Date: 29 June 2020

Eye and Ear Hospital Guidelines for Research-Related Activity during COVID-19 Pandemic

The Eye and Ear is committed to the ongoing support of its patients, staff and the community during the COVID-19 pandemic.

This Guidance relates only to the involvement of the Eye and Ear in research-related activities

a. research site / trial site / investigational site; and / or
b. site for recruitment; and/or
c. site for research related procedures under a service agreement

Organisations that are located at Eye and Ear (main site and Eye and Ear on The Park) must follow Eye and Ear site requirements in Eye and Ear spaces. Organisations should then follow their organisations' COVID-safe Plan in the leased space.

This document dated 29 June 2020 supersedes all previous versions of the Guidelines.

The health and safety of patients, research participants, staff and the community is the priority. All Eye and Ear patients and staff and staff of research partners must follow all current Commonwealth and Victorian Government requirements in relation to illness, quarantine and isolation and Eye and Ear directives related to access to the site and any other directives (for example, staff travel restrictions, isolation requirements).

The Eye and Ear is adopting the following guidance with additional site specific information as set out below:

COVID-19: Guidance on clinical trials for institutions, HRECs, researchers and sponsors (25 March 2020; Australian Government Clinical Trials Project Reference Group (CTPRG)) [Appendix 1][1]

1. **COVID-19 related research projects**
   Any new COVID-19 related research projects involving the Eye and Ear as a site, Eye and Ear data, Eye and Ear resources or the Eye and Ear Human Research Ethics Committee (HREC) will be prioritised and expedited.

2. **Eye and Ear Human Research Ethics Committee guidelines**
   Eye and Ear HREC Guidelines for research projects have been separated from these guidelines and are available on the Eye and Ear Research website.

[1] https://www1.health.gov.au/internet/main/publishing.nsf/Content/Clinical-Trials

3. Eye and Ear Hospital COVID-safe Plan for Research Related Activities

The Eye and Ear has a goal of supporting research activity in context with the following considerations:

1. Providing a safe and supportive research experience for research participants and patients involved in research
2. Providing a workplace where both social distancing and use of PPE keeps research staff healthy
3. Integrating research into a health care service that has had and continues to have serious service disruption and also needs to meet the needs of health care needs of patients not involved in research

The Eye and Ear Hospital has now developed Eye and Ear COVID-safe Plan for Research Related Activities (Appendix 2).

The Eye and Ear will maintain an Authorisation status for use of clinical areas on the Research Website.

4. Projects that are authorised to continue at the Eye and Ear site

All research projects that have current HREC ethical approval (Eye and Ear HREC or other Reviewing HREC) are approved to continue according to

1. the HREC conditions of approval; and
2. Eye and Ear authorisation status for recruitment and procedures.

Subject to:

a. Principal Investigators should review and follow
    a. Eye and Ear site specific Eye and Ear COVID-safe Plan for Research Related Activities or equivalent; and
    b. Guidance as per the CTPRG Guidance [Appendix 1]
b. The Principal Investigator is responsible for
    a. Compliance with COVID-safe Plan for Conduct of Research of the investigational sites / trial sites / involved organisation
    b. Providing the 'Eye and Ear HREC COVID-19 Risk Information Statement for research participants' to participants [Appendix 4]
    c. Assessing the risk to each individual participant
    d. Consult with the participant and make a shared decision regarding the decision for the participant to attend site visits (as per Good Clinical Practice (GCP) Guidelines)
    e. Ensuring all research team members have undertaken COVID-19 infection control training.[2]

[2] There are several options for COVID-19 infection control training. One option is through the Australian Government https://covid-19training.gov.au/login

5. Requests and feedback

Requests for changes to the Guidelines

The Eye and Ear welcomes requests for changes and feedback from research partners and other research organisations, that utilise the Eye and Ear for research-related activities, regarding the requirements / guidelines and plans. The request for changes and / or feedback must be in writing and sent to the Executive Director, Medical Services from the Chief Executive Officer / Managing Director or equivalent on behalf of the organisation and not from individual investigators. The request should be sent by email to the Eye and Ear Research Office.

Project specific requests – Eye and Ear research projects

Project specific related requests and feedback should be discussed firstly with the Principal Investigator. If the query is not able to be resolved then the PI should send the query by email to the Eye and Ear Research Office specifying the specific project reference number it relates to. The Research Office will be pleased to facilitate resolution of the query.

Project specific requests – Research Partner and third party organisations research projects

Project specific related requests and feedback should be discussed firstly with the Principal Investigator and the organisation's research governance officer. If the query is not able to be resolved then the query should be sent by the PI by email to the Eye and Ear Research Office specifying the specific project reference number it relates to and must include the research governance officer/contact person for that organisation in the email.

