Health
Western Sydney
Local Health District

Oral Consent Process

Due to the COVID-19 Pandemic the WSLHD HREC has given consideration to the need for oral consent for non-interventional studies (currently permitted as per WSLHD Clinical Research – continuation and cessation rules in response to the COVID-19 pandemic 23 march 2020) where electronic consent methods are either not possible or practical.

Non-interventional studies that have previously been approved with written informed consent for participants are able to now undertake oral consent following the process outlined below for the interim period during the COVID pandemic until restrictions are lifted on the social distancing measures ordered by the Australian Government.

Consent Process:

Participants should be provided with the Participant Information Sheet to read, this can be provided electronically (e.g. pdf) or paper version. Once the participant has had time to comprehensively consider the study and discuss it with whoever they wish, they should be given the opportunity to ask any questions they may have. This can be performed in person whilst maintaining a 1.5 metre distance, over the phone or digital platform including email.

Once the participant has had all questions answered and the researcher is satisfied that the participant has a good understanding of the study requirements, they can ask the participant if they would like to consent to the study. If the participant is happy to proceed then the researcher should obtain a witness (this should be a witness who is not in any way attached to the study). A note should be added to the participant's medical record (if they are a patient of the institution they are being consented at) stating the date oral consent was obtained, details of the study and the name of the researcher and witness present during oral consent.

Suggested script

Introduce the witness.

Can you please confirm in the on-line presence of this witness that you have read and completely understood the Participant information sheet and all questions you have raised have been adequately answered? _____

Do you understand what will be required of you during this study? _____

Are you well informed and therefore happy to consent to participate in this research?

_____

As we are not able to ask you to physically sign the consent form we will both document and sign that you have verbally agreed to participate in the study documentation and in your medical record.

You may keep the information we have provided you about the study, it has our contact details and you can call us or the research office if you have any questions or concerns.

Researcher Signature: _____ Date:_____

Witness Signature:_____ Date: _____