

Summary of feedback received from the NHSBT Patient and Public Advisory Group regarding the SWiFT participant information documents:

Document	Reviewer	Comment	Change Made?
1	Reviewer A	Comma after behalf (page 1) What are the possible risks and benefits of taking part (p2) <i>Add:</i> There are no known risks linked to/attribution to taking part in this study, at this time. All the blood products that are being used in this study have been approved for use in the UK. Blood transfusions are common procedures and death due to transfusion is extremely rare. <i>(continue on a new line)</i> Most patients who receive a blood transfusion experience no complications or problems. However, there are associated risks from blood transfusion , which fall into two main categories (p3)	Yes Yes Yes Yes
1	Reviewer B	In the section “What will happen if I agree to continue to take part?” in the last paragraph, there is an apostrophe after the word patients which should not be there – it is just a plural.	Yes
1	Reviewer B	What are your choices about how your information is used?”, the final bullet point is red	Yes
1	Reviewer C	“The risk of testing failing to detect a blood unit...” Will patients be clear what a blood unit is? Is that perhaps somewhere where blood is taken or processed? Whereas if it is expressed as a “unit of blood” then there is no ambiguity	Yes, in documents 1, 3, 5
3	Reviewer A	<i>(continue on a new line)</i> You are being given information about this research study because your relative/friend is currently unable to decide for him/herself whether to participate in this study. (page 1)	Yes

		What are the possible risks and benefits of taking part? (p3) There are no known risks or direct benefits... All the blood products that are being used in this study have been approved for use in the UK. Blood transfusions are common procedures and death due to transfusion is extremely rare. <i>(continue on a new line)</i> Most patients who receive a blood transfusion experience no complications or problems. However, there are associated risks, which fall into two main categories: (p3)	Yes Yes Yes
3	Reviewer B	In the section “What will happen if I agree to continue to take part?” in the last paragraph, there is an apostrophe after the word patients which should not be there – it is just a plural.	Yes
3	Reviewer B	What are your choices about how your information is used?”, the final bullet point is red	Yes
5	Reviewer A	You are being given information about this research study so that you can decide whether you agree for your child to continue in the study (page 1) What are the possible risks and benefits of taking part? There are no known risks or direct benefits from participation in this study at the present time. However, information collected as part of your child’s participation in this trial may benefit patients in the future, even if they were randomly allocated to the standard treatment group. All the blood products that are being used in this study have been approved for use in the UK. Blood transfusions are common procedures and death due to transfusion is extremely rare. <i>(continue on a new line)</i> Most patients who receive a blood transfusion experience no complications or problems. However, there are associated risks, which fall into two main categories:	Yes Yes Yes Yes
3	Reviewer B	In the section “What will happen if I agree to continue to take part?” in the last paragraph, there is an apostrophe after the word patients which should not be there – it is just a plural.	Yes
5	Reviewer B	What are your choices about how your information is used?”, the final bullet point is red	Yes
7	Reviewer A	A research study is a way that doctors use to try to find out answers to questions, so that we can help people get better.	Yes Yes

		This study is being done to find out which treatment is best for people who are bleeding. When people are bleeding a lot, the doctors might need to start giving them blood before they are taken into hospital.	
8	Reviewer A	It wasn't possible to discuss the study with you before the blood was given, because you were too ill. A research study is a way that doctors will use to try to find out answers to questions, so we can help people get better. When people are bleeding a lot, the doctors and paramedics might need to start giving a blood transfusion before the person is taken into hospital. Your doctors don't know the answer to this question yet, and the only way to find out is by doing this research study, so that we can find out. This means that half of the people taking part in this study were given the blood separately, and half the people received the blood all together at once. The study may not help you at the moment, but it will help doctors to know which treatment to use for people who are bleeding in the future.	Yes Yes Yes Yes Changed to: This means that half of the people taking part in this study were given the blood with its parts in separate bags, and half the people received the blood with all its parts in one bag. Yes
10	Reviewer B	On 10 SWiFT, at the very end, the bit that starts "when completed" has "fallen off the bottom of the page". "1 copy for legal representative" cannot be read.	Looks OK on Word version – have printed it out in the office and it fits on one page.
General	Reviewer B	Also, in the bit about who has reviewed, I did wonder whether it would be worth saying that there had been lay patient involvement? I don't know whether that would give more comfort or not?	Yes - "The information sheets for the study (like this one that you're reading) have been reviewed by members of NHS Blood and Transplant's Patient and Public Advisory Group" added under 'Who has reviewed this study?' in Documents 1,3,5 Think this is N/A for Document 7. "A different group of people (including members of the public) also checked the

			information sheets for the study, like this one that you're reading" added to Document 8
General	Reviewer D	Where it asks 'who is organising and funding this research' the funding source is not identified	Funding sources are identified in Documents 1, 3, 5. The question is just 'who is organising this research?' – could change to 'who is organising and funding this research?'
General	Reviewer D	It would be useful to state that both procedures are widely used already	No – can't incorporate this as whole blood transfusion is not routine.
General	Reviewer D	Where mention is made of the study being fair it would be good to add that it is designed to answer the question so that patients can get the best treatment, whichever it is	Yes – added: "At the end of the study we will determine which of the transfusion types is better (or whether there is no difference between them) so that more patients in the future will get the best treatment" to documents 1, 3, 5
General	Reviewer C	Perhaps overcapitalisation with: Scientific and Medical Journals General Practitioner	Yes - Capitalisation removed for 'scientific and medical journals' in Documents 1,3,5 Agreed to leave General Practitioner with capitals
General	Reviewer E	My only comment is that the air ambulance is not mentioned till way down, and I think that should be added in the introductions.	Yes - a reference to the air ambulance added to the first page in Documents 1,3,5,8