6. Status of other research-related activities

Research related activity	**Current status**	**Additional details**
Research Office	Continue to function	The Research Office will continue to operate as usual. Research Office staff will be working remotely and available on the usual contact details available from the Research website. Due to clinical prioritisation of resources at the Eye and Ear, all research-related queries must be submitted firstly to Principal Investigators and then to the Research Office. Updates will be regularly added to the Research website: https://www.eyeandear.org.au/page/Research/Updates_during_COVID-19_pandemic/
Eye and Ear Hospital Human Research Ethics Committee (HREC)	Continue to function	The Eye and Ear HREC will continue to function as usual with the following exceptions: 1. Meetings will be conducted remotely **2.** All communication must be in electronic format

Research Governance Authorisation	Continue to function	1. All communication must be in electronic format 2. Eye and Ear will now only use e-signatures on documentation including Clinical Trial Research Agreements and Indemnity Forms
eSignatures	All signatures will be electronic	Eye and Ear cannot provide wet ink signatures Documents will be signed using Docusign Please contact the Research Office if there are any issues related to using Docusign
Research Committee	Currently suspended	
QA Activity (including quality improvement and clinical audit)	All QA activity which requires only access to data may continue subject to usual Head of Unit/Clinic approval.	
Authorised Prescriber applications	Authorised Prescriber applications will continue to be reviewed and approved according to current procedures.	
Early Research Career Support Grants	Current projects may continue according to these Eye and Ear Guidelines	ERCSG 2020 round will be postponed until at least January 2021
Research Day 2020	Cancelled	Research Day has been rescheduled for 2021

These are challenging times and requirements may change frequently. If you have any concerns or queries, please contact the Research Office.

Dr Andrea Johannessen
Research Manager
29 June 2020

Approved by Dr David Marty
Executive Director Medical Services
Chair, Research Committee

Appendices

1 COVID-19: Guidance on clinical trials for institutions, HRECs, researchers and sponsors
2 Research Prioritisation (summary and detailed)
3 Eye and Ear COVID-19 Information Statement for Research Participants
4 Eye and Ear COVID-safe Plan for Research Related Activities

Appendix 1

COVID-19: Guidance on clinical trials for institutions, HRECs, researchers and sponsors

Preface

COVID-19 represents an unprecedented challenge to the health and research sectors. Our response to this challenge should be in line with several key principles and considerations. These are:

- The safety and well-being of patients, research participants and their families, and health care professionals, researchers and other staff involved in patient care and research are paramount.
- It is critical that public health systems remain able to respond to the needs of the community, both those impacted by COVID-19 and in terms of regular workloads.
- The conduct of research related to COVID-19 is a significant priority; however, the initiation and continuation of other ongoing and proposed research may also be critical for the well-being of patients, participants, communities and the research sector.
- Compliance with or adherence to regulations, guidelines, codes, policies and other standards remains necessary. However, interpretation of research responsibilities in the context of a crisis such as COVID-19 should be informed by flexibility, consultation and good sense so as to retain the focus on the safety and well-being of those most at risk in our institutions and communities.

Purpose and scope

This guidance provides general information and advice to institutions conducting or overseeing research, Human Research Ethics Committees (HRECs), researchers and sponsors in the context of the COVID-19 pandemic. It is directed towards those involved in clinical trial research and other relevant clinical research, but also may be of use to institutions, HRECs and researchers in other fields.

The purpose of this guidance is twofold:

1. to assist those overseeing, conducting and reviewing clinical trial research to maximise the safety of research participants and to minimise risks to participants and the community, to researchers and other institutional staff and to trial integrity, and
2. to address prioritisation of clinical trial research.

This advice represents current thinking and best practice at the government level. It reflects the shared views of the all state and territory Departments of Health, the Therapeutic Goods Administration (TGA), National Health and Medical Research Council (NHMRC) and the Clinical Trials Project Reference Group (CTPRG), of which all of these entities are members. Although it may refer to legislation or regulation, it is not legal advice and should not be cited for this purpose. It is a set of recommendations and is not legally enforceable.

COVID-19 and the challenges of responding to it are rapidly evolving and this guidance will be updated in response to changes globally and in Australia, and to reflect feedback received from you and our other stakeholders in the clinical trial research sector. Please check https://www1.health.gov.au/internet/main/publishing.nsf/Content/Clinical-Trials for updates.

Ongoing management of current clinical trials

Contingency planning

- Institutions, individual principal investigators (PIs) and sponsors should be undertaking contingency planning to address the potential impact of COVID-19 and responses to the crisis on current, ongoing clinical trials. This planning should include:
    - priority: assessment of the importance of and the risks associated with continuing the trial as designed or with necessary modifications. Responses could include continuing the trial in its present form, conducting the trial in a modified form, suspending the trial or closing the trial.
    - participation: assessment of the ability of participants to participate in the trial in accordance with protocol requirements and consideration of alternative models for participation that would not compromise the integrity of the trial.
    - capacity: assessment of the resources available for continuing the trial, including research staff, clinical support staff, pharmacy support, other support staff, space, equipment, supplies, etc. A component of a capacity assessment will be consideration of the need to re-allocate research staff to clinical care and other areas of patient support.
- Contingency planning will need to be an ongoing process.

