

**UKCRC Registered CTU Network –**

**Monitoring Access and Source Data Information Sheet**

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Monitoring Access and Source Data

Information Sheet

# Introduction and scope

This Monitoring Access and Source Data Information Sheet is intended for use by trialists at UK CRC Registered units performing remote and on-site monitoring activities. This resource is designed to be completed by the participating site team to confirm how monitoring access can be obtained, via the systems already in place, at a participating site. This resource is not designed to assess the compliance of existing systems, though relevant and useful guidance on considerations of the use of electronic health records (EHRs) in research is provided in Appendix 1. This resource may need to be adapted to meet Sponsor/CTU and/or trial-specific requirements.

# Instructions for use

Complete one sheet for each participating site where monitoring activities will be conducted. This resource is designed to be completed by the participating site team

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With input from the UKCRC Registered CTU Network’s Monitoring Task & Finish Group

# Monitoring Access and Source Data Information Sheet

1. **Participating Site details**

Please complete the following site-specific information

|  |  |
| --- | --- |
| **Trial name** |  |
| **Participating Site** |  |
| **Participating Site - Principal Investigator** |  |
| **Participating Site - Contact for monitoring** |  |
| **Participating Site Department/Address** |  |

1. **Source Data Location**

Please complete the following information to document the location of source data/documents.

| **Source document**  [adapt to trial-specific requirements] | **Format**  (electronic, paper or electronic & paper) | **If electronic, name of system(s)** | **If paper, confirm location/department** |
| --- | --- | --- | --- |
| Informed consent form |  |  |  |
| Informed consent process |  |  |  |
| Eligibility |  |  |  |
| Medical History |  |  |  |
| Clinic letters |  |  |  |
| Inpatient records |  |  |  |
| GP Letter |  |  |  |
| Provision of study contact card |  |  |  |
| Adverse events including grade, seriousness and causality assessment by an investigator |  |  |  |
| Concomitant medications |  |  |  |
| Study-specific worksheets |  |  |  |
| Vital signs |  |  |  |
| Blood tests |  |  |  |
| Biochemistry, haematology,  other blood results |  |  |  |
| Drug charts and prescriptions |  |  |  |
| CT/MRI/PET Scans & Reports |  |  |  |
| X-rays & reports |  |  |  |
| ECGs |  |  |  |
| Histopathology reports |  |  |  |
| Bone Marrow reports |  |  |  |
| IMP stock control (where managed at point of care) |  |  |  |
| Other |  |  |  |

1. **Access to Electronic Health Records**

Please respond to the following questions providing information on access to EHRs

* 1. **On-site access to EHRs**

For the purposes of **on-site** monitoring or audit can monitoring staff/auditors receive direct access to the electronic source data? Please complete the relevant fields of the table below to provide the required information for each scenario.

|  |  |  |
| --- | --- | --- |
| **YES** | If yes, please provide the on-site EHR access policy. |  |
| If yes, please confirm how access is requested and provided. Please give details of any training required, provide any agreements that require signature and confirm timelines for access. |  |
| If yes, please confirm the type of access staff with be granted to EHRs (e.g. read-only, limited to trial patients See Appendix 1) |  |
| **NO** | If no, please clarify how monitors will be able to review electronic source documents e.g. print outs of the electronic records (See Appendix 1) |  |

* 1. **Remote access to EHRs**

For the purposes of **remote** monitoring or audit can monitoring staff/auditors receive direct access to the electronic source data? Please complete the relevant fields of the table below to provide the required information for each scenario.

|  |  |  |
| --- | --- | --- |
| **YES** | If yes, please provide the remote EHR access policy |  |
| If yes, please confirm how access is requested and provided. Please give details of any training required, provide any agreements that require signature and confirm timelines for access. |  |
| If yes, please confirm the type of access staff with be granted to EHRs (e.g. read-only, limited to trial patients See Appendix 1) |  |
| **NO** | If no, please confirm which of the following remote monitoring methods you permit:   * Source data screen shared/guided access via secure video conferencing platforms (e.g. Teams) * Source data shared via secure document repository * Other please specify |  |

# Appendix 1 – Useful guidance on external use and access to EHRs

For helpful guidance on the considerations and requirements for access Electronic Health Records (EHRs) please refer to the MHRA’s Guidance on “Access to Electronic Health Records by Sponsor representatives in clinical trials” found here: <https://www.gov.uk/guidance/on-site-access-to-electronic-health-records-by-sponsor-representatives-in-clinical-trials>. To note, it is recommended the Guidance be read in conjunction with the HRA/MHRA joint advice on Data Protection Impact Assessments (DPIAs) found here: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/what-law-says/data-privacy-impact-assessments/>

According to the above referenced MHRA guidance, provision of research monitor access to Electronic Health Records (EHR) should be an integral part of organisational level (or EHR level) planning and risk assessment. EHR system design should ensure research monitor access is limited to only the records of clinical trial participants and that this access is auditable. Where EHR systems have not been designed to allow this, this should be addressed at the next system update.

If external access to EHRs is not supported, one option is to use printouts from the EHR for external review. According to an MHRA Blog entitled “Electronic health records” posted on 23 July 2019 if this approach is to be used, printouts should be comprehensive and certified copies, and consideration should also be given as to how printouts will be retained and archived so there is evidence of what the monitor reviewed during monitoring visits. The full blog can be found: <https://mhrainspectorate.blog.gov.uk/2019/07/23/electronic-health-records/>

If original documents are scanned into an EHR, please note that, according to the above referenced blog article, the system should be robust. It is recommended that the scanning and uploading of paper originals is done using a formalised procedure, which covers the scanning, uploading and QC of the paper records to ensure these are certified copies before they are destroyed. If there is no formalised procedure for the certification of original copies, it is recommended that original, hard copy trial related source documents are retained.