# AV Research Application Guidelines

## Contents

# Background and context

## 1. Purpose

The Research Application Form and Guidelines are designed to help you provide the information that is used by Ambulance Victoria (AV) to prioritise participation in research projects involving AV's people, patients or data. Individuals considering the development of research proposals are requested to provide information using the Research Application form – FOR/STP/001, which is available upon request.

**It is highly recommended that prior to formulating and submitting a research proposal, researchers contact the AV Centre for Research & Evaluation to discuss the proposed protocol.** This will help to reduce delays in the application process, which can be caused by incomplete or inappropriate applications, or applications for topics which are already being studied.

Please contact:

Research Governance Manager
Email: researchgovernance@ambulance.vic.gov.au

## 2. Responsibility

| Role | Responsibility |
|---|---|
| **Professional ethical standards** | • Provide every patient with dignity and Best Care.<br>• Assume responsibility, and accept accountability, for professional decisions.<br>• Protect the privacy and confidentiality of personal and health information handled while performing functions.<br>• Avoid any real or apparent conflicts of interest.<br>• Report improper conduct. |
| **Researchers** | • Submit a complete research application form and project protocol.<br>• Obtain research project approval from a Human Research Ethics Committee.<br>• Submit progress reports annually using appropriate forms.<br>• State the expected time it will take to complete the project. |

## 3. Advice and instructions to applicants

AV supports and encourages high quality research within an ethical framework designed to improve the care it provides to patients. Such research may encompass a wide range of activities including analysis of routinely collected data or randomised clinical trials.

AV encourages collaborative research projects. It is expected that at least one approved AV team member is included as a co-investigator for projects requiring significant use of AV data and/or people. AV may choose to nominate an appropriate team member if required. Also note that any clinical trials will be run through the AV Centre for Research and Evaluation with appropriate representation from the Centre for Research and Evaluation team.

The Research Application form – FOR/STP/001 is modified and updated on occasion. Please ensure you contact the Centre for Research and Evaluation prior to making a new application to

ensure that you are using the latest version of the form. The application is the main source of information available to the AV Research Committee. The application must contain all the information necessary for consideration of the project without the need for further written or oral explanation, or reference to additional documentation. Please write in clear, everyday English. Define all terminology and abbreviations.

All details in the application must be current at the time of application and should reflect the research protocol approved by the Human Research Ethics Committee. The checklist at the end of the Research Application form – FOR/STP/001 will assist you in ensuring that all relevant documents are included in your application.

All project applications will be reviewed and are subject to approval in accordance with AV's Research Governance Procedure – PRO/STP/003. AV will notify the applicant of the success or otherwise of the proposal following consideration of the project. AV will assess projects based on the following criteria:

- Alignment with AV's strategic priorities
- The potential benefits arising from the research
- Existence of research funding
- Credentials or technical competence of the researchers
- Risks and impacts to AV, including resourcing, time, or 'over-surveying' of the AV workforce
- Human Research Ethics Committee approval

In general, AV will not approve research proposals that:

- Involve interventions with substantial clinical risk
- Are likely to involve any delays in the provision of usual care
- Involve additional costs that are not fully funded
- Are not submitted in accordance with the advice and instruction to applicants
- Provide incomplete or misleading information
- Conflict with current research projects in operation
- Employ a research design that is unlikely to have translatable or actionable insights (e.g. limited surveys or focus groups)

In 2023, AV adopted a cost recovery model for external data requests which are supported by project funding. The cost recovery model aligns with the Victorian Department of Treasury and Finance 'Pricing for value – Pricing principles' and the DataVic Access Policy. See Section 9 below for additional details.

Because of resource limitations and a need to integrate research activities with normal business requirements, it is necessary to prioritise research requests. This can sometimes lead to delays in project approval and the provision of AV data during times of significant workload.

## 4. Collaborative funding submissions or expressions of interest for funding

Funding applications and Expressions of Interest that require AV participation and/or data require a letter of organisational support prior to submission to the funding body. Once funded, final project applications are required to be processed via the full AV research governance pathway using the Research Application form – FOR/STP/001.

## 5. Progress reports

Annual progress reports are required for approved projects. Researchers will be requested to submit a progress report every twelve (12) months using a Progress and Final Report form – FOR/STP/002. Reports are required to be submitted to AV electronically within four (4) weeks of request. AV approval is provided subject to timely completion of progress reports, and failure to provide updates may lead to project termination.

