PEPPER
Pulmonary Embolism Prevention after hiP and kneE Replacement

Patient Initials

			-					

Patient study ID

Protocol Deviation Form

THIS FORM IS TO BE COMPLETED WITHIN 2 BUSINESS DAYS OF PROTOCOL DEVIATION DISCOVERY AND SENT TO PEPPER@MUSC.EDU

Site Name: _____ **Deviation Number: (site specific)** ☐

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

Date of Deviation (mm/dd/yy): _____/_____/_____

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

Deviation Timing:

☐ Consent	☐ Month 1	☐ Study Exit
☐ Baseline	☐ Month 3	☐ Other (please specify):_____
☐ Randomization	☐ Month 6	_____
☐ Operation	☐ Adverse Event	_____

Deviation Type:

- ☐ Consent procedures not followed
- ☐ Patient did not meet eligibility criteria
- ☐ Study procedure/visit not completed
- ☐ Study procedure/visit completed but not according to protocol
- ☐ Study procedure/visit completed outside of window
- ☐ Study medication prescribing/administration/dosage did not follow protocol guidelines
- ☐ Other (please specify): _____

Increased Risk (to be determined by the PI at your site): Did the protocol deviation result in increased risk or consequences to the subject(s)? ☐ Yes ☐ No

If YES, explain: _____

_____

_____

Summary Information: Please describe the deviation in detail.

_____

_____

_____

Was the subject informed of the deviation? ☐ Yes ☐ No

Will the subject remain in the study? ☐ Yes ☐ No

Preventative Action: Describe measures taken to prevent the possibility of a similar violation or deviation from occurring in the future:

_____

_____

_____

_____

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