Communications

- Decisions and actions in response to the crisis will be most effective if they are taken after appropriate consultation with the key stakeholders in a clinical trial: institutions, researchers, sponsors, regulators (if relevant) and, in some cases, participants. However, the need for rapid responses may require decisions and actions by one or more parties without prior consultation with the others. In such cases, all key stakeholders should be informed of the decisions and actions taken at the earliest opportunity.

Participants

- The safety and well-being of trial participants, other patients, family members, researchers and other clinical and support staff is paramount.
- In trials that proceed without modification, participants should explicitly be given the following options:
    - continuing to participate in the trial
    - suspending their participation, if this is viable, or
    - withdrawing from the trial.
- Participants who do not attend clinic visits or complete other trial activities may be reminded that these are required; however, if a patient declines or actively refuses to participate in trial activities, then their decision should be respected and they should be considered to have withdrawn from the trial. These participants should be informed that their decision will not affect their ongoing treatment or participation in future clinical trials.
- Participants who choose to move off the investigational product and onto standard care, and who do not wish to continue with site visits may be able to remain on trial for follow-up only.
- Participants should be informed of any modifications to the trial, including medical and other trial procedures, ongoing treatment or care and any tests or assessments that will have, or have the potential to have, an impact on them.
- In trials that have been modified, participants should explicitly be given the following options:

- participating in the trial, as modified, inclusive of alternative mechanisms for engagement such as remote visits, data collection, monitoring, etc., as appropriate
- suspending their participation, if this is viable, or
- withdrawing from the trial.

- In a situation where a trial participant is unable to attend a visit or otherwise fulfil a condition of participation due to public health directives or government policy (such as restricted travel between states and territories), sponsors and researchers are encouraged to facilitate the participant being able to continue to participate in the trial at a site that is within the limits of any such restrictions. If available, such adjustments could be 'pre-approved' per the guidance provided below for amendments. Data collected could then be transmitted to the site that the participant would normally have attended.

Participants who are symptomatic for COVID-19

- Participants should be informed of the importance of notifying the research team in advance of attending any trial visits if
  - they are experiencing one or more symptoms suggestive of COVID-19 infection
  - they have recently (within 14 days) returned from overseas or have been in close contact with someone who is known to have contracted COVID-19 or has symptoms suggestive of COVID-19 infection, or
  - they are experiencing one or more symptoms not suggestive of COVID-19 infection, but suggestive of influenza or other infectious disease or condition that includes respiratory symptoms.
- The PI should ensure that appropriate follow-up with symptomatic participants is arranged and may advise the participant to present to another site or service for assessment, testing and/or further investigation.

Recruitment of new participants

- Decisions to recruit new participants to ongoing trials should take into account the potential benefits and burdens on Australia's health system and should depend on individual trial factors. The focus should remain on the safety and well-being of those most at risk in our institutions and communities. Any new recruitment should reflect the most current public health advice on social distancing.

Alternative models for conducting clinical trials

- Researchers and sponsors should educate themselves about novel approaches to the conduct of clinical trials, such as decentralised trials (i.e. teletrials) and hybrid models in which participants can be recruited and participate remotely and data can be captured remotely via available technology.
- HRECs should consider whether to actively encourage alternative models for conducting clinical trials, where possible and appropriate.

Notification of serious adverse events, significant safety issues, urgent safety measures, serious breaches, amendments and protocol deviations

- Researchers, sponsors, institutions, and HRECs should consult and adhere to existing guidance for safety monitoring and reporting published by NHMRC and the TGA (see https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods). Any proposed modifications to standard practice should be discussed between the relevant parties and authorised, if appropriate, by the responsible party.