# Application form

## 6. Investigators

Please provide details of the Chief Investigator, Responsible Investigator and other investigators, including the AV co-investigator(s). Indicate the responsibilities of the researchers with respect to the project, and the experience of the research team.

## 7. Proposal Information

### 7.1 Relationship to other projects

Indicate whether the project is a new stand-alone project or related in some way to a previously approved project. A related project is one that is a follow-up or extension of previous work and will usually not have been flagged in the original application.

### 7.2 Type of Research Study

Indicate the category that best fits the application.

Note - Quality assurance projects submitted by external researchers must be classified as non-research by a recognised Human Research Ethics Committee.

Please indicate if the project is a student project (e.g. forms part or all of an Honours or PhD thesis) and the type of qualification currently being undertaken.

Indicate if the project is a feasibility study for a larger study (e.g. a retrospective case review of patients with respiratory distress to ascertain the potential sample size for a clinical trial). If the study is a feasibility study, provide brief details of the proposed larger study.

### 7.3 Description of the study (plain language summary)

Provide a plain language statement regarding the background and specific aims of the project.

### 7.4 Project Summary

Indicate participant / intervention information, as applicable to the project.

### 7.5 Data Collection, Study Design and Methodology

Provide details of proposed data collection methodology, including sample size, information / data required, how the information will be used, and consent processes (if applicable). Please refer to the AV VACIS variable list (available upon request) for projects requiring VACIS data. Only variables that are necessary to achieve the research aims should be requested.

Please fully justify the need to use paramedic time, particularly via administration of a survey. Researchers are requested to be cognisant of the fact that AV is frequently requested to participate in projects which involve surveying and interviewing paramedics. Projects involving surveys and/or interviews may be rejected in order to prevent “over-surveying” of the AV workforce. Please see Appendix B: Guidelines for Recruitment of Paramedics as Research Participants. The AV Research Committee has a commitment to assess each research project application on its merits. If your research project involves surveys, interviews or focus groups, please ensure that:

- Your survey instrument is of the highest quality
- You have experience in conducting effective focus groups and translating focus group data into meaningful research outcomes
- You have discussed your project with the Centre for Research and Evaluation to eliminate duplication of research, and explore alternative methods of data gathering that may provide an answer to your research question without requiring unnecessary paramedic surveys or focus groups.

**Note: AV will only provide identified/potentially re-identifiable data if it is essential to the research methodology. These projects must have appropriate Human Research Ethics Committee approval and may require completion of a Privacy Impact Assessment.**

### 7.6 Proposed Study Timing

State the expected project start and finish dates. In general, the duration of the project starts on the date of AV and/or Human Research Ethics Committee approval (whichever is latest) and ends on the date of completion of data analysis and the production of a final report.

## 8. Impact to Ambulance Victoria

### 8.1 Benefit to AV

Provide a description of how the research will directly benefit AV. Describe how the aims of the study relate to AV.

### 8.2 Presentation and publication of results

Describe the proposed method of publication of results (e.g. conference presentations, study summary for participants, peer reviewed journals, PhD thesis etc.). Describe how AV will be involved in the review of study results and proposed presentations and publications. Proposed publications should be sent to the AV co-investigator for review prior to submission to conference organisers or journal editors.

AV ideally require co-ownership of the results of the research. If any party publishes the results and outcomes, AV should receive appropriate recognition. AV will generally not approve projects where authorship is not offered to an AV co-investigator.

### 8.3 Ownership of Results

Describe the proposed ownership of study results, particularly in relation to AV. Projects which form part of a body of study (e.g. PhD) are still expected to involve an appropriate AV team member as a co-investigator.

### 8.4 AV Personnel

Indicate exactly what will be required of AV personnel (e.g. data extract, data linkage, paramedic time). Paramedic participation time should be clearly summarised in the table provided. Provide details of training requirements for AV personnel. This could include briefing of relevant AV personnel regarding study methodology.

AV requests that the AV co-investigator will be allowed to take an active role in the research project. It is expected that the AV co-investigator will be provided the opportunity to participate in the project in a manner which warrants co-authorship on study publications. Participation should align with the International Committee of Medical Journal Editors (ICMJE) guidelines (http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html).

