PHASE 1 – clinical trials

The Executive of SALHN has recently undertaken a review of the conduct of phase 1 clinical trials by SALHN. Previously 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.

Effective **6 June 2018** the following decision (referred to as the "new pathway") was made by Executive:

1. Director of Research 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 application, the Director of Research (or delegate) to write to the Principal Investigator to advise of the need for an independent toxicology report to be submitted, in order to progress for review.
3. An independent toxicology report to be provided by the Principal Investigator. The Office for Research (OFR) to provide both a template for correspondence that provides direction on the issues to be addressed, advice about options and the process to be followed, as determined by the Director of Research. This will take into account the precise nature of the phase 1 study.
4. Following initial review of the report, Human Research Ethics Committee (HREC) and Governance processes to proceed *simultaneously.*
5. Director of Research 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 6 June) – as per the new pathway;
- Studies in the system (lodged with the OFR and undergoing Quality Assurance and not yet before the HREC) – as per the new 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 (legacy system) subject to any concerns the committee may have about the desirability of independent input in the review process;
- Existing studies (approved) – minor amendment – no change (legacy system);
- Existing studies (approved) – **major amendment** – as per below.

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

a. If significant change to the nature of the study and the consequent **risk** – deal with under the new pathway as if a new study;
b. If not a significant change to the nature of the study (and consequent **risk**) then they can continue under the legacy system;
c. 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.

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

These arrangements will be reviewed in 12 months' time.

Professor Andrew Bersten
Acting Director of Research
13 June 2018