GUIDANCE SUMMARY **Clinical Trials**
(Based on COVID-19 Guidance on Clinical Trials from OHMR 19 March 2020)

Signatures

- Use of electronic / digital signatures over “wet-ink” signatures.

    - An electronic signature is an electronic symbol attached to a contract or other record, used by a person with an intent to sign.
    - In contrast, digital signatures guarantee that an electronic document is authentic.

      Both signatures are binding.

Non-serious breaches

- In lieu of reporting individual events – a post COVID-19 Deviation Report be submitted **after** COVID-19 has resolved. Provide summary information:
    - Number of patients impacted
    - Changes to medication dispensing
    - Dose interruptions
    - Changes to visit schedules and visit activities
    - Use of external services (pathology, imaging, visit sites)
    - Missing data

Amendments

In no case may a sponsor create an amendment that creates an additional burden on your site.

- If this occurs, the sponsor must liaise with the Principal Investigator to discuss

Monitoring

Site monitoring / administrative arrangements to reduce the burden of physical contact:

- Be made as a non-substantial amendment NOT REQUIRING HREC approval.
  Can be implemented through communication with the study team and RGO.

Participant Visit Arrangements

Sponsor-proposed changes to avoid exposing patients to COVID-19 or to reduce the burden on clinical services:

- Be made as a non-substantial amendment NOT REQUIRING HREC approval
  Can be implemented through communication with the study team and RGO
- **NB:** where an amendment may potentially increase the risk to participants (eg resulting in fewer participant checks) the HREC must be notified and the amendment processed via the expedited pathway.

Study Product - Continuity of Investigational Product (IP) to participant

- Please liaise with the RPAH Pharmacy Clinical Trials Pharmacist if the Sponsor wishes them to courier the IP to the participant. This would be at the Sponsor’s expense.

Temporarily Halting a Study

- **Study using an Investigational Product:**
  - The Sponsor must issue a substantial amendment to the HREC which would expedite the approval
- **Study <u>not using</u> Investigational Product:**
  - The Sponsor submits a non-substantial amendment NOT REQUIRING HREC approval.
    Can be implemented through communication with the study team and RGO

Closing a Study

Please discuss with the Research Governance Officer.

Suspending Recruitment

- Sites must raise this issue with the Sponsor as early as possible.
  - *Participant safety is paramount*: If continuing a trial according to the Protocol is judged to pose an unacceptable risk to participants or research coordination staff and any reasonable amendment to the Protocol would compromise the study results or outcome:
    - Sites should consider temporary suspension of participant recruitment.
    - If this occurs sites and sponsors should amend CTRAs through an exchange of letters to minimise any applicable recruitment targets.

Terminating a Study due to COVID-19

- Sites are encouraged to work with trial Sponsors to come to an arrangement so that trials can continue without posing an unacceptable risk to participants or trial staff.
- You are reminded that termination provisions are included within the CTRA.

Moving Participant visits due to staff / resources being reallocated to clinical care or limiting participant contact:

- The site must raise these issues with the Sponsor as early as possible. Any additional transport for the participant should be covered.
- Arrangements should be handled prospectively as an amendment.

If there is no time to arrange this:

- Changes should be implemented as an urgent safety measure and reported retrospectively.

Withdrawing Participants

Sites must raise such issues with the Sponsor as early as possible with careful consideration of post-study care for the participant.