Requirements for research governance approval of COVID-19 related research – guidelines for Health Service Providers

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The Department of Health (DoH) has developed an expedited research governance approval process for urgent COVID-19 research projects deemed by the relevant Health Service Provider (HSP) to have significant potential to assist the state’s or national response to the COVID-19 pandemic. This document provides guidance for HSPs on this expedited process.

The expedited process will provide exemptions to the usual requirements for research applications to be submitted and reviewed in the Research Governance Service (RGS) before they can be approved. Researchers should be encouraged to discuss their research project with RGOs (and HSP Executive where appropriate) as early as possible to determine whether they are eligible for this expedited review process.

This expedited research governance approval process only applies to research that is urgent within the COVID-19 pandemic. It does not apply automatically to all COVID-19 related research. These guidelines are provided to inform HSPs of the minimum requirements for projects that qualify for this expedited process. The decision of whether a project qualifies for this expedited research governance process is ultimately at the discretion of the reviewing HSP.

The requirements for research governance applications that are eligible for COVID-19 expedited approval are:

- **Minimum requirements for RGS**
  - The project workspace must be created in RGS, and a Chief Principal Investigator (CPI) and Principal Investigator (PI) must be assigned to the workspace prior to site authorisation.
  - The project must at a minimum have been submitted for review to a Human Research Ethics Committee (HREC) and site authorisation cannot be given until HREC approval is granted.
  - RGOs may review application documents outside RGS, including requesting and receiving amendments to application documents from researchers.
  - All approvals must be obtained in written form by the reviewing RGO.
    - Unless there is a contractual obligation regarding approvals (e.g. a contractual requirement for hardcopy signatures), it is permissible to obtain approval via email, for example when gaining approval from data custodians. Emails should be converted to a PDF format and uploaded to ‘Documents’.
    - Site authorisation letters can be written outside of RGS (i.e. in Word) and must specify all conditions of the authorisation.
  - RGOs must upload the following documents to the ‘Documents’ section under the ‘Files & Documents’ tab on RGS prior to sending the site authorisation letter:
    - any governance-specific application documents\(^1\) that were reviewed and approved outside RGS;

\(^1\) Duplication of uploaded documents should be avoided. RGOs should check the ‘Applications’ tab to ensure that documents uploaded as part of the ethics applications are not re-uploaded to ‘Documents’ in RGS.
- evidence of approvals, including PDF copies of emails where relevant; and
- site authorisation letter.

A full retrospective research governance application must be submitted on RGS by the researchers within a pre-defined time.

- The deadline for submission of the full research governance application is at the RGO’s discretion but should not be more than 6 months after site authorisation.
- RGOs must explicitly state the requirement for the retrospective RGS application within the site authorisation letter.
- Site authorisation must be withdrawn or temporarily halted if retrospective requirements are not met. This should be clearly stated as a condition on the site authorisation letter.
- Sites should ensure that processes are in place to closely track and monitor retrospective submission compliance, bearing in mind the elevated level of risk assumed by the site under the expedited approval pathway.

RGOs should note that authorising research under this expedited pathway may lead to an increased level of risk being assumed by the site. In particular, the following areas of potential risk should be noted.

1. **Insurance and indemnity**

   Insurance requirements should be comprehensively addressed. The insurance policy should be reviewed by the RGO where possible. If the policy cannot be made available and the certificate reflects exclusions (or remains silent), written confirmation should be ascertained from the relevant party to confirm WA Health is not an exclusion of the insurance coverage, and that any litigation can be held within Australia.

   The DoH Research Development Unit (RDU) has consulted the Insurance Commission of WA (ICWA) regarding the insurance/indemnity implications of this expedited pathway, to raise the possibility of an increased volume of WA Health requests for ICWA review of COVID-19 related research, accompanied by an elevated level of urgency. The ICWA advise that HSPs should continue to use current processes to request ICWA review.

   HSPs should note that it may still be applicable to seek indemnity for the HREC, and that this should be addressed using standard templates, as required.

2. **Research contracts and agreements**

   Research agreements remain mandatory for commercial/CRG engagements.

   Intellectual Property (IP) agreements may be required, noting that these may be of particular significance within the COVID-19 context. IP agreements may be applicable to multi-centre projects sponsored by WA Health.

   For the purposes of expediting processes, it will likely be in parties’ best interests to use WA Health templates in their unamended form.

   The RDU has discussed this matter with Legal and Legislative Services (LLS) who confirm that requests for legal review of agreements should be submitted via the usual ‘Request for Legal Advice’ process.
All requests for review by ICWA or LLS should clearly indicate if they are related to COVID-19 research in the title/subject and body of request. Requests should ideally include specific questions or points of concern, to facilitate an efficient review process.

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