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 AV participation in prehospital research projects. 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.

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 employee is included as a co-investigator for projects requiring significant use of AV data and/or staff. AV may choose to nominate an appropriate staff member if required. Also note that any clinical trials will be run through the AV Centre for Research and Evaluation with appropriate representation from Centre for Research and Evaluation staff.

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:

Director, Centre for Research & Evaluation
Phone: 9896 6083
Email researchevaluation@ambulance.vic.gov.au

All project applications will be reviewed and are subject to approval by the AV Director, Centre for Research and Evaluation and/or the AV Research Committee. Comments and opinions from external sources may also be considered.

AV will assess projects based on the following criteria:

- The benefits arising from the research and how the research fits with AV's strategic direction
- Operational impacts to AV
- Existence of funding for the research
- Credentials or technical competence of the researchers
- Risk to AV in relation to conducting the research
- Ethics Committees' approval

In general, AV will not usually approve research proposals that:

- Involve interventions with any substantial clinical risk
- Are likely to involve any delays in the provision of usual care
- Are likely to require significant increases in the training requirements or work-load of ambulance paramedics
- Require paramedics to consent emergency patients
- Involve additional costs that are not fully funded
- Are not submitted in accordance with the advice and instruction to applicants (see Section 2)

- Provide incomplete or misleading information
- Conflict with current research projects in operation

In some cases, it may be more appropriate for a staged approach to be proposed (e.g. a pilot/feasibility study prior to the commencement of a clinical trial).

AV will notify the applicant of the success or otherwise of the proposal following consideration of the project.

2. Responsibility

Role	Responsibility
Professional ethical standards	• Provide every patient with dignity and Best Care. • Assume responsibility, and accept accountability, for professional decisions. • Protect the privacy and confidentiality of personal and health information handled while performing functions. • Avoid any real or apparent conflicts of interest. • Report improper conduct.
Researchers	• Submit reports regularly using appropriate Report forms. • State the duration expected it will take to complete the project.

3. Advice and instructions to applicants

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 pages must be clearly numbered.

All details in the application, particularly concerning any successful applications, must be current at the time of application. 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. Include the completed checklist with your application.

Because of resource limitations and a need to integrate research activities with normal operational requirements, it is necessary to manage research activities. This will often lead to prioritisation of projects and may lead to rejection or delay of otherwise valuable proposals. This may also lead to delays in the provision of AV data. It is recommended that researchers allow approximately three months between submission of their research application and provision of any AV data. High risk applications may take up to six-months to process.

4. Funding submissions or expressions of interest for funding

Funding applications and Expressions of Interest (EOI) that require AV participation and/or data require sign-off by the AV Director, Centre for Research and Evaluation 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 status reports are required for approved projects. Researchers will be requested via e-mail to submit a report every twelve (12) months using a Progress and Final Report form. Reports are required to be submitted to AV electronically within four (4) weeks of request.

Application form

6. 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. 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 (HREC).

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 RCT of pre-hospital non-invasive ventilation). If the study is a feasibility study, provide brief details of the proposed larger study.

8. Benefit to AV

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

9. Plain language summary

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

10. Project Summary

Indicate participant / intervention information as applicable to the project.

11. Data Collection, Study Design and Methodology

Provide details of proposed data collection methodology. Please refer to the AV VACIS variable list for projects requiring VACIS data. Researchers should be aware that extraction of AV data can be highly complex and time consuming. Only variables that are necessary should be requested. Data extraction may take up to six weeks following final approval of a project.

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 paramedics. Projects involving surveys and/or interviews may be rejected in order to prevent “over-surveying” of AV staff. Please see Appendix B: Guidelines for Recruitment of Paramedics as Research Participants.

Provide a brief description of key aspects of the project and details of the methodology, including:

- Method of collection
- Sample size
- Information required
- Use of information
- Consent process (if applicable)

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

12. Proposed Study Timing

State the number of months you expect it will take to complete this project. In general, the duration of the project starts on the date of AV and/or HREC approval (whichever is latest) and ends on the date of completion of data analysis and the production of a final report. State the expected project start and finish dates.