## 9. Funding and cost recovery

Attach a detailed project budget with particular emphasis on costs directly related to AV. Include estimated costs associated with the entire project. For example, participant reimbursement, salaries, on-costs, administrative costs, consumables. If the research is funded, please disclose the source of funding.

In 2023, AV adopted a cost recovery model for external data requests which are supported by project funding. The cost recovery model aligns with the Victorian Department of Treasury and Finance 'Pricing for value – Pricing principles' and the DataVic Access Policy. Under the pricing principles, the cost of data extraction should not limit data access for those researchers with a lower ability to pay. As such, AV will charge a cost recovery fee of $93 per hour or $746 per day (plus GST) for external data requests, and this fee will only be payable by those researchers and research organisations that are able to demonstrate project funding. In general, AV will not seek to recover costs associated with student projects, unless the project has direct funding for data collection, data management or analysis. Project funding will not impact the priority or outcome of research governance reviews and approvals.

## 10. Ethical considerations

### 10.1 Ethics Committee details and ethical considerations

All required ethics clearances and approvals must be obtained from an officially approved / endorsed Human Research Ethics Committee. Provide details of the Human Research Ethics Committee(s) that have or will review the protocol. Please attach a copy of the ethics application and approval certificate from the relevant Committee.

Projects which have been amended after Human Research Ethics Committee approval will need to be re-submitted in order for the amended protocol to receive approval. Please ensure that there are no discrepancies between the protocol approved by the Human Research Ethics Committee and the protocol submitted to AV. This could cause significant delays in obtaining AV approval.

Describe the ethical considerations that are specific to AV, including the AV workforce and patients. Issues include privacy, confidentiality, data storage and transfer, consequences of participation and consent. Individuals considering new research proposals should be aware that prehospital research often raises specific ethical issues, in particular the issue relating to informed consent. Ethics committees rarely approve research projects undertaken without informed consent, except in a specific and limited range of circumstances.

Provide details of potential risks to participants and AV in relation to participation in the project. Give a likelihood estimate of risks and provide information on strategies, which will be employed to reduce the likelihood of potential risks.

Explain the monitoring, reporting and other procedures set up to manage serious adverse events and unforeseen events. Adverse events may relate to the participants or to unintended events in relation to information. Where applicable, an adverse event monitoring committee may need to be established. All adverse events must be reported in writing to AV.

### 10.2 Potential Conflict of Interest

Please disclose any affiliation or financial interest of the researchers in relation to the project. Specifically, researchers should indicate whether they have received any funds or gifts from pharmaceutical or device companies associated with the research and whether this information will be disclosed to participants.

## 11. Governance process

Projects submitted to AV will be processed via the AV Research Governance Procedure – PRO/STP/003. Depending on the nature of the project and data required, different levels of organisational endorsement requirements will be imposed. The AV Research Governance Manager will assess the likely risk of a project and determine the required endorsement.

# Appendix A: Project protocol

Attach a detailed project protocol. The following elements should be included in the proposal:

| | | |
|---|---|---|
| **1.** | **Literature review** | An analysis of previous literature and studies, including references. |
| **2.** | **Rationale for project** | Description of how your proposed research will compliment, enhance, or contribute to existing knowledge. Explain why this research is necessary given existing knowledge in this field. Note that replication of previous studies in the field is acceptable if, for example, the aim is to confirm or extend existing results, using more rigorous experimental criteria. |
| **3.** | **Primary hypothesis** | And/or research questions, if applicable. Some projects may not have specific hypotheses. |
| **4.** | **Aims** | All projects should have aims, including those that do not have a specific research question or hypothesis. |
| **5.** | **Methodology** | Scientific description of experimental procedures, surveys and questionnaires, recruitment strategies and other relevant information.<br>• Please provide sufficient detail to enable AV to determine the project's methodological rigour. Indicate any limitations of the project design and any potential sources of bias and how these will be dealt with.<br>• For questionnaires and data collection instruments that are not well-known, details of validation or other publications should be provided. |
| **6.** | **Inclusion/exclusion criteria** | Include details of criteria for inclusion and/or exclusion of participants or data.. |
| **7.** | **Randomisation procedures** | Where applicable. |
| **8.** | **Sample size / power calculation** | Where applicable. |
| **9.** | **Statistical or other analyses** | To ensure rigorous research design, seek professional advice from a clinical epidemiologist or biostatistician. |
| **10.** | **Project timeline** | Attach a Gantt chart describing the proposed project timeline and associated tasks and milestones. |

# Appendix B: Guidelines for recruitment of paramedics as research participants

There are many applications submitted annually to the AV Research Committee requesting to survey/conduct focus groups with the paramedic workforce for research purposes. The AV Research Committee has a responsibility to ensure all research is of high quality, aligns with organisational needs, and creates research that is of maximum benefit with minimal risks. Please consider the following carefully when submitting your research application.

