



## Telephone Script for Obtaining Consent for Remote Access to EMR by Sponsors of Clinical Trials

Hello,

My name is [Doctor, Nurse or Research Coordinator Name].

I would like to speak to [participant's first name] (if it is not the trial participant who answered the phone).

I am the [Position of person calling e.g. Study Coordinator] for the [Name of Clinical Trial] that you are participating in.

Firstly in order to proceed, I shall need to confirm your identity.

Can you please tell me your full name?

Could you please tell me your address and date of birth?

Thank-you for that [participant's first name].

When you consented to participate in the Clinical Trial, you agreed to the trial test results and other study data being made available to trial monitors, in order to ensure that the trial is being run to the expected ethical and medical safety standards. Under normal circumstances, this is done by monitors coming to Monash Medical Centre and reviewing your files – both paper and electronic records.

Monash Health is currently not permitting any one to visit the hospital that does not have an essential reason to be here due to the COVID-19 outbreak. This includes the monitors of the clinical trial, so we are seeking your permission by way of verbal consent in order for the monitors to access your electronic medical records remotely, by computer outside Monash Health. They will access your personal information in the same way that they would have accessed it if they were on site in order to verify the trial procedures you have undertaken and make sure any results are recorded correctly.

I am phoning you to ask whether you would be willing to give me your verbal consent so that monitors would be able to access your personal medical records. Access would be limited to the same study test results that you agreed to provide when you signed the consent form. I can answer any question that you may have.

Name of Person taking verbal consent \_\_\_\_\_

Signature of Person taking verbal consent \_\_\_\_\_

Date: \_\_\_\_\_

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Telephone Consent for Remote Monitoring Version 1.0 dated 14 May 2020