



# OFFICE FOR RESEARCH

FINDING YOUR WAY TO THE APPROPRIATE APPROVAL PATHWAY

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# OFFICE FOR RESEARCH

- coordinates and convenes the Human Research Ethics Committee, its subcommittees and all research approval processes
- reviews and makes recommendations in relation to site-specific assessments for multi-site research
- coordinates Celebrating Research events and associated activities
- facilitates training and support for researchers
- produces the Research Report annually in conjunction with Corporate Communications and Philanthropy
- works closely with the Academic Unit, Department of Medicine on strategic issues
- coordinates the implementation of the National Clinical Trials Governance Framework.







## FOUR APPROVAL PATHWAYS

- Recruitment Request
- QA/Audit
- Low Risk
- More than Low Risk



# RECRUITMENT REQUEST

If external researchers wish to recruit Peninsula Health staff or patients to their projects and no research is conducted on-site a request can be made via e-mail for approval.

What we need:

- Protocol
- Ethics Committee Approval
- Support of PH Head of Service involved
- Any material to be given to patients/staff eg surveys, advertisements, brochures

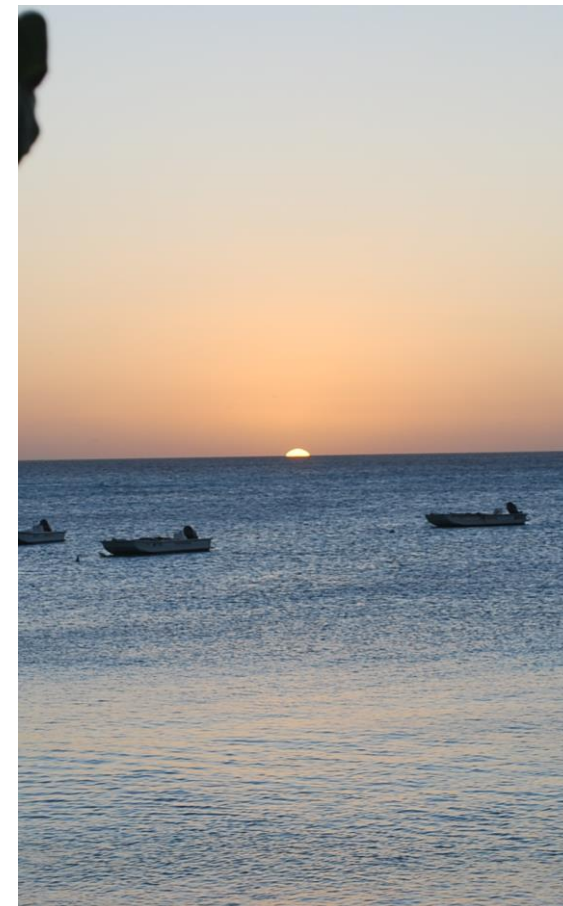


# QA/AUDIT/NEGLIGIBLE RISK RESEARCH (HREC EXEMPTION)

The primary purpose of the project is to monitor or improve the quality of service delivery. The project involves minimal risk, burden or inconvenience to participants.

Irrespective of whether an activity is QA, evaluation or research, the activity must be conducted in a way that is ethical.

This should include consideration of whether the people involved will be exposed to any harm as a result of the activity. Those conducting the activity need to consider a range of issues including consent, privacy, relevant legislation, national/professional standards.





## QA/AUDIT

Usually QA projects are conducted by a Peninsula Health staff member accessing existing Peninsula Health data. To be eligible for review as a QA project, the project must meet the following criteria:

The data being collected and analysed is coincidental to standard operating procedures with standard equipment and/or protocols;

The data is being collected and analysed expressly for the purpose of maintaining standards or identifying areas for improvement in the environment from which the data was obtained;

The data being collected and analysed is not linked to individuals;  
and

[Ethical Considerations in Quality Assurance and Evaluation Activities](#)



# HREC REVIEW AND APPROVAL

## Single-site Low Risk & More than Low Risk Projects are reviewed by the Human Research Ethics Committee

Where the only foreseeable risk is one of discomfort.

