Department of Health

Queensland Ambulance Service

Information Support, Research and Evaluation

Queensland Ambulance Service

Research Application Guidelines

Applicable to: External parties and all of QAS

Last updated: August 2023

433QAS

Queensland Government

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Purpose

The Queensland Ambulance Service (QAS) 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.

The Research Application Guidelines (Guidelines) are designed to help you provide the information that is used by QAS to prioritise QAS participation in pre-hospital research projects. The purpose of these guidelines is to set out the criteria by which QAS assesses proposals to conduct research by QAS staff or external parties in conjunction with QAS.

Legal Framework

Under section 22 and 50P of the *Ambulance Service Act 1991*, the Commissioner, QAS as a delegate of the Director General, Department of Health, Queensland, may authorise the disclosure of confidential information if satisfied, on reasonable grounds, that the disclosure is:

- in the public interest; or
- necessary to assist in averting a serious risk to the life, health or safety of any person, including the person to whom the confidential information relates to; or
- made for the purpose of research which has the approval of an appropriate ethics committee.

Application and Evaluation Process

All applications for access to data held by QAS (QAS data) or access to QAS staff for the purposes of research must be submitted to the QAS Information Support, Research and Evaluation (ISRE) Unit for consideration (see 'How to apply' on page 5). The ISRE Unit will assess the alignment of the proposed research to QAS priorities, and the feasibility and risk level of the project. Projects that are deemed to be in the public interest and have appropriate merit will be considered for approval by the Commissioner, QAS. Consideration will be given to:

- The benefits arising from the research and how the research fits with QAS's strategic direction;
- Project methodology;
- Risk (operational, clinical, privacy, reputational);
- Operational impacts to QAS;
- Project funding;
- Ethics approvals;
- QAS co-investigator(s);
- Resource allocation and endorsement;
- Track record of investigators (credentials or technical competence).

QAS 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;
- 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;
- Fail to submit the application in accordance with the advice and instruction to applicants;
- Provide incomplete or misleading information;
- Are in 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).

Due to 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.

QAS encourages collaborative research projects, and it is expected that at least one approved QAS staff member be included as a co-investigator for projects requiring significant use of QAS data and/or QAS staff. QAS may choose to nominate an appropriate staff member if required.

Depending on the nature of the project and data required, different levels of organisational endorsement requirements will be imposed (refer Appendix A - Delegation Matrix for more information). Comments and opinions from external sources may also be considered.

How to apply

- It is highly recommended that prior to formulating and submitting a research application, researchers contact the ISRE Unit to discuss the proposed protocol. This will help reduce delays in the application process, which can be caused by incomplete or inappropriate applications (in particular, regarding the use of paramedic time).
- Researchers **must consult** with QAS (as the data custodian) *prior* to applying for ethics approval to ensure that relevant data items are available and that there are adequate local resources available to be able to provide the information requested.
- The QAS Application for Research form can be obtained from ISRE or found on the QAS website https://ambulance.qld.gov.au/research.html.
- In addition to the form, applicants also need to provide an introduction letter addressed to the Commissioner, QAS and other supporting documentation as outlined below.
- Applications are to be emailed to the ISRE Unit: QAS.Research@ambulance.qld.gov.au.
- Your **Application for Research** pack should include:

QAS RESEARCH APPLICATION PACK CHECKLIST	
☐	**Introduction letter** (1-2 page maximum) Letter should be addressed to the Commissioner, QAS outlining exactly what you are requesting, e.g., data, or surveying / interviewing QAS staff; the background and purpose of your study; brief methodology; and any ethical approvals associated with the study.
☐	**Application for Research** form (including completed variable list, if applicable) Must contain all the information necessary for consideration of the project without the need for further written or verbal explanation, or reference to additional documentation. Please define all terminology and abbreviations. All details in the application, particularly concerning any successful applications, must be current at the time of application.
☐	**Research Protocol** (if applicable)
☐	**Copy of ethics application** (if applicable)
☐	**Copy of ethics approval certificate** (if applicable)
☐	**Copies of surveys/questionnaires/focus group questions** (if applicable)
☐	**Participant Information Sheet/consent forms etc.** (if applicable)
☐	**Draft recruitment email for surveys / communication to be distributed to QAS staff** (if applicable)

Advice and Instructions to Applicants

- Your application should consider the following guidelines.
- These align directly with the **Application for Research** form which can be found on the QAS website https://ambulance.qld.gov.au/research.html.
- Refer to **Page 5 and onwards** of Application for Research form.

Project Title

Please fill in your full project title.

Contact Details

Please complete the contact details for the Principal Investigator and the project contact (if different from Principal Investigator). Please also list names of ALL members of the project team.

Type of Research

Please indicate whether the project is:

- a new stand-alone project, a sub-component of a previously approved project, or related in some way to a previously approved project.
- a student project (e.g. forms part or all of an honours or PhD thesis) and the type of qualification currently being undertaken.
- a feasibility study for a larger study (e.g. a retrospective case review of patients with respiratory distress to ascertain the potential sample size and need for a RCT of pre-hospital non-invasive ventilation). If the study is a feasibility study, provide brief details of the proposed larger study.

Please also list any other sites or agencies involved or that may be involved in the research.

