



Consultee Information Sheet (Personal and Nominated) Version Control Log

Version number	Document Date	Submission Date	REC Approval Date	Reason for Change	Summary of Changes
1.2	08/09/2017	21/07/2017	20/10/2017		
2.0	12/02/2019	08/03/2019	28/03/2019	Amended in line with changes to GDPR and DPA 2018	<ul style="list-style-type: none"> • Number of participating centres updated • Follow-up & Medical information section clarified. • Patient confidentiality section updated in line with GDPR and Data Protection Act 2018 • Publication section - removal of reference to Citizen Scientist which no longer exists • Addition of patient identification number
3.0	03/09/2020	21/09/ 2020	21/10/2020	Updated to add sub study	<ul style="list-style-type: none"> • All information sheets updated to remove reference to contacting the patient or their nominated contact at 28 days -this is in line with the protocol. • All information sheets have been updated to include reference to RISC-Sepsis sub-study blood samples
4.0	05/11/2020	13/11/2020	n/a	Non-substantial amendment, extra wording added for data transparency	<ul style="list-style-type: none"> • Additional wording to all Patient information sheets for data transparency- 'The data collected from your medical records will include information about your health and your ethnicity. This data is considered to be special category data and will be collected so that the relevance of the patient population to the NHS patient population can be evaluated'.

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5.0	04/10/2021	14/10/2021	n/a	Non-substantial amendment, wording removed to reflect no longer collecting ethnicity	<ul style="list-style-type: none"> all consultee/guardian information sheets altered to reflect that ethnicity data no longer collected. Stopped collecting this to reflect GDPR requirements where no data not needed should be collected. Ethnicity stopped being needed when trial ceased to be UPH badged.
6.0	25/11/2021	07/02/2022	11/02/2022	Substantial	<ul style="list-style-type: none"> all Patient information sheets amended to reflect the increase in the amount of blood required for the additional blood samples for the RISC Sepsis sub study.
6.1	25/11/2021	21/01/22	n/a	For information purposes to correct typographical error	<ul style="list-style-type: none"> an error was noticed in the footer of the documents and point 1 of the consent form was not amended to refer to the updated document so this was amended and REC notified.
6.0	25/11/2021	(Scotland 15/02/2022)	22/02/2022	Substantial	<ul style="list-style-type: none"> Guardian/Attorney information sheets amended to reflect the increase in blood volume required for the additional blood samples for the RISC Sepsis sub study.

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6.1	25/11/2021	(Scotland 15/02/2022)	22/02/2022	For information purposes to correct typographical error	<ul style="list-style-type: none"> Error noticed in the footer of the Guardian / Attorney information sheet and point 1 of the consent form not edited to reflect updated document version, so this was amended and REC notified.
7.0	22/09/2022	05/10/2022	05/10/2022	Non-substantial to reflect study extension	<ul style="list-style-type: none"> Updated to include new study end date to 2024 as well as updating how long the study will run for.
7.0	22/09/2022	05/10/2022	05/10/2022	Non-substantial to reflect study extension	<ul style="list-style-type: none"> Updated to include new study end date to 2024 as well as updating how long the study will run for.