Amendment Tool

v1.6 06 December 2021

For office use

QC: No

Section 1: Project information

Short project title*:	Yorkshire and Humberside Haematology Network Register
IRAS project ID* (or REC reference if no IRAS project ID is available):	188782
Sponsor amendment reference number*:	Amendment 18
Sponsor amendment date* (enter as DD/MM/YY):	25 July 2024
Briefly summarise in lay language the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained (note: this field will adapt to the amount of text entered)*:	1.Request an extension to allow the study to continue for the next five years (31.08.2029) This project has proved to be very successful, and funding from Cancer Research UK and Blood Cancer UK is ongoing. 2. Our current consenting and information gathering systems are all paper-based. To update our systems and align them with current practice, we now wish to provide patients with the opportunity to participate online via a secure website. Importantly, both online and paper-based consenting and questionnaire options will be available. Based on feedback from patients we wish to implement these changes to make it easier to participate (#2). 3.We wish to update the questionnaire; adding additional questions about the patient's experience of seeking medical help in the period leading up to their blood disorder diagnosis, and removing questions around lifestyle, including smoking history. As a consequence, a separate questionnaire for parents/guardians to complete on behalf of their child is no longer required. Instead parents/guardians can complete questionnaire v4, specifying that they are doing so on behalf of their child. Importantly, in order to ensure that the data we are collecting (#3) is relevant and addressing issues that are important to patients, the updated instrument was developed and reviewed in consultation with our PPI group. 4.In line with Health Research Authority guidance we have updated the text in the leaflets and consent forms in relation to data shared with NHS England to obtain information about participants illnesses, stays in hospital and long-term health. This change (#4) reflects the name change from NHS Digital to NHS England, and ensures we are following the most up to date guidance. 5.The information leaflet text about how samples and data may be used has been updated; explicitly stating that they could be used in the development and approval of new treatments, and that such work could be carried out in collaboration with academic research partners and the pharmaceutical industry. Previous versions of the leaflets have stated that samples may be used in the development of new treatments. However, aggregated information from the project can also be used by agencies such as NICE to support the approval of new drugs to be used in the NHS.

Project type (select):	**Specific study**			
	Research tissue bank			
	Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	**Yes**		No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	**NHS/HSC REC**			
	Ministry of Defence (MoDREC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a **modified amendment** (i.e. a substantial amendment previously given an unfavourable opinion)?	Yes		**No**	
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	Yes	No	No	No
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	Yes		**No**	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	Yes		**No**	
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	Yes		**No**	
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	Yes		**No**	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	Yes		**No**	

Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	**Yes**		No	
Did the study involve prisoners or young offenders who are in custody or supervised by the probation service OR does the amendment introduce this?:	Yes		**No**	
Did the study involve children OR does the amendment introduce this?:	**Yes**		No	
Did the study involve NHS/HSC organisations prior to this amendment?:	**Yes**		No	
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	Yes		**No**	
	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	**Yes**	No	No	No
Which nations had participating NHS/HSC organisations prior to this amendment?	**Yes**	No	No	No
Which nations will have participating NHS/HSC organisations after this amendment?	**Yes**	No	No	No
Was this a "single site, self sponsored" study in England or Wales prior to this amendment?	Yes		**No**	

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the Amendment Tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, click the "Add another change" box.

Change 1				
Area of change (select)*:	Study Design			
Specific change (select - only available when area of change is selected first)*:	Extension to study duration that will have additional resource implications for participating organisations - Please specify in the free text below			
Further information In particular, please describe the additional resource arrangements that participating organisations will need to have in place to implement this change (free text - note that this field will adapt to the amount of text entered)*:	We wish to continue the study for a further 5-years to 31/08/2029. This will mean a continuation for the centres in terms of the support currently provided to ensure patients are only given/sent a consent pack if appropriate.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	**All**		Some	
			Remove all changes below	

Change 2				
Area of change (select)*:	Study Documents			
Specific change (select - only available when area of change is selected first)*:	Other minor change to study documents (e.g. information sheets, consent forms, questionnaires, letters) that can be implemented within existing resource in place at participating organisations - Please specify in the free text below			
Further information In particular, please describe why this change can be implemented within the existing resource in place at the participating organisations (free text - note that this field will adapt to the amount of text entered)*	The study materials have been updated to reflect the requested changes - these are highlighted in red.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	**Yes**	No	No	No
Will all participating NHS/HSC organisations be affected by this change, or only some? (**please note** that this answer may affect the categorisation for the change):	**All**		Some	
			Add another change	

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Name [first name and surname]:*	Michael Barber
Email address:*	michael.barber@york.ac.uk

Lock for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed amendment tool which must be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Lock for submission

After locking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for **information only**. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

	Review bodies																	
	UK wide:						England and Wales:				Scotland:				Northern Ireland:			
	REC	Competent Authority MHRA - Medicines	Competent Authority MHRA - Devices	ARSAC	Radiation Assurance	UKSW Governance	REC (MCA)	CAG	HMPPS	HRA and HCRW Approval	REC (AWIA)	PBPP	SPS (RAEC)	National coordinating function	HSC REC	HSC Data Guardians	Prisons	National coordinating function	Category:
Change 1:						(Y)		(Y)		(Y)									A
Change 2:						(Y)		(Y)		(Y)									C
Overall reviews for the amendment:																			
Full review:						N		N		N									
Notification only:						Y		Y		Y									
Overall amendment type:	Non-substantial, no study-wide review required																		
Overall Category:	A																		