ST VINCENT'S HOSPITAL
MELBOURNE
A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

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St Vincent's Hospital Melbourne
Plan for managing Clinical Trials in the setting of COVID19 disruption (18th March 2020)

Introduction

As a tertiary acute hospital in Melbourne, SVHM is preparing for the interruption to usual activity and provision of additional services required by the global COVID19 pandemic. It is essential that all Units involved in Clinical Trials and research comply with all requirements for activity changes and practices as determined by the SVHM Executive.

It is expected that all Units conducting Clinical Trials will continue to provide support for participants enrolled in their clinical trials and maintain their current clinical trial treatment programs as defined by each study protocol approved by the SVHM HREC and/or SVHM Research Governance Office.

The safety of our trial participants and staff is the priority in all actions and decisions regarding trial activities.

The following guidelines are recommended for ongoing management of clinical trials and participants at SVHM during the COVID19 pandemic, in addition to the advice from SVHM Executive that will be changed as required as the situation evolves.

HREC, AEC and IBC Committees

- All meetings will be conducted virtually with online video and phone access. There will be no face-2-face meetings held until further notice.
- Meetings will continue on the current planned schedule for 2020, with 2 meetings per month for the HREC. This will be reviewed depending on demand in coming months.
- Agendas, meeting papers and minutes will be circulated by email and using BaseCamp as per standard practice.
- All ethics and governance submissions will be in electronics format
- Legal documents such as CTRAs, MTAs and RCAs with e-signatures (as opposed to wet inked) are acceptable. E-signatures include Docusign, scanned copy or photo image of the signature page or of the entire document are acceptable.

Sponsored Clinical Trial site visits

- All study monitoring by sponsors and CROs must be conducted by remote means only
- No site visits will be allowed for external study monitors, site support staff from sponsors or CROs or other external trial staff
- Site Selection visits and Site Initiation visits should be postponed or conducted by video/teleconference
- No audits will be undertaken

Participant study visits

- All participant study visits will be assessed for their urgency and necessity
- Participants will be contacted prospectively by telephone to discuss the plans for study visits
- Where possible, participant routine checks will be undertaken by telephone review
- Laboratory checks including standard blood/urine pathology, ECGs and other standard tests can be performed at local pathology laboratories close to the participant's home. This may limit the availability of Central Pathology blood collection for dates when participants do not need to attend the hospital.
- In studies where imaging is required, access to local providers or attendance at SVHM for essential imaging only should be considered in advance of scheduled requirements.
- Access to oral study medication will need to be considered on an individual study basis when non-essential visits are cancelled. Options may include increasing the amount dispensed at essential study visits or couriering drug to participant home as required.
- If a trial participant refuses to attend SVHM due to fear of COVID19, all assessments will need to be undertaken by phone, pathology and imaging requirements will need to be undertaken at local providers as far as is possible, and in extreme circumstances, an alternative visit site may be arranged in consultation with SVHM and the trial sponsor/CRO.

If a study participant has suspected or proven COVID19

- Unless requiring admission, participants should not attend SVHM for any study visits if they are unwell and should be advised to contact the study staff immediately
- Study staff will maintain contact with the participant by phone during their period of isolation and monitor participant safety the need for study interruption as appropriate.

- During isolation, participants will not be able to visit local pathology or imaging centres, so all study-related testing will stop during this period.
- Management of the participant must focus on their acute COVID19 illness and their safety at all times.

Study Management and Study Staff at SVHM

- The priority for SVHM at all times is the safety of the study participants and staff
- Staff must comply with the directions and instructions put in place and updated regularly by the SVHM Executive
- If study staffing is limited due to infection or isolation, the priority for remaining staff is ensuring current study participants are reviewed and treated as per the approved study schedule.
- Data entry will prioritise essential SUSAR, SAE and AE reporting
- Protocol violations/breaches relating to COVID19 disruption will be accepted late providing there is no associated SUSAR, SAE or AE. It may be advisable to batch the non-significant COVID19 related protocol deviations for submission at a later date.
- Other data entry and administrative tasks will undertaken according to staff availability. Data lock timetables may not be followed.

Conclusion

These Guidelines relate to any clinical trial, including sponsored, collaborative group or investigator-initiated being undertaken at SVHM. It is anticipated that clinical trial activity will continue as far as possible and that participants will be able to remain on critical trial-related medications during the COVID19 pandemic.

If you are uncertain how to proceed, would like to seek advice, or would like to notify the Research Directorate/Research Governance Unit of a critical event, please contact either:

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