**PHASE 1 – clinical trials – Revised Pathway December 2018**

The Executive of SALHN has recently undertaken a review of the conduct of phase 1 clinical trials by SALHN. Prior to 2018 they were dealt with as per any other phase of a clinical trial (referred to as the "legacy system"). A decision has been made that they require an additional level of review in an endeavour to balance their heightened risk with the value of such trials to the network and research in general and this has now been refined further since the earlier process implemented in June 2018 following user feedback and discussions with internal stakeholders.

Effective **12 December 2018** the following decision (referred to as the "new pathway") was made by Executive:

1. A/Director Research Operations to communicate to research community within SALHN/FUSA about the process of managing phase 1 trials within SALHN.

2. Upon receipt of a phase 1 trial, the application to be **managed and referred** by the Office for Research to:
   - **Drug related**: the SALHN Drug and Therapeutic Committee (DTC) for safety evaluation, prior to being listed for review by the SAC HREC or;
   - **Device related**: the New Health Technology and Clinical Practice Innovation Committee or safety evaluation, prior to being listed for review by the SAC HREC or;
   - any relevant subcommittee of either of these two bodies as advised from time to time.

*3.* Following initial review of the report, Human Research Ethics Committee (HREC) and Governance processes to proceed *simultaneously.*

4. Acting Director, Research Operations to then make a recommendation to the SALHN CEO regarding authorisation.

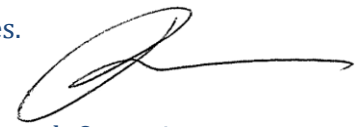
The following **transitional** arrangements will take effect and the Office for Research has now been directed to implement these changes.

- New studies (received by the OFR on or after 12 December 2018) – as per the revised pathway;*
- Studies in the system (lodged with the OFR and undergoing Quality Assurance and not yet before the HREC) – as per the revised pathway;*
- Studies in the system (and currently for consideration by the HREC) – these continue as per the arrangements in place at the time that the committee was seized of the matter;
- Existing studies (approved) – minor amendment – no change;
- Existing studies (approved) – major amendment – as per below.

For **MAJOR** amendments the following to occur:

- If significant change to the nature of the study and the consequent risk – deal with under the revised pathway (as if a new study);
- If not a significant change to the nature of the study (and consequent risk) then they can continue as with any other non-phase 1 study;
- Any issues as to what the change in underlying risk means to be determined by the Chair of the HREC in consultation with relevant clinical members of the HREC and/or the other members of Executive of the HREC (by way of a sub-committee convened for this purpose prior to submission to the Full Committee of the SAC HREC for review).

Please contact the Office for Research on 8204 6453 or **Health.SALHNOfficeforResearch@sa.gov.au** should you have any queries.



Paula Davies
Acting Director, Research Operations
12 December 2018

**Should the researcher be in the process of obtaining an independent toxicologist report (under the earlier iteration of this system) then they may proceed under the existing pathway which will remain an option for them until 31 January 2019.*