SLHD Clinical Trials Patient Reported Experience Measures (PREMs)

To ensure clinical trial participants have the opportunity to provide direct, comprehensive and timely feedback about their experiences specific to clinical trials, a Clinical Trial PREMs questionnaire has been developed by the SLHD Research Support team.

Effective 17 September 2024, all clinical trials studies conducted in the SLHD will now require a new statement, and a QR Code, to be added to the local Participant Information Statement prior to authorisation. Refer below for further information and instructions on how to include the PREMs survey in the documents.

Trial participants who wish to provide additional feedback about their clinical trial or about any member of the clinical trials team will be encouraged to email SLHD-ResearchFeedback@health.nsw.gov.au. Such correspondences will be followed up by a member of the Research Governance team for appropriate escalation and resolution of any concerns identified.

This feedback will provide useful data to comply with the requirements of the National Clinical Trials Governance Framework (NCTGF).

INSTRUCTIONS:

What should the local Clinical Trials Participant Information Sheet and Consent Form (PISCF) contain?

The wording of the local Participant Information Sheet and Consent Form (PISCF) should be the same as that approved by the lead HREC for the Master PISCF. A tracked local Participant Information Sheet based on a clean Master Participant Information Sheet should be provided and must contain the following information:

- Name and contact details of the [RPAH][CRGH][Canterbury][Balmain] [Other SLHD-site] investigator.
- Retain the name and contact details of the lead HREC.
- A statement which reads:

  “The conduct of this study at [RPA] [Concord] [Canterbury] [Balmain] Hospital has been authorised by the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study may contact the Research Governance Officer on [CRGH -02 9767 5622] or [RPA 9515 7899] and quote protocol number 202X/STExxxxx”.

- Effective 17 September 2024 ***Clinical Trial studies only (refer to examples on following pages):***

  A second statement inserted after the above Research Governance Office complaints section, and which reads:

> **We value your feedback**
>
> Sydney Local Health District is committed to ensuring that clinical trials are conducted to the highest possible standards. We are keen to understand your experience at all phases of the trial. We encourage you to access the below survey at any time to provide us with your anonymous feedback of your experience as a participant. Your feedback will be used to continue to improve our clinical trial services. To access the survey, please scan the following QR code:

- A footer which reads "[RPAH][CRGH][Canterbury][Balmain] [Other SLHD-site] Version x dated xx/xx/20xx based on Master Version x dated xx/xx/20xx".

- If relevant: Recommended radiation safety risk wording made by the local Radiation Safety Officer (RSO). For more information on radiation please see our website.

Refer to the examples on the following pages:

EXAMPLE 1: FOR CLINICAL TRIALS STUDIES ONLY

11. Ethics Approval and Complaints

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on 02 9515 6766 or SLHD-RPAEthics@health.nsw.gov.au and quote protocol number X??-0???.

The conduct of this study at [RPA] [Concord] [Canterbury] [Balmain] Hospital has been authorised by the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study may contact the Research Governance Officer on [CRGH -02 9767 5622] or [RPA 9515 7899] and quote protocol number 202X/STExxxxx.

12. We value your feedback

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EXAMPLE 2: FOR CLINICAL TRIALS STUDIES ONLY (REFER TO NEXT PAGE)

Participant Information Sheet

Interventional Study - *Adult providing own consent*

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on *[phone number]* or any of the following people:

*List the names and contact phone numbers of other appropriate persons involved in the project including research nurses and study coordinators. The name and contact phone number of a person who can act as a 24-hour medical contact **must** be provided and clearly denoted.*

Clinical contact person

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

This person should be someone independent of the research, such as the Executive Officer of the reviewing HREC that approved the project (if a multi-centre clinical trial). Contact your local HREC administrator (single site trial) for the requirements at your institution.

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	*[Name of HREC]*
HREC Executive Officer	*[Name]*
Telephone	*[HREC Executive Officer Phone number]*
Email	*[HREC Executive Officer Email address]*
Protocol Number	*{insert}*

Local HREC Office contact (Single Site -Research Governance Officer)

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

We value your feedback

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