- Any incidents associated with the attendance at a clinic (or other relevant context) of a participant known, or later discovered, to be symptomatic should be promptly reported as an adverse event or safety issue, as relevant, in accordance with existing guidance.
- If a planned modification of a protocol is likely to have a negative impact on participants' safety or increase risk to participants, then review by an HREC, or an approved delegated process, may be required. Institutions should consider identifying an individual, such as the HREC Chair or the most senior ethics officer, to make the decision as to whether a review is required prior to implementation of the proposed change. Substantial amendments should be submitted and approved by the HREC or via delegation as per processes authorised by the institution.
- The use of strategies to pre-approve certain categories of amendments is encouraged and should be adopted subject to the directions of jurisdictional health departments. Amendments eligible for pre-approval would be at the discretion of the institution and/or HREC and might include modification of a trial to:
    - employ virtual visits, telehealth, electronic consent or otherwise implement teletrials
    - change the 'site' to a location outside of a hospital or clinic or permit referral to another hospital or clinic
    - extend protocol timeframes for visits, procedures, trial medication delivery or follow-up to accommodate isolation periods or other disruptions
    - ensure that all returned investigational medical product is destroyed in accordance with standard protocols for the destruction of biohazards, and
    - any other changes that do not implicate participants' safety or well-being and are intended for the purpose of safeguarding the health of participants, researchers and staff or the community via infection control or reducing the burden of participation in a trial for the participants or researchers.
- Amendments to existing protocols that are designed to limit exposure of participants, researchers or staff to infectious agents or to change methodology, procedures or project activity to ease the burden on participants, researchers or staff do not need to be approved by HRECs before being implemented, if timing does not enable this. In addition, necessary amendments that suspend recruitment or testing of participants, or that modify research locations or staffing and other administrative matters can be implemented as necessary. If there is time for an amendment of this type to be reviewed in accordance with existing administrative amendment approval processes, that is optimal; but, participant and staff safety are the paramount concerns in all cases.
- If such changes are made, they should be reported to the sponsor in accordance with usual processes and to the HREC, when that becomes possible, in accordance with usual processes and in conformance with the National Statement.
- Protocol deviations can be reported to HRECs in the usual manner or collected and submitted in bulk form at the end of the crisis.
- Researchers are reminded that, although all deviations must to be reported to the trial sponsor, only the sub-set of deviations that have a significant impact on the continued safety or rights of participants or the reliability and robustness of the data generated in the clinical trial must be reported to the HREC. These deviations (also known as 'serious breaches') should also be reported by the PI to their institution, as they may impact on medico-legal risk, the responsible conduct of research, or adherence to contractual obligations.

Amendments related to COVID-19 testing or analysis

- Amendments to clinical trial protocols that include the addition to an existing trial of new COVID-19 related elements, e.g. to enable epidemiological analysis of COVID-19, to add patients with COVID to an existing trial of a treatment or to add in testing for SARS-CoV-2 for safety purposes, (for example where studies include taking samples), is acceptable, so long as appropriate protection is put in place for handling of samples. Such arrangements would be treated as an urgent safety measure with subsequent

notification in accordance with usual processes. Use of a separate specific information sheet and consent form to provide information about additional tests rather than modifying an existing form should be considered.

- Submission of template forms or separate individual PICFs for COVID-19 related testing for pre-approval by HRECs is recommended.

Continuation of delivery of trial medication

- PIs, pharmacies and sponsors, where relevant, should develop plans to manage the continuation of clinically essential trial medication delivery to participants affected by self-isolation quarantine periods or as a result of testing positive for COVID-19. While there are no specific requirements under TGA legislation or the CTN scheme regarding the movement of clinical trial medications across state and territory borders, sponsors should ensure compliance with all relevant state and territory legislation.
- Any such arrangements should include a process for obtaining the agreement of the participant to the delivery changes.

Suspension or cessation of research

- Decisions by researchers to halt a study or suspend recruitment can be dealt with administratively between institutions and sponsors; however, a decision to close a study where an investigational product (IP) or an unregistered device, diagnostic or biological is being provided is a substantial amendment requiring HREC review.
- In assessing the proposed closure of a study where an IP or an unregistered device, diagnostic or biological is being provided, careful consideration should be given to any post-trial care or access to the IP, device or biological that is planned, or not planned, for relevant participants.

TGA response to COVID-19

- The Therapeutic Goods Administration (TGA) is providing active support for monitoring a number of issues relating to therapeutic goods including medicines and medical devices in response to COVID-19. Additionally, any trial that works toward a treatment or a vaccine for COVID-19 will be considered a priority by the TGA.
- With respect to clinical trials notified to the TGA under the CTN scheme, the TGA acknowledges that there may be deviations from trial protocols related to the supply of the Investigational Medicinal Product (IMP) and resulting from potential quarantine and travel restrictions or other factors that precipitate the need to manage patients remotely. Under the CTN scheme requirements, these deviations do not need to be notified to the TGA.
- With respect to variations to the trial responsive to COVID-19, such as trial start/finish date change, change in PI, number of participants or the name of the trial approving authority, these do not need to be notified to the TGA. Variations to the trial such as changes to existing therapeutic goods, addition of therapeutic goods or addition of sites and those variations that are not responsive to COVID-19 will continue to require notification to the TGA.
- With respect to variations to clinical trials being conducted under the CTX scheme, where the TGA assesses only the safety aspects of a trial protocol, these can be assessed on a case by case basis.

Site monitoring visits

- Remote monitoring visits are encouraged as the first option in all cases and sponsors and institutions should ensure that these are facilitated, taking into account the need to avoid undue burden on hospital or

institutional resources. These arrangements must adhere to patient confidentiality protocols already in place. Remote source data verification may be done electronically as long as appropriate security arrangements either are or can be put in place.