### Low Risk exclusions:

Qualitative research projects by a person without appropriate experience

Research being conducted overseas

Research investigating illegal activity or research that is likely to discover illegal activity

Research investigating issues focusing on Aboriginal or Torres Strait Islanders or the identification of any Aboriginal or Torres Strait Islanders recruited as a separate subgroup of participants

Research involving patients who cannot consent for themselves

Research involving:

- Collection of tissue (eg blood, urine, biopsy tissue)
- Collection, use or disclosure of identifiable information without the consent of the individual whose information it is (including waiver of consent requests)
- Covert observation, deception of participants or concealment of the purpose of the research



# HREC REVIEW AND APPROVAL

## Low Risk & More than Low Risk Projects are reviewed by the Human Research Ethics Committee

Where the where the foreseeable risk is greater than that of discomfort.

### More than Low Risk:

- All research where the foreseeable risk is greater than that of discomfort to participants, patients, clients, residents or staff of Peninsula Health.
- eg clinical trials, some interventional research, research excluded from Low Risk Review.
- The only difference between the process for Low or More than Low Risk research is the application form.
- Should it be unclear whether the project is Low Risk then a More than Low Risk Application is required.





# MULTISITE REVIEW AND APPROVAL

**Multisite Research is reviewed by a Reviewing HREC and Site Review and Authorisation is conducted at Peninsula Health**

## HREC Application

Submitted to Approved reviewing HREC:

Alfred Health

Austin

Melbourne Health

Monash Health

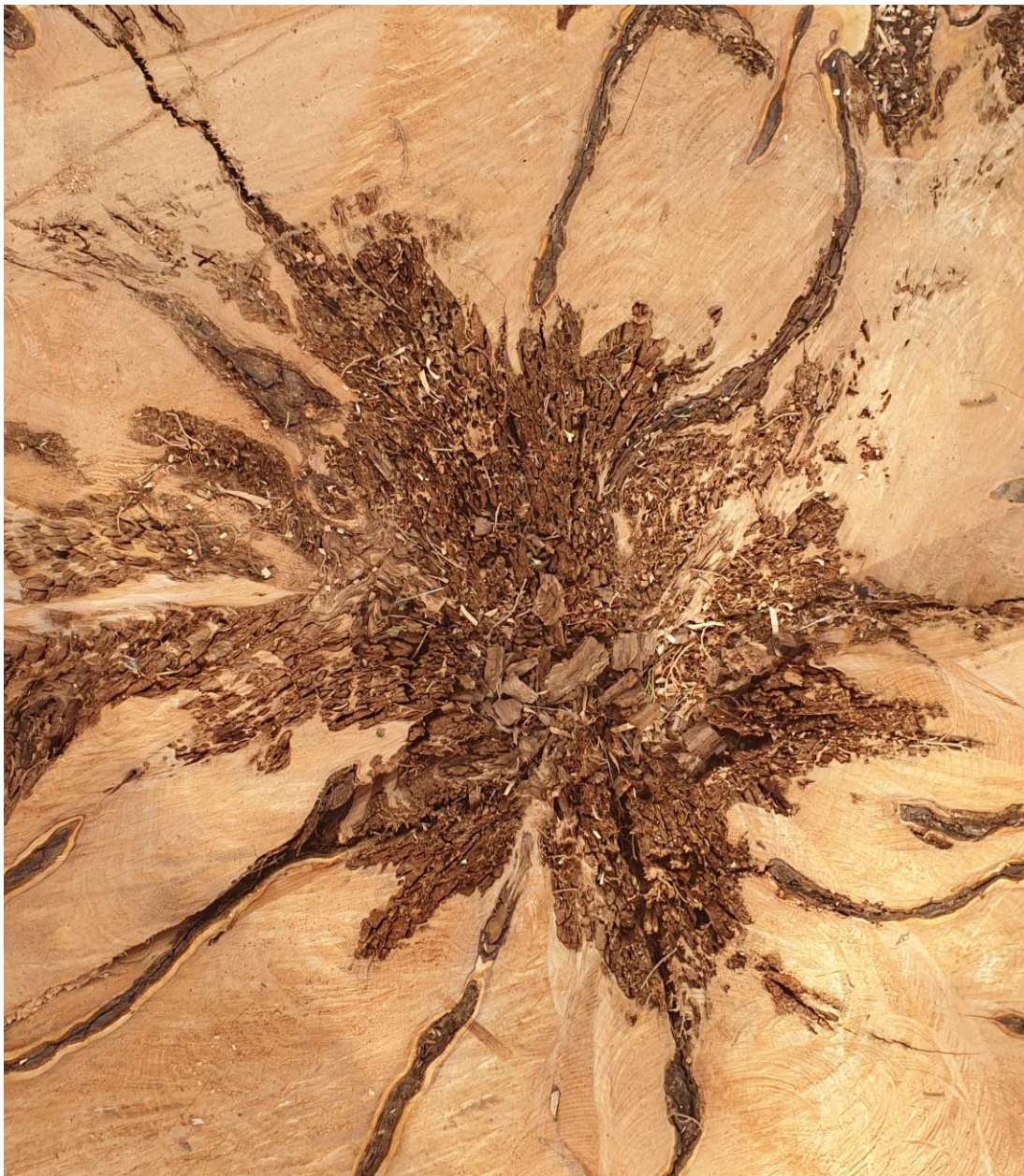
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St Vincent's Health

