South Eastern Sydney Local Health District
**Consumer Engagement Plan (CEP)**

 **Instructions: Please complete this form if there is no statement or plan about consumer involvement included in your Protocol document. If possible, please incorporate into the Protocol with the next amendment.**

The introduction of the Australian Commission on Safety and Quality in Health Care standards for the conduct of clinical trials in Australia, called the National Clinical Trials Governance Framework was implemented in January 2023. The Framework exists to ensure that everyone, including frontline staff undertaking clinical trials and members of governing bodies, is accountable to patients and the community for assuring the delivery of clinical trials is of high quality, integrated into clinical care and continuously improving.

The South Eastern Sydney Local Health District HREC recommends the inclusion of a statement in the Protocol (or submission of this template with your application), detailing how consumers will be involved in the design, delivery and measurement of the clinical trial. The aim is for researchers to begin taking steps in developing capabilities and processes to embed consumer involvement across the clinical trial lifecycle.

*Under Standard 2 “Partnering with Consumers”;* <https://www.safetyandquality.gov.au/standards/national-clinical-trials-governance-framework>

*To create an organisation in which there are mutually beneficial outcomes by having:*

* *Consumers as partners in planning, design, delivery, measurement and evaluation of systems to deliver clinical trial services*
* *Trial participants and patients as partners in their own care, to the extent that they choose.*

A statement about how the research team plan to address the above should be detailed below.

**Detail the status of the study** (i.e. currently recruiting, recruitment complete, patients in follow up, results currently being analysed etc.)

**Note:** Studies that are closed/closed post analysis/closed to recruitment are not required to submit a consumer engagement plan.

Depending on the status of the study, detail how you will seek to involve consumers in the planning, design, delivery of the study and/or seek feedback from consumers about the participant information statement or other study related documents.

**Examples of how to partner with consumers in research:**

* Eliciting and documenting individual needs, preferences, and goals during all stages of the clinical trial
* Inviting research participants to research meetings to discuss completed or new studies
* Holding an annual forum with participants and seeking their feedback on completed or new studies
* Using patient and trial participant decision aids
* Encouraging and prompting patient questioning during clinical trial visits
* Providing trial related information in engaging and accessible formats, such as print, mobile apps, online channels and story boards
* Providing education to support self-management
* Establishing self-help and support/reference groups
* Developing tools to encourage adherence to the trial treatment

**Examples of how you may already be engaging with consumers:**

* Surveys that you currently undertake regarding consumer feedback such as; Patient Reported Experience Measures (PREMs)
* Feedback during the consent process – ensure this is documented
* Discussing with Patients the practicalities of visits and minimising patient visiting requirements
* Inviting former clinical trial participants to research meetings to discuss new Protocols, study materials
* Research forums inviting consumers to take part in discussions/surveys

**Ethics approval of this document:** This form should be submitted to the lead HREC for review and acknowledgment.

The HREC will review progress of the plan upon review of the study's first annual progress report and/or when subsequent amendments to the Protocol/Participant Information Statement have been submitted.

**Key Resources:**

* Guidance for SESLHD staff

<http://seslhdweb.seslhd.health.nsw.gov.au/Community_Partnerships/SESLHD_Staff_Guidance/>

* NHMRC Guidance

<https://www.nhmrc.gov.au/about-us/consumer-and-community-involvement/consumer-and-community-engagement>

* Australian Clinical Trial Alliance CT:IQ Consumer Involvement & Engagement Toolkit

<https://involvementtoolkit.clinicaltrialsalliance.org.au/>

* National Clinical Trials Framework Website

<https://www.safetyandquality.gov.au/standards/national-clinical-trials-governance-framework>

* Australian Commission on Safety and Quality in Health Care You Tube Info Video

[You Tube Link for Safety and Quality in Health Care](https://www.bing.com/images/search?view=detailV2&ccid=NMhmh6RA&id=8A71DB69C732E89DF0D897D67F1D20612C167B90&thid=OIP.NMhmh6RAcf7WOB7k73Nc2gHaEK&mediaurl=https://i.ytimg.com/vi/tGXmj9ReeLw/maxresdefault.jpg&exph=720&expw=1280&q=National+Clinical+Trials+Governance+Framework&simid=608056314598545936&FORM=IRPRST&ck=F0FF7748C87900461D1EA18039F7B289&selectedIndex=2)