- If remote monitoring visits are not feasible, then clinical research associates may continue to undertake on-site monitoring visits as long as they are not symptomatic, have not returned from overseas in the last 14 days or had contact with a known case of COVID-19, in accordance with the most current public health guidance and advice from jurisdictional health departments.

Investigator meetings

- Investigator meetings and other meetings to plan, conduct or monitor a clinical trial should employ the use of remote technology wherever possible. Where researchers are temporarily co-located for the purposes of the delivery of clinical care or the conduct of the trial, engaging in any necessary interaction may be efficient, but should be subject to current public health advice.

Advice for HRECs and research governance offices

- HREC members, ethics administrative officers, research governance officers and executive officers should conduct contingency planning related to their operations and employ sensible approaches to fulfilling their responsibilities in accordance with the National Statement and institutional policy and procedures. These approaches should not be overly rigid or generate onerous requirements on researchers or sponsors.
- HREC members, ethics administrative officers, research governance officers and executive officers should be aware of the guidance provided in this document and any updated guidance or advice, as well as current public health advice related to COVID-19.
- NHMRC, TGA, all Australian Departments of Health and the CTPRG support efforts by institutions, HRECs, researchers and sponsors to ease the burden of adhering to relevant regulation and guidelines by employing creative and streamlined strategies for doing so.

HREC meetings and procedures

- HRECs are encouraged to consider conducting meetings remotely by the use of video technology. This approach is permitted by the National Statement. (NHMRC has released a statement to HRECs supporting and encouraging the use of remote technology for meeting, where indicated).
- HRECs should review and determine what matters may be dealt with by delegation from the HREC (as authorised by the host institution, if applicable). This may require the development and publication of interim terms of reference.
- HRECs should strongly encourage or require the use of electronic document transfer and the use of digital/electronic signatures, wherever possible.

New Clinical Trials

Prioritising and expediting approval and variations for COVID-19 research and other clinical trials

- An expedited review process should be made available for research relating to COVID-19 or where there are public health grounds for rapid review. Researchers are advised to consult their institutions and their jurisdictional health departments for more information.
- Extraordinary meetings of HRECs should be organised where review of this research is indicated. These meetings should be promoted at the institutional and jurisdictional level.
- When assessing other proposed research, where proposals have already been submitted for review, HREC requests for modifications to protocols that are designed to limit physical contact between researchers or staff and participants (or between participants and each other) are appropriate.
- If researchers feel that changes intended to limit physical contact between researchers or staff and participants (or between participants and each other) should be put in place subsequent to approval, but prior to commencement of the research, then the change does not need to be approved by HRECs before being implemented, but should be notified to the HREC at the earliest opportunity.
- Researchers and sponsors should educate themselves about novel approaches to the conduct of clinical trials, such as decentralised trials (i.e. teletrials) and hybrid models in which participants can be recruited and participate remotely and data can be captured remotely via available technology.
- In proposing and reviewing new research, and in considering authorisation of new research, researchers, reviewers and institutions should consider the impact of the proposed research on patient and participant well-being and institutional resources (including ward and clinic capacity and availability of supporting services) and the impact on the health system and the community, more generally.
- If an HREC considers new proposed research to be inadvisable in the current environment, either as designed or with necessary modifications to accord with public health guidelines, then it is within the HREC's discretion to decline to approve the project. In such cases, the HREC may choose to indicate an in-principle acceptance of the merits and design of the research, but defer its approval until circumstances permit approval and commencement of the research.

Authored by:

