CTRC
Clinical Trials Research Centre

GUIDANCE ON WHAT DATA CAN BE RECEIVED AT THE MEDICINES FOR CHILDREN CLINICAL TRIALS UNIT FOR THE PREVAIL TRIAL

For all studies being run through the MC CTU we have a responsibility for ensuring that we are compliant with the Data Protection Act 1998, Medicines for Human Use (Clinical Trials) Act (S.I 2006 No 1928) and other regulatory requirements relating to the collection and processing of data.
This guidance document outlines which data we have permission to receive and the methods by which we can receive the data without contravening these regulations.

If you have any queries at all about whether data is appropriate to provide please contact the Trial Co-ordinator who will advise you further on prevail@liv.ac.uk or 0151 282 4716.
Thank you in advance for your co-operation.

General guidelines:

- When referring to trial participants please use randomisation number or enrolment/screening number to identify which participant rather than participant names.

- To ensure that data remains pseudoanonymised please ensure that data is not sent in to the unit with consent forms.

- Names of participants, names of members of their family, NHS numbers, patient contact details etc. should not be recorded on any CRFs or patient completed diaries/questionnaires.

- The University of Liverpool email system is not encrypted to the same standard as NHS mail so we are unable to receive any personal identifiable data through email (unsecure transmission).

- If any data being sent to the MC CTU has personal identifiable data present this needs to be redacted and replaced by the randomisation number/enrolment number before sending to us.

The table below provides more specific guidance about what data can be received at the CTU for the PREVAIL trial.

1. Data Transmission Guidance Document

		Acceptable data transfer methods			
Data item/document	**MC CTU authorised to receive?**	**Fax**	**Email**	**Post**	**Telephone**
Participant name	✘ *only allowed on consent form*	✘	✘	✘	✘
Participant DOB	✘ *as part of CRF only*	✘	✘	✘	✓
Participant Address	✘	✘	✘	✘	✘
Participant NHS number	✘ *only allowed on consent form or collected over phone*	✘	✘	✘	✓
Medical record numbers	✘	✘	✘	✘	✘
Consent Form	✓ *If posted, ensure this is supplied separate to any clinical or screening data*	✓	✓ *By secure email only and on prior discussion with TC*	✓	**N/A**
Case Report Forms (CRFs)	✓	✓	✘	✓	**N/A**
Screening logs	✓	✓	✘	✓	**N/A**
SAE Report Form	✓	✓	✘	✓	✓