

SHINE	Visit : Baseline	_____ Site ID	_____ Subject ID		
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Form 26: I-SPOT Eligibility Form (version 1)

<p>I-SPOT INCLUSION CRITERIA: To be eligible for I-SPOT, patient must meet all SHINE eligibility criteria and question 1 must be YES.</p>		
1	Obtained valid informed consent to be in the I-SPOT study (self or their legally authorized representative). The approved consent form must be initialed in accordance with federal and institutional guidelines.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown
<p>I-SPOT EXCLUSION CRITERIA: To be eligible for I-SPOT, patient must meet all SHINE eligibility criteria and Questions 2 through 4 must be NO.</p>		
2	Known moderate or severe hepatic insufficiency (as defined by INR >1.5, if known, or history of variceal bleeding or hepatic encephalopathy) at baseline.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown
3	<p>Current or planned use of full dose anticoagulation from baseline to the 48 hour sample collection, for example:</p> <ul style="list-style-type: none"> • IV or IA tPA/other fibrinolytics • IV heparins, warfarin • direct thrombin inhibitors • factor Xa inhibitors • GIIB / IIIA inhibitors <p>SQ DVT prophylactic heparin doses and antiplatelet drugs (aspirin, clopidogrel) are allowed.</p>	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown
4	<p>Prior or concurrent thrombotic or hypercoagulable condition, for example:</p> <ul style="list-style-type: none"> • Antiphospholipid antibody syndrome • Antithrombin III • Protein C or S deficiencies • Congenital or Inherited Factor deficiencies • Sickle cell disease 	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown
<p>BASELINE BLOOD DRAW To participate in I-SPOT, question 5 must be yes. Baseline blood draw must occur directly after randomization into SHINE and prior to study treatment.</p>		
5	Was a baseline blood sample drawn?	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown
General Comments:		
Name of person who collected these data (not for data entry):		

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SHINE	Visit : Baseline	_____	_____	Data Collected?	-
		Site ID	Subject ID	<input type="radio"/> No <input type="radio"/> Yes	


Form 24: I-SPOT Blood Sample Collection Form (version 2)

<p>Please refer to the I-SPOT Laboratory Manual. Baseline blood draw must occur directly after randomization and prior to study treatment. 48 hour blood draw must occur between -2/+6 hours from the 48 hour time point.</p>		
1	Date of blood draw	_____ - _____ - _____ (dd-mmm-yyyy)
2	Time of blood draw	____:____ (hh:mm, 24 hour clock)
<p>Remove 2 mL of whole blood and place in 2 cryovial tubes (1 mL each cryovial tube). Allow no more than 60 minutes from time of blood draw to centrifuge start time. Centrifuge remaining blood for 20 minutes at 1500 RCF(g). Sample may only be spun once.</p>		
3	Centrifuge start date	_____ - _____ - _____ (dd-mmm-yyyy)
4	Centrifuge start time	____:____ (hh:mm, 24 hour clock)
<p>Fill the cryovial tubes with 0.3 mL of plasma, filling up to 8 cryovial tubes. All cryovial tubes must have the same barcode number (except for the number that precedes the hyphen). Place all cryovial tubes into the corrugated cardboard cryovial box and freeze specimens immediately at -80 until ready to ship. (-70 degree freezer is acceptable.)</p>		
5	Date samples placed in freezer (-80 C)	_____ - _____ - _____ (dd-mmm-yyyy)
6	Time samples placed in freezer (-80 C)	____:____ (hh:mm, 24 hour clock)
21	Was blood drawn from an existing venous line?	<input type="radio"/> No <input type="radio"/> Yes
7	Difficulties or deviations when obtaining/processing blood samples. Check all that apply.	<input type="checkbox"/> Tourniquet not removed prior to filling the tube. <input type="checkbox"/> Wrong gauge needle/catheter was used (should be 14 to 21 gauge) <input type="checkbox"/> 5 cc of blood was not discarded before specimen collected from existing IV site <input type="checkbox"/> Blood was clotted prior to centrifugation <input type="checkbox"/> Unable to fill tube <input type="checkbox"/> Blood was not spun for the appropriate amount of time <input type="checkbox"/> Mixing of red blood cells with plasma after spinning <input type="checkbox"/> Blood was re-spun <input type="checkbox"/> Other <input type="checkbox"/> None
8	If 'other' difficulties with blood samples, specify:	
General Comments:		
Name of person who collected these data (not for data entry):		

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SHINE	Visit : Baseline	_____	_____	Data Collected?	
		Site ID	Subject ID	<input type="radio"/> No <input type="radio"/> Yes	-


Form 24: I-SPOT Blood Sample Collection Form (version 2)

9	I-barcode number (lab kit number) for cryovials: _____		
<p>The cryovial numbers below correspond to the number printed on the cryovial tube that comes before the 5 digit I-barcode number (e.g. 5-XXXXX).</p> <p>For example, the cryovial number for the image above, is '5'. The I-barcode number is '10001'.</p> <p>Indicate the sample type of each cryovial: 'Plasma' or 'Whole blood'. For cryovials not collected, mark 'Not collected'.</p>			
10	Cryovial 1	<input type="radio"/> Plasma	<input type="radio"/> Whole Blood <input type="radio"/> Not collected
11	Cryovial 2	<input type="radio"/> Plasma	<input type="radio"/> Whole Blood <input type="radio"/> Not collected
12	Cryovial 3	<input type="radio"/> Plasma	<input type="radio"/> Whole Blood <input type="radio"/> Not collected
13	Cryovial 4	<input type="radio"/> Plasma	<input type="radio"/> Whole Blood <input type="radio"/> Not collected
14	Cryovial 5	<input type="radio"/> Plasma	<input type="radio"/> Whole Blood <input type="radio"/> Not collected
15	Cryovial 6	<input type="radio"/> Plasma	<input type="radio"/> Whole Blood <input type="radio"/> Not collected
16	Cryovial 7	<input type="radio"/> Plasma	<input type="radio"/> Whole Blood <input type="radio"/> Not collected
17	Cryovial 8	<input type="radio"/> Plasma	<input type="radio"/> Whole Blood <input type="radio"/> Not collected
18	Cryovial 9	<input type="radio"/> Plasma	<input type="radio"/> Whole Blood <input type="radio"/> Not collected
19	Cryovial 10	<input type="radio"/> Plasma	<input type="radio"/> Whole Blood <input type="radio"/> Not collected
20	Number of cryovial tubes collected:	_____ cryovial tubes	
General Comments:			
Name of person who collected these data (not for data entry):			

SHINE version 2 13Mar2013

SHINE	Visit : Day 2 (24-48 h)	_____	_____	Data Collected?	
		Site ID	Subject ID	<input type="radio"/> No <input type="radio"/> Yes	-

Form 24: I-SPOT Blood Sample Collection Form (version 2)

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