## Survey fatigue

Research has shown that repeated surveying of a population can lead to 'survey fatigue'. This results in reduced response rates, poor quality survey responses and an aversion to participating in future research. Therefore it is important that the Research Committee carefully select survey-based projects to ensure paramedics remain optimally receptive to research participation. This also means that surveys that replicate previous studies or aspects of previous studies are unlikely to be approved. Similarly, focus groups that are poorly conducted or yield outcomes of minimal benefit are of concern to AV.

## Ethics

Does your recruitment of paramedics comply with the principle of Justice according to the National Statement on Ethical Conduct in Human Research?

- Is asking paramedics to complete this survey or participate in your focus group fair?
- Is it likely that paramedics will have to complete this activity in their own personal time?
- Are there any benefits to paramedics for participation in your research?
- Are you likely to obtain a high response rate or a biased sample? How will this impact the value of your research?
- Do you have training, skills, and experience in conducting focus groups?
- Is the survey of exceptionally high quality and has it been validated?
- Is your research protocol likely to yield unique, publishable results that will be of interest or benefit to AV and its paramedics?

## Organisational responsibility

As an organisation and an employer, AV has a responsibility to ensure that its workforce is protected from unnecessary stressors. A constant stream of unsolicited emails to a work-based personal email, internal mail survey packages, branch visits and other methods of recruitment do create pressure to participate, even when subtle.

- How do you plan to recruit your paramedic participants?
- What is the risk to their privacy?
- What is the chance of coercion when surveys are distributed via their employer?
- What is the impact on their levels of workplace stress?
- Does the quality and impact of your survey mitigate these risks via its extensive benefit to paramedics or the organisation?

# DOCUMENT CONTROL

| | |
|---|---|
| **Document name** | **AV RESEARCH APPLICATION** |
| **Applies to** | ☒ Operational ☐ Patient Transport ☐ ACOs<br>☒ Corporate ☐ ARV ☐ CERTs<br>☐ Auxiliaries ☐ Co-responders |
| **Document no.** | PRO/STP/001 **Stored:** Content Manager PRO/STP/001 |
| **Version** | 7.0 **Review:** ☐ Annual ☒ 3-Yearly |
| **Division** | Quality and Patient Experience |
| **Responsible Executive** | Executive Director Quality and Patient Experience |
| **Responsible Manager** | Research Governance Manager |
| **Key stakeholders: (including external)** | **Consulted:**<br>• Director Centre for Research and Evaluation<br>**To be informed:**<br>• None |
| **Review date** | By **23 November 2026** or in accordance with applicable legislative or regulatory changes. |
| **National Safety and Quality Health Service Standards** | **To be completed by the National Standards Accreditation Lead:**<br>☒ 1. Clinical governance ☐ 5. Comprehensive care<br>☒ 2. Partnering with consumers ☐ 6. Communicating for safety<br>☐ 3. Healthcare-associated infection ☐ 7. Blood management<br>☐ 4. Medication safety ☐ 8. Recognising and responding acute deterioration<br>☐ NSQHS standards are NOT applicable |
| **Material legislation** | The following legislation, regulations and/or standards are material to this document:<br>• Australian Code for the Responsible Conduct of Research<br>• Health Records Act 2001 (Vic)<br>• Privacy and Data Protection Act 2014 (Vic) |
| **Material associated documents** | The following documents are material to this procedure:<br>• **Parent policy:** Research Governance Procedure – PRO/STP/003<br>• Guidelines for AV co-investigators on research projects – PRO/STP/004<br>• Research Application form – FOR/STP/001<br>• Progress and Final Report form – FOR/STP/002 |

## Version control and change history

| Version | Date approved | Date superseded | Amendment |
|---|---|---|---|
| 5.0 | 17 January 2018 | 23 November 2023 | Minor updates to reflect updates to Research Application Form |
| 6.0 | 23 November 2023 | Current | Restructured document to align with Research Application Form.<br>Added information regarding Cost Recovery Model. |