Dear Investigators/Clinical Trial Staff:

We are writing to provide further guidance around the management of CTC clinical trials through this pandemic, following

1. our initial request for you to notify CTC of local COVID-19 related changes to processes, and
2. our subsequent memo providing general guidance/principals for your consideration while you contemplate required changes to study processes.

CTC trial teams & Trial Management Committees have been discussing the impacts of COVID-19, and the potential changes required/associated risks for each specific trial, in order to generate trial-specific COVID-related guidance which they will share with you in due course, if they have not done so already. This memo is to introduce a COVID-19 deviation tracking log, and instructions for use. Once COVID-related study-specific procedural changes have been agreed to between TMC/CTC Trial Team/Investigators & Site staff, this log is to be used specifically to capture any COVID-related protocol or other deviations that arise impacting a trial participant, or group of participants, on any CTC-coordinated trial.

We are providing you with this template in order that you can commence documenting any deviations arising from COVID-related changes to your trial processes, which participants are affected, and how.

Please share these instructions and logs with all dedicated trial staff and backup staff who may need to cover should staff absences or redeployment occur. These logs should be submitted on a fortnightly basis and to the respective CTC trial mailbox ie: [study name]@ctc.usyd.edu.au. The CTC trial team will review/track each entry in a central study-specific deviation tracker, and produce reports of study-specific COVID-related deviations for notification to central ethics committees.

Note: We are still engaged in discussions with central HREC’s as to an acceptable reporting process for these COVID-related changes, and will commence reporting to them once agreement has been reached. In the interim, we would like all sites to begin collecting these issues on the logs. Site-specific COVID notifications provided to CTC, along with study-specific guidance from the CTC trial team/TMC, and these study-specific deviation logs taken together are meant to provide a comprehensive view of changes at the site, study, and participant level related to COVID which can be used for reporting purposes to HREC’s and other organisations as required.

We hope that these logs will simplify the capture/reporting of COVID-related deviations to your trial participants. Please contact your CTC trial mailbox if you have any questions or require further clarification about the use of these logs. As the COVID situation continues to
evolve, and further changes to processes are required at your site, please continue to notify CTC as you have been doing.

CTC Trial Operations
The attached log is to be used to capture any study-specific protocol deviations or changes to usual trial processes as a result of the COVID-19 outbreak.

**Note:** any deviations impacting **patient safety** must also be reported via safety reporting processes in place prior to the onset of the pandemic (i.e., may require expedited reporting)

**Examples** of deviations that should be recorded include, but are not limited to:
- Investigations not done per protocol or conducted off site
- Treatment not given per protocol (changes to dispensing or dose interruptions)
- Late reporting of serious and non-serious adverse events
- Delays to data entry
- Source documents or PRO questionnaires not submitted on time
- Participant unable or unwilling to attend site visit
- Visit conducted at an alternate location or via telehealth/phone/Skype.

In addition to this, we would also like you to record the following as a deviation:
- Any changes to the usual consenting process (e.g., use of Telehealth/telephone) or any verbal consents obtained in relation to COVID-19 changes (e.g., consent to changes that impact the participant, consent to provide participant personal information to courier for shipping IP, etc.)
- Participant request to withdraw from study due to COVID-related changes.

Please also document the reason the deviation occurred, e.g.:
- Insufficient resources placing additional burden on site
- Back up staff inadequately trained on protocol
- Participant not able to meet requirements of visit due to travel restrictions or self-isolation
- Telephone consultation
- Any other reasons resulting in the deviation

Please record as much detail as possible, and contact the trial team with any questions. Logs are to be emailed to the [trial name]@ctc.usyd.edu.au mailbox on a **fortnightly** basis.
[**trial name**] COVID-19 Deviation Log

Please complete this log to document all COVID-19 related deviations. Please email logs **fortnightly** to [**trialname**]@ctc.usyd.edu.au

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Site</th>
<th>Site Number</th>
<th>Date of first issue</th>
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<tr>
<th>Participant ID ('ALL' if applies to all participants)</th>
<th>Date issue occurred (DD/MM/YYYY)</th>
<th>Visit date (DD/MM/YYYY) (if deviation relates to a required protocol visit)</th>
<th>Data recorded in CRF? (yes/no)</th>
<th>Detailed description of deviation, including the cause(s)</th>
<th>Actions/Resolutions</th>
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