All State and Territory Departments of Health

Clinical Trials Project Reference Group

https://www1.health.gov.au/internet/main/publishing.nsf/Content/Clinical-Trials

National Health and Medical Research Council

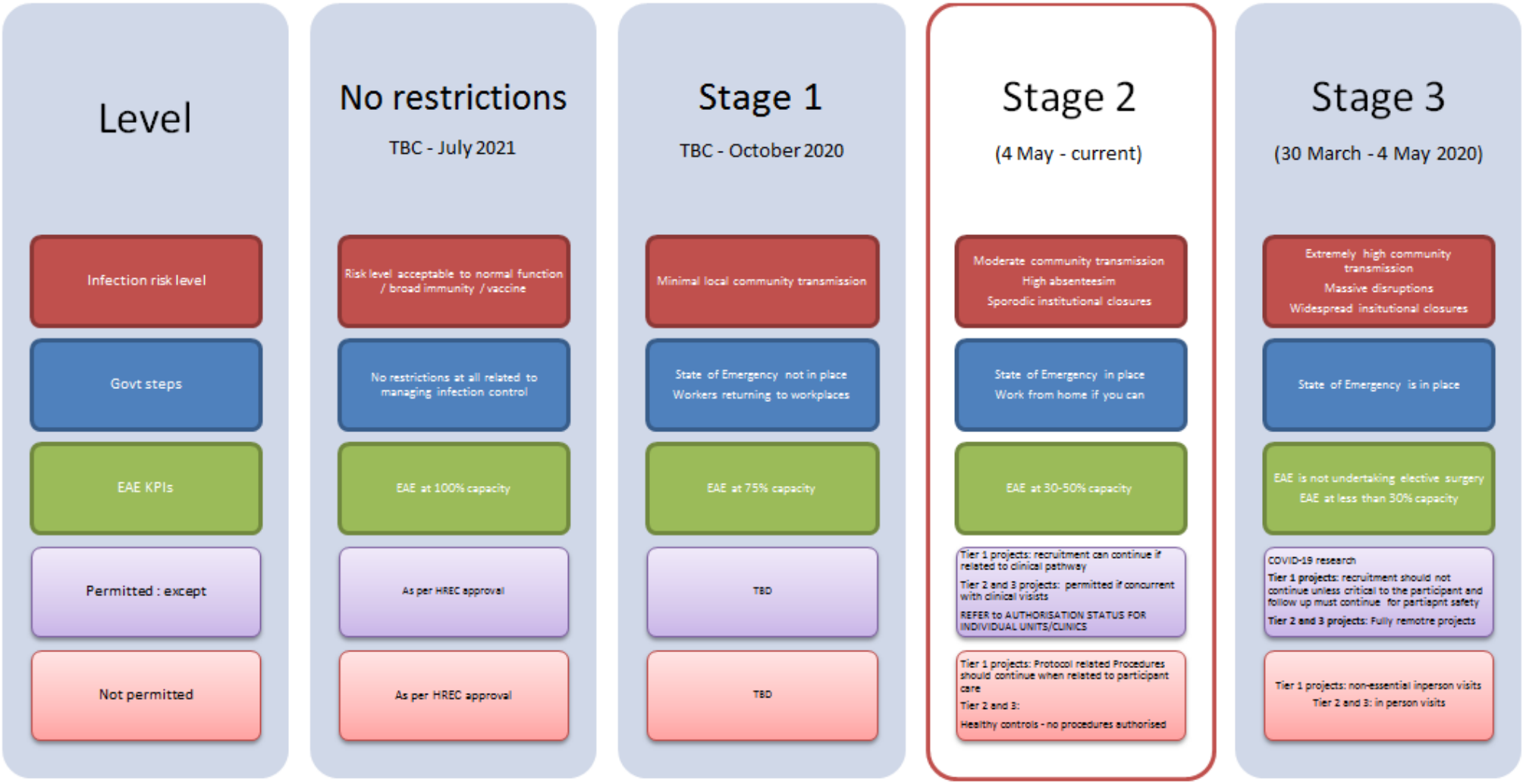
https://www.nhmrc.gov.au/research-policy/COVID-19-impacts

Therapeutic Goods Administration

https://www.tga.gov.au/

Appendix 2

Research Prioritisation – Stages 1-3 summary



Research prioritisation – Steps 1 – 4 - detailed

CLASSIFICATION OF RESEARCH

Classification	Definition	Examples
Tier 1 - High Direct Benefit to Research Participants **Also classified as "Essential"**	All protocols in which serious or immediate harm could be caused to the research participants if stopped.	• Research protocols involving treatments for acute, life threatening health conditions (e.g. treatment trials for cancers). • Protocols where stopping the intervention (e.g., some investigational drugs or vaccines or preventative drug regimens) could be harmful.
Tier 2 - Low to Moderate Direct Benefit to Research Participants	Protocols which, if stopped, may pose a low or negligible risk to the research participant.	• Protocols in which research participants are receiving interventions or clinical care that is very interrelated to their research participation (e.g., test results coming back that might have clinical implications for their care). • Protocols in which delays to starting or pausing of research does not substantially impact on research objectives of the research protocol. • Protocols in which exposure risk to research participants is high (e.g., potentially exposing elderly vulnerable individuals to COVID) and benefits of the study to the participants remain minimal. • Some protocols evaluating treatments for chronic conditions (e.g., asthma, hypertension, depression, etc.). • Protocols involving assessment of the safety or efficacy of an intervention in which, if stopped, the potential societal benefit of the science would be significantly and adversely impacted, for example where a research assessment (blood collection or imaging study) is only valuable if collected at a very specific time. This must be measured against the risk to participants, including the risk of exposure of COVID-19. • Research with healthy volunteers. • Any minimal risk studies that require research subjects to travel, that involve undergraduate students, or that are in a community setting and require direct interaction with researchers.
Tier 3 - Low Direct Benefit to Research Participants		• Cohort and natural history studies where delays in data collection have limited impact on scientific objectives • Protocols in which delays to starting or pausing of research does not substantively impact on research objectives of the research protocol • Protocols in which risks to research participants are higher (e.g., potentially exposing elderly vulnerable individuals to COVID) and benefits of the study to the participants remain minimal • Research with healthy volunteers • Any minimal risk studies that require research subjects to travel, that involve undergraduate students, or that are in a community setting and require direct interaction with researchers