(RCH)

## Site Specific Assessment

Following HREC approval Site Specific Authorisation is required from each site involved.



# WHICH WAY DO I GO??

Please ask?

We are happy to review your protocol/project plan and provide advice/discuss

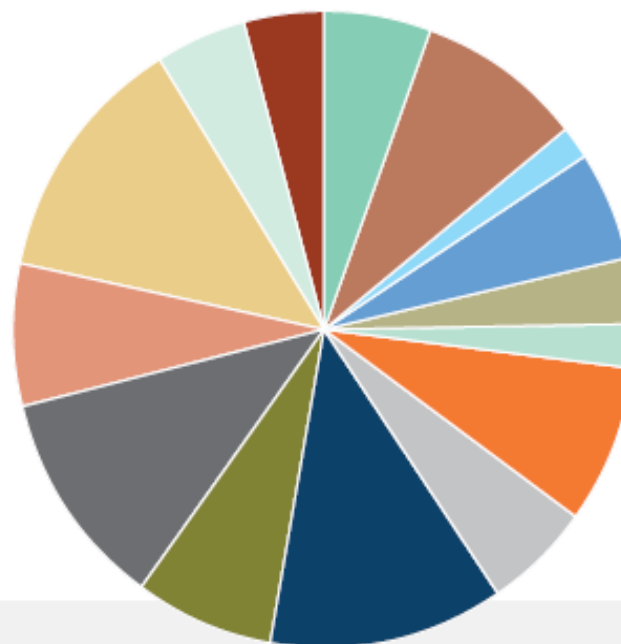
Having this conversation early can save you angst and work

Sometimes it is difficult even for us to decide!!!!

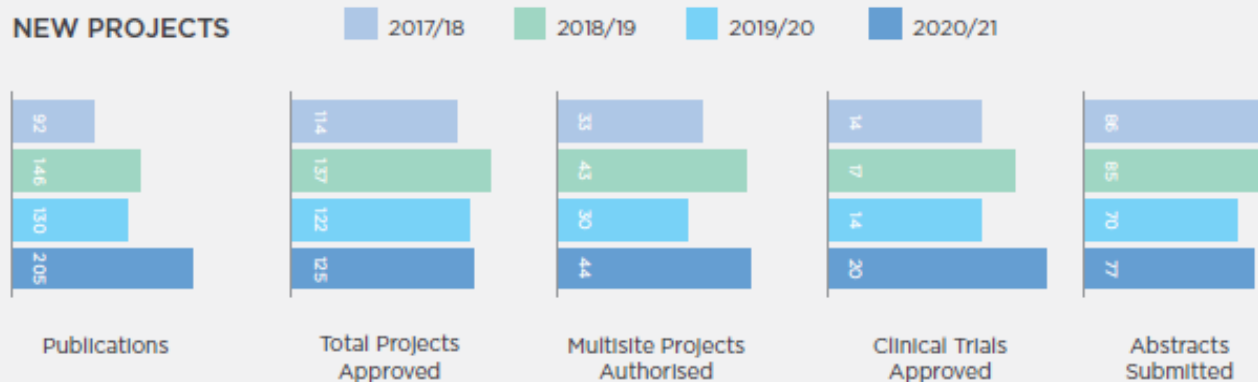


# RESEARCH ACTIVITY

RESEARCH ACTIVITY BY DEPARTMENT



NEW PROJECTS







# QUESTIONS & THANK YOU

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