A. Reported Event/s.

Report ONLY if the event falls into one or more of the categories below. Events that are reported (other than fatal events) should be related to the index operation or use of the anticoagulant. Supporting documents are required.

☐ PE/DVT	☐ Hemorrhagic event	☐ Sepsis/Infection (of surgical site)
☐ Transfusion	☐ Reoperation	☐ Aspiration of index joint
☐ MI	☐ Fatal event (from any cause)	

B. Reported Event/s.

Did the above event/s result in any of the following:

☐ Unplanned visit to a physician	☐ Readmission to hospital
☐ Visit to ER/urgent care clinic	☐ Return to OR
☐ N/A, please explain: _____	

C. Study Safety.

Is the event:

Unexpected	☐ Yes ☐ No	***To be determined by site PI. ONLY if you answer "Yes" to all 3 boxes, this event is reportable to the central and/or local IRB.***
Related/possibly related (**to study medication**)	☐ Yes ☐ No	***PI Signature***_____ ***Date***_____
Serious	☐ Yes ☐ No	

Note: *An event is considered unexpected if it is* ***not*** *described in the protocol, informed consent, package inserts, and/ or Investigator's Brochure.*

D. Supporting Documents.

Email documents to PEPPER@musc.edu. REDACT all PHI, ensure dates remain visible.

Document Type	Redacted and Attached?
Operative Note (s)	☐ Yes ☐ No
Imaging Report (s)	☐ Yes ☐ No
Discharge Summary	☐ Yes ☐ No
Death Certificate	☐ Yes ☐ No
Autopsy Report	☐ Yes ☐ No
Other, please specify: _____	☐ Yes ☐ No
Other, please specify: _____	☐ Yes ☐ No

Total Number of Documents Attached: _____ **Completed By:** _____

Summary Information: Please describe the event including reason for care, whether it was the same or different hospital as the original operation, and any other pertinent comments. _____

_____

_____

Please retain a copy of this form and supporting documentation for your records.

Version 6.0