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| Form number | **Form 53.004P** | Version  | **1.0** |
| Title | **Clinical Trial Monitor Remote Monitoring Agreement** |

The UK legislation requiresa that the sponsor assures themselves that the trial is being conducted according to the principles of GCP, the legislation, the authorisation from the competent authority, the favourable opinion from the ethics committee and the trial protocol and procedures. There is also a requirement that the monitoring policy mustb be contained in the trial protocol.

1. ***SI 2004/1031 (as amended) Regulation 28, (1) & (2) and Regulation 29***
2. ***ICH E6 6.10***

The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s). ICH E6 1.38

Monitoring can be a combination of on-site, remote, central and statistical and the method of trial/investigation monitoring is dependent on risk, resource, location and the objectives within the Monitoring Plan.

Safe Information Handling is part of the Statutory/Mandatory Training undertaken by a NHSGGC employee. Therefore, NHSGGC Clinical Trial Monitors (CTMs) must endeavour to meet the standards outlined in the training and adhere to Good Clinical Practice (GCP).

**This form will be completed and signed off as requested by site/sponsor in addition to any further documents required by the site for remote monitoring access. The site is responsible for the security of data at their site and the monitor is responsible for ensuring they follow NHSGGC policy on Safe Information Handling.**

I can confirm:

* I have up-to-date GCP training (within 2 years)
* I have undertaken Safe Information Handling training
* I will not deviate from the Research Participants agreed for the scheduled visit
* I will not share the account details with anyone
* I will confirm my identify prior to the sharing of information
* I will confirm the equipment used is provided by NHS and that I am the sole user

**Monitor/Auditor**

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| --- | --- |
| **Print Name** |  |
| **Role** |  |
| **Signature** |  |
| **Date** |  |

**Research Site Staff**

|  |  |
| --- | --- |
| **Print Name** |  |
| **Site Role** |  |
| **Signature** |  |
| **Date** |  |

**Guidance from MHRA & HRA: -**

*As per MHRA guidance: During the pandemic, the need for remote access to the health records of trial participants is necessary for monitoring (or auditing) activities to continue for the protection of participant safety and reliability of the results.*

*HRA: On the 13th of July NHSE/I cascaded an operational note to NHS Trusts via the COO’s Health Leadership update and the National Incident Response Board’s communication system. Both notices supported non-NHS research staff (monitors) access to NHS sites to ensure the safety of patients. The wording of the latter was as follows:*

*To enable the restart of non-COVID-19 research it is essential that research monitors can gain safe access to NHS facilities, to support the safety of patients in vital research studies and to meet regulatory requirements. Research monitors need to access on-site electronic patient record systems. Monitors will comply with the COVID-19: infection prevention and control guidance.*

*Research monitors may come from commercial or non-commercial organisations. Most are members of the professional bodies for clinical research, Association of Clinical Research Organizations (ACRO) and Clinical & Contract Research Association (CCRA). They will have a risk assessment with their line manager before any on site work commences. This should inform both parties regarding their own personal risk (age, ethnicity, gender, certain long-term conditions and pregnancy). They will follow the guidelines on testing, self-isolation, and contact tracing for COVID-19 available on www.nhs.uk.*

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