ACTVITY RESTRICTIONS AT EYE AND EAR SITE

		Authorised Actions for Researchers		
		TIER 1	**TIER 2**	**TIER 3**
Step 1	**Infection risk level**	**No local community spread** **All workers returned to workplace** **No institutional closures** **No herd immunity** **No vaccine**		
	Timing	**ADVISORY ONLY AND TO BE CONFIRMED - October 2020**		
	Guidelines	**Not released**		
	PERMITTED	TBD	TBD	TBD
	NOT PERMITTED	TBD	TBD	TBD
Step 2	**Infection risk level**	**Local community spread** **High absenteeism** **Sporadic institutional closures**		
	Timing	**May - October 2020**		
	Guidelines	**EASE HREC Guidelines dated 29 June 2020 - CURRENT** **EAE Guidelines dated 29 June 2020 - CURRENT** **EAE Guidelines dated 4 May 2020 - RESCINDED**		
	PERMITTED **RECRUITMENT** **PROCEDURES** **OTHERS**	Research in Tier 1 can continue if the PI agrees the research can be conducted in a safe manner that protects subjects, research, and the community. Procedures in Tier 1 must continue to ensure safety of research participants PIs must pause on enrolling new research participants unless there is a compelling reason Remote monitoring	On-line visits or data collection that does not require participant interaction may continue. In person visits concurrent with clinical visit	On-line visits or data collection that does not require participant interaction may continue. In person visits concurrent with clinical visit
	NOT PERMITTED	On-site monitoring	Research activities in Tier 2 must not enroll new participants in studies requiring in-person interaction nor continue to conduct in-person visits unless the PI demonstrates a compelling need to continue. Healthy controls must not be involved in onsite procedures	Tier 3 studies must not enroll new participants in studies requiring in-person interaction. Tier 3 studies must not continue to conduct in-person visits. Healthy controls must not be involved in onsite procedures

Step 3				
	Infection risk level	**Extremely high** **Massive disruption** **Widespread institutional closures**		
	Timing	**30 March – 4 May 2020**		
	Guidelines	**EAE Guidelines dated 30 March 2020**		
	PERMITTED **RECRUITMENT** **PROCEDURES** **OTHER ACTIVITIES**	1. COVID-19 related research 2. Tier 1 clinical trials / research project Tier 1 studies must cease any in-person visits specifically for research purposes that require subjects to travel. All other in-person interactions may only continue for Tier 1 studies if the PI presents a compelling justification to continue these interactions and the request to continue is approved by the HREC using a Contingency Plan. Requests for new recruitment in this Tier must continue to be submitted to the HREC. Procedures in Tier 1 must continue to ensure safety of research participants Remote monitoring may continue	Data collection that does not require in-person participant interaction (e.g. telephone or online) may continue. Remote monitoring	Data collection that does not require in-person participant interaction (e.g. telephone or online) may continue.
	NOT PERMITTED	On-site monitoring	No new enrolment is permitted for Tier 2 studies. Tier 2 studies must cease all in-person interactions. The Eye and Ear will no longer authorise requests to continue in-person activities for this Tier.	Tier 3 studies must not enrol new participants in studies requiring in-person interaction. Tier 3 studies must not continue to conduct in-person visits.

Sources used for development of the Research prioritisation Guidelines are listed below:

Johns Hopkins University

https://hub.jhu.edu/novel-coronavirus-information/research-preparedness/research-preparedness-human-subjects/

https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information.html/JHUSOM_Clinical_Research_Visit_Guidelines.pdf

Children's Hospital of Philadelphia

https://irb.research.chop.edu/

Appendix 3

THE ROYAL VICTORIAN EYE AND EAR HOSPITAL

COVID-19 Risk Information Sheet for Research Participants

The primary responsibility of the Eye and Ear Hospital related to research is to protect the safety of research participants.

COVID-19 refers to the Coronavirus that is being spread across people in our communities. We need to provide you with important information about COVID-19, and to tell you about ways your study participation might change because of COVID-19 related risk.

If you are considering joining a study at this time or are currently enrolled in a study, it is important that you consider the following information to determine if study participation is right for you at this time.

How is COVID-19 spread?
COVID-19 is a respiratory virus spread by respiratory droplets, mainly from person-to person. This can happen between people who are in close contact with one another (less than 6 feet). It is also possible that a person can get COVID-19 by touching a surface or object (such as a doorknob or counter surface) that has the virus on it, then touching their mouth, nose or eyes.

