Safety information form ACTION-1 –study

Site number		Project name	ACTION-1
Local investigator		Project number	NL66759.029.19
Country	The Netherlands	Sponsor	Dijklander ziekenhuis
Investigational Product (IP)		Heparin	
Intervention		☐ACT guided heparinization	☐5000 IU

Subject information			
Subject-number		Sex	F ☐ M ☐

Informatie SAE	
Event diagnosis	
Date of notification (dd-mm-yyyy)	
Type of report	☐ **Initial report** ☐ **Follow-up report ***
To which category does the SAE relate?	☐ An unexpected outcome of an expected serious side effect. ☐ A SAE related to research treatment or study procedure (☐Surgery or ☐ Heparin) ☐ A SAE related to a medical device. ☐ A SAE related to equipment failure. ☐ Other
If answer above question is 'Other', specify?	
Description of the SAE	
On what date did the SAE occur? (dd-mm-yyyy)	
To which of the categories does the SAE relate?	☐ Mortality ☐ Life threatening ☐ (Prolongation of) hospitalization ☐ Permanent disability of incapacity

*In case of a follow-up report only fill-out SUBJECTNUMBER and EVENT INFORMATION on page 2.

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Event information	
If above question is not equal to 'Mortality': Answer: Has the patient been recovered?	☐ Yes ☐ Is still recovering* ☐ No ☐ Recovered with residual symptoms ☐ Passed away ☐ Unknown
If above question is equal to 'Yes':' Answer: On what date was the patient recovered? (dd-mm-yyyy)	
Additional comments	-

*Provide follow-up report after recovering or patient passed away
If applicable: also provide a copy of the comprehensive report

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Name Investigator | Signature Investigator (natte handtekening) | Date (dd-mm-yyyy)

To be completed by Dijklander Ziekenhuis		
Date safety information received ? (dd-mm-yyyy)		
Expectedness	☐ Expected	☐ Not expected
Causality	☐ Related	☐ Not related
Does this incident have consequences for the safety of the patients in this study?	☐ Yes	☐ No
If YES, what are the consequences for the conduct of the study?	☐ Study on hold ☐ End of study ☐ Adaption of patient information letter ☐ Adaption medication use ☐ Adaption in/exclusion criteria ☐ Another consequences	
If 'Another consequences', specify?		
Date of this report (dd-mm-yyyy)		

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Signature Dijklander Safety Responsible person: dr. A.M. Wiersema | Date (dd-mm-yyyy)