13. AV Personnel

Indicate exactly what will be required of AV personnel. 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 staff regarding study methodology.

AV requests that an AV staff member be included as a co-investigator for most projects. In general, the Director Centre for Research and Evaluation, or the relevant Executive Director, will nominate the most appropriate AV employee to act as a co-investigator. The co-investigator will take an active role in the research project to ensure that research is conducted in accordance with AV Research Governance Framework. It is recommended that researchers contact the Centre for Research and Evaluation prior to final submission of their application form to finalise an AV co-investigator. It is expected that the AV co-investigator will be provided the opportunity to participate in the project is 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).

14. Budget / Funding

Attach a detailed budget with particular emphasis on costs directly related to AV. Include estimated costs associated with the entire project. For example, participant reimbursement, salaries (if requiring staff during work hours), on-costs, administrative costs, consumables.

Please disclose the source of funding including internal funding (where applicable). There should be sufficient funding to conduct and complete the project. If a shortfall in funding is anticipated, explain how this will be dealt with.

15. Ethical considerations

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

Projects which have been amended after HREC approval will need to be re-submitted in order for the amended protocol to receive HREC approval. Please ensure that there are no discrepancies between the protocol approved by the HREC(s) 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 AV staff and patients. Issues include privacy, confidentiality, 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.

16. Ownership of Results

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

17. Presentation and Review 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.

18. Research Experience

Provide a description of the researchers' experience conducing similar projects. Please attach recent curriculum vitae for the Chief Investigator and the Responsible Investigator.

19. Potential Conflict of Interest

Please disclose to AV 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.

20. Governance process

Projects submitted to AV will be processed via the AV Research Governance Process. Depending on the nature of the project and data required, different levels of organisational endorsement requirements will be imposed. The Director, Centre for Research and Evaluation will assess the likely risk of a project and determine the required endorsement.

Summary

It is highly recommended that prior to formulating and submitting a research proposal, researchers contact AV to discuss the proposed protocol.

The AV Research Committee has a commitment to assess each research project application on its merits. If your research project involves surveys and focus groups, please ensure that:

- Your research application form has addressed these concerns
- Your survey instrument is of the highest quality, and evidence of this has been provided in your application
- 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 staff 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 survey or focus groups.

Appendix A: Project proposal

Attach a detailed project proposal. 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 complement, 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. • 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. • 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. Note that exclusion criteria should not be given as "anyone who does not meet the inclusion criteria"; only independent criteria for exclusion should be given.
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 (e.g. by novice researchers with no training) 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 ☒ Corporate ☐ ARV ☐ CERTs ☐ Auxiliaries ☐ Co-responders
Document no.	PRO/STP/001 **Stored:** CM: PRO/STP/001
Version	6.0 **Review:** ☐ Annual ☒ 3-Yearly
Division	Medical Directorate
Responsible Executive	Medical Director
Responsible Manager	Research Governance Manager
Key stakeholders: (including external)	**Consulted:** • Director Centre for Research and Evaluation **To be informed:** • None
Review date	By **27 September 2024** 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:** ☐ 1. Clinical governance ☐ 5. Comprehensive care ☐ 2. Partnering with consumers ☐ 6. Communicating for safety ☐ 3. Healthcare-associated infection ☐ 7. Blood management ☐ 4. Medication safety ☐ 8. Recognising and responding acute deterioration ☐ NSQHS standards are NOT applicable
Material legislation	The following legislation, regulations and/or standards are material to this document: • Australian Code for the Responsible Conduct of Research • Health Records Act 2001 (Vic) • Privacy and Data Protection Act 2014 (Vic)
Material associated documents	The following documents are material to this procedure: • **Parent policy:** Guidelines for AV co-investigators on research projects – FRA/STP/002 • Research Application form – FOR/STP/001

Version control and change history

Version	Date approved	Date superseded	Amendment
5.0	17 January 2018	27 September 2021	Minor updates to reflect updates to Research Application Form
6.0	27 September 2021	Current	