23rd December 2020

Statement on Remote Monitoring Alternatives for Clinical Trials

The following alternatives to onsite monitoring have been reviewed and approved by the Office for Research at Austin Health

- Shared Screen e-monitoring via Microsoft Teams
- Redacted Source Documents using SiteDocs Portal
- Remote Access to Austin Health's Electronic Medical Record system (Cerner and Scanned Medical Record (SMR)).

There is no requirement for supplementary "*Participant Informed Consent*" for remote data monitoring. Every Participant Information and Consent Form (PICF) contains a statement on privacy and confidentiality stating that de-identified data will be shared with the sponsor.

Two examples of this are cited below:

The study data sent by the study doctor to the sponsor does not include your name, address, or other information that directly identifies you.

AND

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your health records and any information collected and stored by the study doctor during the study may be reviewed (for the purpose of verifying the procedures and the data) by the ethics committee which approved this study or by regulatory authorities. In these circumstances, we will not collect or record your personal identifiable information.

Austin Health (and its HREC) does not require supplementary and/or amended PICFs to explain and/or seek consent for remote monitoring.

Digitally signed by Dr Sianna Panagiotopoulos
Date: 2020.12.23 14:49:45 +11'00'

Dr Sianna Panagiotopoulos
Manager, Office for Research
Email: research@austin.org.au
Phone: (03) 9496 5088