Study of the effectiveness and safety of treatments to help patients with anaemia recover from major emergency surgery. Perioperative Iron and ESA Intervention Study (POP-I)

Participant Informed Consent Form

IRAS Project ID		**Site Name**	
Site No.		**Principal Investigator**	

Name of Participant	
Participant Trial ID (To be completed after randomisation)	

		Please initial box
1.	I confirm that I have read and understand the Participant Information Sheet, 1.0 dated 27-Jun-2023 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw, then the information collected so far cannot be deleted and that this information may still be used in the study analysis.	
3.	I understand that relevant sections of my medical notes and data collected in the study may be looked at by authorised individuals from the Nottingham Clinical Trials Unit (University of Nottingham), the Sponsor (University of Nottingham), NHS bodies, the study research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and I understand that my personal details will be kept confidential.	
4.	I give permission for a copy of this signed consent form to be sent to and be retained by the Nottingham Clinical Trials Unit	
5.	I understand that an additional blood sample (approximately 3-5 teaspoons of blood) may be taken for the purpose of this study and research associated with this study. I understand that, where possible, one of my existing routine blood samples will be used instead. This sample will be tested by routine hospital laboratory. I agree to the collection, storage and analysis of this sample. All samples will be anonymised, and I will not be identified in any way.	
6.	I give permission for the Nottingham Clinical Trials Unit, the Sponsor and the study research group to collect, store, analyse and publish information obtained from my participation in this study.	
7.	I understand that the NCTU and the study research group will be provided with my personal details to send me study questionnaires and important study communications. I understand that I may also be contacted for the purpose of obtaining follow-up information if I do not return completed study documents as requested. If I am unable to complete the study questionnaires, then members of the research team may contact another person who has close contact with me (e.g. a home carer or nursing home staff). I give my permission for this information to be kept until the end of the study at which point it will be deleted, unless I have stated that I wish to be	

	contacted regarding any future research. I understand that if I withdraw my personal details will be deleted.	
8.	I understand that the information held and maintained by my GP, NHS Digital and other central UK NHS bodies may be used to help contact me or provide information about my health status.	
9.	I agree to my GP being informed of my participation in this study.	
10.	I understand that the anonymised information collected about me may be used to support other research in the future and may be shared with other researchers.	
11.	I agree to take part in the above study.	

		Please initial either box	
	Optional	**Yes**	**No**
12.	I agree to be contacted and informed about future studies that I may be eligible for. I understand that there is no obligation, and I will just be informed of what the future study will involve.		
13.	I understand, that if I provide a mobile telephone number to receive study information, that my name and telephone number will be held by Esendex (text messaging provider) and their subprocessors and will be used to contact me by text message. I give permission for this information to be retained by Esendex for two years or until the end of the study (whichever occurs first). I understand that if I withdraw my personal details will be deleted.		
14.	I agree to be sent the findings at the end of the study and I understand this will be after my participation in the study is complete.		

Name of Participant _____ Date D D - M M M - Y Y Y Y _____ Signature

Name of person taking consent _____ Date D D - M M M - Y Y Y Y _____ Signature

(You must be on the delegation log and authorised to perform this task)

Witness consent: This section is ONLY to be used when a participant has indicated consent and is unable to physically sign the consent form for themselves. The witness must initial the above boxes on behalf of the patient.

Name of witness _____ Date D D - M M M - Y Y Y Y _____ Signature

Witness job title _____

ICF copies to be retained by: Participant (personal copy), Site (Patient medical notes), NCTU (uploaded to trial database.