Can COVID-19 be prevented?
Current ways to minimize the risk of exposure to COVID-19 include "social distancing" which is a practice to decrease the potential for direct exposure to others who may have been exposed to COVID-19, for example by avoiding large gatherings or refraining from shaking hands with others. It is important to understand that since study participation may include increased travel outside of your home and increased exposure to others within a clinical care environment or research site it may increase your exposure to COVID-19. At this time there is no vaccination to prevent COVID-19 infection.

What are the risks of COVID-19?
For most people, the new coronavirus causes only mild or moderate symptoms, such as fever and cough. For some, especially older adults and people with existing health problems, it can cause more severe illness, including pneumonia. While we are still learning about this virus, the information we have right now suggests that about 3 of 100 people who are infected might die from the virus.

Who is most at risk?
Individuals over 60 and with chronic conditions such as cancer, diabetes and lung disease have the highest rates of severe disease from the infection.

How could your participation in this research change as a result of COVID-19?
There are several ways we try to minimise your risk. If possible, we limit the number of times you have to come to a clinical care or research site. We ask every research participant if they have the symptoms of COVID-19 or have been in close contact with anyone who has or had COVID-19. During your research visits, we try to reduce the time you are exposed to other people as much as possible. If you are suspected to be positive for COVID-19, there may be last minute changes to how research procedures are performed [such as a change from an in-person visit to a telephone call] or cancellations of research tests or procedures to ensure your safety. It is even possible that your research procedures will be put on hold or stopped because of COVID-19.

The information related to risks of COVID-19 changes every day. The leaders at The Royal Victorian Eye and Ear Hospital and affiliated research sites are monitoring these risks and deciding how these risks should change our research. If you have questions about COVID-19 and your participation in research, please talk to your study team.

Adapted from Johns Hopkins University Guidance:
https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information.html/JHUSOM_Clinical_Research_Visit_Guidelines.pdf

Appendix 4

THE ROYAL VICTORIAN EYE AND EAR HOSPITAL

Eye and Ear COVID-safe Plan for Research Activity

Essential on-site procedures

Eye and Ear staff and visitors including Honorary Researchers

1. Review and follow the current Eye and Ear Guidelines
   https://www.eyeandear.org.au/page/COVID-19/

2. Follow DHHS COVID-19 Infection Control Guidelines
   https://www.dhhs.vic.gov.au/health-services-and-general-practitioners-coronavirus-disease-covid-19

   These guidelines are significant and must be reviewed in full. The key elements are:
   i. Utilise Personal Protective Equipment according to DHHS Guidelines for Tier 0 to Tier 4
   ii. Implement physical distancing requirements
   iii. PIs and research staff must eliminate face-to-face contact where possible and utilise telehealth options
   iv. Waiting areas must comply with DHHS requirements

3. Provide Research Participants with the Eye and Ear COVID-19 Risk Information Statement for Research Participants in advance of the visit (Appendix 3)

4. Screen research participants who are scheduled to visit the site according to the DHHS Guidelines

   https://www.dhhs.vic.gov.au/health-services-and-general-practitioners-coronavirus-disease-covid-19

5. Advise research participants of the requirements detailed in the DHHS Hospital Visitor Guidelines

   https://www.dhhs.vic.gov.au/health-services-and-general-practitioners-coronavirus-disease-covid-19

6. Principal Investigators of research projects involving Eye and Ear patients, staff or spaces or other resources are responsible for ensuring that all research team members have undertaken COVID-19 infection control training and retain evidence in research files.

Authorised site activities

1. Tier 1 Clinical Trials

   Tier 1 Clinical Trials and research projects are authorised to continue according to the current approved conditions of approval and Sponsor COVID plans.

2. Tier 2 and 3 research projects

   Tier 2 projects may continue if

   a. utilising eConsent and telehealth procedures that have been approved by the Reviewing HREC
   b. face-to-face visits are concurrent with clinical appointments

Recruitment and procedures authorisation from the various hospital clinics and units is listed and updated on the Research website for example:

AS AT 23 June 2020	**Recruitment**	**Procedures**
Specialist clinics	Tier 1 Recruitment authorised if attending for clinical appointment Tier 2 and 3 1. utilising eConsent and telehealth procedures that have been approved by the Reviewing HREC 2. face-to-face visits are concurrent with clinical appointments	Tier 1 Procedures authorised if attending for clinical appointment Tier 2 and 3 3. utilising eConsent and telehealth procedures that have been approved by the Reviewing HREC 4. face-to-face visits are concurrent with clinical appointments
Surgery	Face to Face recruitment not authorised unless related to clinical pathway	Face to Face procedures not authorised unless related to clinical pathway
Cochlear Implant Clinic	Face to Face recruitment not authorised unless related to clinical pathway	Face to Face procedures not authorised unless related to clinical pathway
Audiology / BDAS	Face to Face recruitment not authorised unless related to clinical pathway	Face to Face procedures not authorised unless related to clinical pathway

Dr Andrea Johannessen
Research Manager
29 June 2020

Authorised by Dr David Marty
Director, Medical Services