Memo

NSW GOVERNMENT Health
Sydney Local Health District

TO	General Managers, SLHD Clinical Managers, SLHD Clinical Directors, SLHD Heads of Department, SLHD	
FROM	Dr Teresa Anderson AM, Chief Executive, SLHD	
TEL	9515 9641	DATE
SUBJECT	**Important Communication to Researchers Regarding COVID-19**	

SLHD Human Research Ethics Committees (HRECs) acknowledges clinical trial units (and other research units) may need to undertake actions to reduce the risk of COVID-19 transmission to study participants and that this may lead to deviations from study protocols.

Examples might be:

- minimising face to face interactions with participants when not required for clinical assessment,
- undertaking clinical assessments at locations other than the study site,
- increased use of telephone or other methods of communication, telephone consent,
- or even cancelling some study visits.

Notification of Protocol Deviations

The HREC believes that changes to study procedures or protocol by investigators or sponsors in order to reduce the risk of COVID-19 disease should be regarded as analogous to an Urgent Safety Measure as defined in the NHMRC Report on "Safety monitoring and reporting in clinical trials involving therapeutic goods" (2016). They can thus, in cases of urgency, be implemented prior to notifying the HREC.

Changes to the Conduct of Studies

Researchers and sponsors should be pro-actively assessing the potential impact of COVID-19 on the conduct of their studies, and be planning how to minimise those impacts and inform the appropriate HREC* of:

- what steps they have already taken (and/or are planning to take) for the protection of already enrolled trial participants
- whether they have altered recruitment procedures for new participants (or considered temporary suspension of recruitment)
- what impact (if any) this will have on scientific validity of the study
- what advice (if any) have they received from their sponsors

- what information they have provided participants and investigators re changes to protocols/procedures
- whether they plan to obtain renewed consent.

Initially the HREC* only requires a brief description of steps to be taken. More detailed information should be forwarded by units when feasible.

Changes to study procedures should be undertaken by the investigators as follows:

- based on current clinical advice regarding COVID-19 precautionary measures
- having considered the balance between the risks to the participant from the potential exposure to SARS-CoV-2 and from the proposed change
- in consultation with the clinical trial sponsor
- in consultation with the institution, where appropriate
- having obtained informed consent from the affected participants, where appropriate
- be notified to the sponsor and the HREC as for any other protocol deviation.

The HREC also acknowledges that the Sponsor of a study may decide to modify an approved study protocol to minimise the exposure of participants to COVID-19.

Consent Issues

Documentation of informed consent will be required if the proposed changes to study procedures are more than low risk for the participant.

Where documentation of informed consent is required for modifications to study procedures or to a revised Participant Information Sheet and obtaining written informed consent would expose the participant to increased risk of contracting COVID-19, then a verbal process of obtaining informed consent would be acceptable to the HREC. The consent process should be carefully documented in the clinical notes.

Should a participant have given verbal consent and the sponsor requires written consent, or written documentation of consent appears appropriate given a materially changed risk-benefit balance for participants, confirmatory written consent should be obtained at the first opportunity that is convenient and safe for the participant.

The HREC and Sponsor should be notified when verbal rather than written consent is obtained, as for any other protocol deviation. Investigators intending to obtain verbal rather than written consent should consult with the Sponsor about how best to fulfil the Sponsor's requirements.

Amendments to the Participant Information Sheet and/or Protocol

Should the Investigator or Sponsor decide that the Participant Information Sheet and/or Protocol should be amended due to modifications in study procedures intended to reduce the risk of participants contracting COVID-19, the amended Participant Information Sheet and/or Protocol, together with a covering letter outlining the proposed changes and the justification for them, should be forwarded by email to the SLHD HREC Executive Officer. The HREC will review these as a matter of priority.

As stated above, urgent changes to reduce the risk of COVID-19 may be notified to HREC following their implementation. ***Participant safety always remains paramount.***

**For studies governed by one of the SLHD HRECs, an email should be submitted to the Executive Officer. Studies which are governed by other HRECs, advice should be sought from the HREC.*

The SLHD HRECs will be happy to provide advice on any ethical issues that arise from the conduct of clinical studies during the pandemic and can be contacted though the HREC Executive Officers as follows:

- CRGH – Ms Kate Flinders – 9767 5622 or SLHD-ConcordEthics@health.nsw.gov.au
- RPAH Zone – Ms Sanaa Thomas – 9515 7035 or sanaa.thomas@health.nsw.gov.au

Over the next few days, the Research Office's websites will have dedicated information posted regarding COVID-19 which will be updated on a regular basis.

Suggestions for improvements to these guidelines and questions about them should be addressed to the HREC Executive Officers.

Dr Teresa Anderson AM
Chief Executive
28.3.20

Definitions of terms in this document:
Low risk *Research is 'low risk' where the only foreseeable risk is one of discomfort. Where the risk, even if unlikely, is more serious than discomfort the research is not low risk. (From "National Statement on Ethical Conduct in Human Research" NHMRC (2007, Updated 2018)*
Urgent Safety Measure *A measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety. (From "Safety monitoring and reporting in clinical trials involving therapeutic goods" NMHRC (2016))*