Clinical Research – continuation and cessation rules in response to the COVID-19 pandemic

23 March 2020

On advice from the NSW Office of Health and Medical Research and of the executive of our LHD, participant recruitment to all clinical trials should be suspended initially for the next 8 weeks.

Additionally, to reduce risk to patients and staff from the COVID-19 pandemic and to reduce the research workload for clinicians, all clinical research activity (including all investigator-initiated trials) that requires patient contact (i.e. contact within the social isolation distance of 1.5m including physically signing consent, enrolment in studies, physical examination etc.) and that necessitates participants attending a WSLHD facility solely for the purpose of the research will be suspended for the next 8 weeks.

The few circumstances under which a study may be exempted from these restrictions are specified below. The three categories of study considered are first, new pharma-sponsored studies, second, ongoing pharma-sponsored studies, and third, investigator-initiated studies. We then advise about sponsor-visits to our hospitals.

Recruiting new patients to pharmaceutical-sponsored or medical device studies:

If you feel that recruitment should continue for a study for which you are the principal investigator please write a brief explanation and send via email to WSLHD-Research-EducationExecutive@health.nsw.gov.au. Once you send your request to the REN Executive it will be reviewed by a committee of experienced researchers and a decision will be returned to you.

Possible exemptions to the suspension of participant recruitment may occur where:

- A study involves a life-extending or life-saving treatment
- There are no readily available, alternative treatments for the participant population

Research activities requiring person-to-person contact for ongoing pharmaceutical-sponsored or medical device studies where patients have already been enrolled:

The same exemption criteria as described in the dot points above apply here. We will need to consider for each study whether an exemption is justifiable. You should email your request for consideration for exemption to WSLHD-Research-EducationExecutive@health.nsw.gov.au. Once you send your request to the REN Executive it will be reviewed by a committee of experienced researchers and a decision will be returned to you.

For studies where these criteria for exemption from cessation do not apply, you should liaise with your sponsor and discuss possible options such as suspension of study or complete cessation and withdrawal of treatment.
Remember that if you are conducting a trial under Clinical Trial Research Agreements, termination provisions are contained in the *Force Majeure* clause of the agreements. Sites needing to invoke a *force majeure* provision must follow the process described in the clause.

**Managing investigator-initiated trials or research:**

If your study involves retrospective or prospective medical record reviews, questionnaires that can be emailed to participants, Interviews with participants that could be conducted by phone then these studies can continue at this stage assuming you have the research staff to perform them. Otherwise all studies should be suspended.

**Sponsor monitoring and audits of existing studies:**

No sponsor monitoring visits, or audits, are permitted in within WSLHD until further notice. Site-initiation visits are not to be conducted.

**NEW STUDIES:**

No new studies should be planned unless the start date is after October this year – this will be reviewed regularly.

The only exceptions for new studies are COVID-19 related research studies – these can be submitted at any time and will have expedited review. Please contact the research office once you have submitted so the application can be fast tracked.

The research office will be distributing a guidance document about reporting to the lead HREC and Local Research Governance Office regarding these studies.

The conditions relating to the conduct of research during the coronavirus crisis are best discussed with the sponsor or funding body.

We realise that these are difficult times and we are very willing to provide what assistance we can to you. We should try and work together to support each other through this time.

Please contact if you have questions or concerns:

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