Department of Research and Development

University Hospital Southampton NHS Foundation Trust
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Southampton
SO16 6YD

PLEASE ADDRESS ALL EDMS ACCESS FOR RESEARCH ENQUIRIES TO:
Email: MonitorAccessRequest@uhs.nhs.uk

30th November 2018

TO WHOM IT MAY CONCERN:

ALL INVESTIGATORS, EXTERNAL SPONSORS AND CLINCIAL RESEARCH ORGANISATIONS

UNIVERSITY HOSPITAL SOUTHAMPTON NHS FOUNDATION TRUST PROCESSES FOR EXTERNAL MONITOR AND REGULATOR ACCESS TO THE A NEW TRUST ELECTRONIC DOCUMENT MANAGEMENT SYSTEM (EDMS).

Working with the UHS IT team, there has been a long process of ensuring that a) the UHS record keeping for patient notes is compliant with the regulations and other legislation and b) that it can be accessed by monitors and inspectors. We are certain that the new system meets best practice statements from the MHRA and the Department of Health and Social Care, is compliant with Information Commissioner's Office (ICO) advice, and that these processes will save external Sponsors considerable costs compared to alternative solutions.

1. When a monitor comes on site they are given a monitor account whereby they can log into the Trust patient records, on a read only basis, via a Trust computer. This account is fully auditable by the IT department and the R&D QA Manager. There are a number of safeguards built in, for example there are only 3 people in the Trust that can request these accounts, the name of the monitor and the study they are working on is recorded; they are only accessible through Trust managed computers; and they are time limited to expire when the Monitor is off-site.

2. All Monitors need to sign a code of conduct (example attached). Monitors are expected to formally record all patient records accessed, and any inadvertently access in case of error (to avoid potential inappropriate disciplinary report to the Monitor's employer). UHS contracts with Sponsors state that Data Protection and Confidentiality will be maintained by employees of the Sponsor or CRO. As per national guidance, this is considered best practice to avoid the need for personal supervision of external organisation employees accessing hospital systems.

This process has been discussed with the MHRA. Specifically, the UHS process complies with the recent MHRA position statement stating their expectation that monitors can access the whole record and are bound by duty of confidentiality not to view irrelevant material. The MHRA have notified this standard to all Trust CEOs and it is expected where Trust and Health Boards or GP practices are putting in a new EHR or upgrading older systems.

The link to GCP forum thread with the MHRA moderators response, verifying that the MHRA have also discussed this detail with the ICO is available at: http://forums.mhra.gov.uk/showthread.php?4052-Electronic-Source-Data-Access-for-Monitors-and-Inspectors

Many thanks for your understanding. Please do not hesitate to contact me or my colleagues if you have any major concerns. Any logistical queries should be sent to MonitorAccessRequest@uhs.nhs.uk

Saul Faust
Associate Medical Director for R&D

Mikayala King
R&D Quality Assurance Manager

Monitor Code of Practice:
Accessing UHS Electronic Patient Records

University Hospital Southampton NHS Foundation Trust has created a process to allow monitors to access Electronic Patient Records for the purpose of Source Data Verification (SDV) and any other study related activities.

The Trust has an expectation that all patients' information held on the electronic patient record will be treated in a confidential manner and will not be used for any purpose other than for the care of that patient.

To ensure this, all monitors are expected to:

- ❖ Have a form of ID on them at all times whilst on the hospital site.

- ❖ Use the log in details on a Trust issued device only.

- ❖ Treat any information held by University Hospital Southampton NHS Foundation Trust in a confidential manner and in compliance with Research Governance regulations and NHS Information Governance guidelines.

- ❖ Report any patient records that have been inadvertently viewed. Not doing so may be considered to be a breach of confidentiality.

- ❖ Be aware that the UHS QA Manager for R&D and Informatics Project team will conduct audits between the patient listed on the following form and the audit trial of the Guest Access at their discretion. If the outcome of the audit suggests a breach of patient confidentially, the UHS Information Governance team will act accordingly. If there is more than one incident, the monitor access will be reconsidered.

- ❖ Report any breaches of confidentiality that you may come across to a member of staff.

Declaration:

As the name monitor below, I accept the patient's and staff rights to confidentiality and the Trust's code of practice for security of Health Records and Computerised Systems.

I verify that I have only viewed the records listed below in line with the Research Governance regulations and UHS Information Governance guidelines, and have made known to the named study staff of records that I have inadvertently viewed.

This undertaking bounds me during my time in the Trust and also when I terminate that service/visit.

R&D/Forms/028
Monitor's Code of Practice V1 16 October 2017
Please file in the ISF

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Monitor Signature Page:
Please sign as confirmation you have read and understood the previous page.

Monitor Print Name :

Signed:

Date:

Monitor Print Name :

Signed:

Date:

Monitor Print Name :

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Monitor Print Name :

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Monitor Print Name :

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EXAMPLE ONLY

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Study short title		Ethics No.			
R&D No.	RHM			Principal Investigator	
Sponsor				Site	

Monitor Access Log

Date	Monitor Log in	Participant hospital/ NHS number required for monitoring visit	Study ID number	Participant hospital/ NHS number inadvertently accessed	Staff signature

Page _____ of _____

Date	Monitor Log in	Participant hospital/ NHS number for m	Study ID number	Participant hospital/ NHS number inadvertently accessed	Staff signature

EXAMPLE ONLY

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Monitor Patient Record Access Form V1 02Nov2017
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