Study Outline: Background, Aims, Design and Methodology

You will need to provide a description of the project which must be easily understood by QAS staff with no clinical background. Provide a brief description of key aspects of the project including major phases of the research. You should also identify and summarise key issues that the project raises. Your application may include a literature review (an analysis of previous literature and studies, including references).

Outline your primary hypothesis and/or research questions – if applicable. Some projects may not have specific hypotheses. All projects should have aims, including those that do not have a specific research question or hypothesis.

To ensure rigorous research design, seek professional advice from a clinical epidemiologist or bio-statistician for statistical analyses. Provide details of proposed data collection methodology, including scientific description of experimental procedures, surveys and questionnaires, recruitment strategies and other relevant information. Provide details of data collection including: method of collection; sample size; and consent process (if applicable).

Note: QAS will only provide Identified Data if it is essential to the research methodology and if appropriate Human Research Ethics Committee (HREC) approval is granted (see Ethical Considerations on below for more information).

A Note on Surveys

Please justify in detail the need to use paramedic time, in particular, via the administration of a survey. Researchers are requested to be cognisant of the fact that QAS 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 QAS staff. Please refer to Appendix B for more information. **Please provide a copy of your survey / questionnaire as part of your application.**

Proposed Study Timing

State the expected project start and finish dates. In general, the project starts on the date QAS and/or HREC provides approval (whichever is latest) and ends on the date of completion of data analysis and the production of a final report.

Ethical Considerations

Describe the ethical considerations that are specific to QAS including QAS 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.

All required ethics clearances and approvals must be obtained through a National Health and Medical Research Council (NHMRC) Human Research Ethics Committee (HREC), as QAS does not have an ethics committee.

If researchers require information that is **identifiable data or potentially re-identifiable data** (see table below for definitions), then ethics approval will need to be granted by a NHMRC *certified* HREC (please note the difference between registered and certified ethics committees). This includes all projects that involve **linked** data.

The ethics application and approval must specifically reference the use of QAS data / staff. Please ensure that there are **no discrepancies between the protocol approved by the HREC(s) and the protocol submitted to QAS.** It is crucial that there is coverage in the ethics application that **specifically lists QAS as a data custodian, or other involvement by QAS.** Discrepancies could cause significant delays in obtaining QAS approval.

Please attach a copy of the ethics application and approval certificate from the relevant ethics committee.
QAS will not provide final approval for a project until the HREC approval certificate plus the approved application is received. Projects which have been amended after HREC approval will need to be re-submitted in order for the amended protocol to receive approval.

Definitions

Confidential information:	means information, whether recorded in a material form or not, that is capable of identifying a person as someone who is receiving, or has received, an ambulance service including any identifiable data and/or re-identifiable data.
Identifiable data:	means data, whether recorded in a material form or not, that will enable the identity of a person to be established.
Unidentifiable data:	means data, whether recorded in a material from or not, that **do not contain** any identifiers such as **names, street and postal address** of a person.
Re-identifiable data:	means when Unidentifiable Data is ascertained and used in various combinations, it may reveal sufficient details and characteristics of a person to the extent it will enable the identification of a person to be made.

An example of potentially re-identifiable data would be data that holds date of birth and an area code – in an area consisting of 200 – 300 residents. Researchers should consider the following factors when determining whether their research involves potentially re-identifiable data:

- Presence of rare characteristics in a statistical local area (SLA);
- Accuracy of the data;
- Age of the data;
- Coverage of the data (completeness);
- Presence of other information that can assist in identification, including:
    - publicly available information;
    - restricted access data holdings that a data user may have access to; and
    - personal knowledge that a user may have.

Rationale for Using Identifiable Confidential Information

Your application should include a rationale for the project, particularly if using Confidential Information. This is a 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.

Benefit to the Community

Your application should provide a brief description of how the research will directly benefit the community. Also outline how the benefits to the public outweigh the risks for the individuals whose Confidential Information and Identifiable Data and/or Re-Identifiable Data will be used.

QAS Involvement

Benefit to QAS

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

Innovation & Research Translation

Provide a description of how the research is innovative or unique, and how it is proposed to translate the findings into practice.

QAS Personnel

Indicate exactly what will be required of QAS staff. Paramedic participation time should be clearly outlined in the application. Please refer to Appendix B for more guidelines on recruitment of paramedics as research participants.

QAS Co-investigator

QAS requests that a QAS staff member be included as a co-investigator for most projects. The Director, ISRE Unit, or the relevant executive can nominate the most appropriate QAS 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 these guidelines. It is recommended that researchers contact the ISRE Unit prior to final submission of their application form to finalise a QAS co-investigator.

Ownership of Results / Authorship

Describe the proposed ownership of study results in particular in relation to QAS. Describe what will be offered to QAS in terms of authorship for publications resulting from the study. QAS ideally would require co-ownership of the results of the research and the ability to publish the results and present the outcome. Further, if any party publishes the results and outcomes, QAS should receive appropriate recognition. QAS will not generally approve projects where authorship is not offered to a QAS co-investigator. Projects which form part of a body of study (e.g. PhD) are still expected to involve an appropriate QAS staff member as a co-investigator.

Budget / Funding

Your application should outline provision for cost recovery associated with QAS supporting your research (where applicable).

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.

Funding applications and Expressions of Interest (EOI) that require QAS participation and/or data, require sign-off by the Director, ISRE Unit, prior to submission to the funding body. Once funded, final project applications are required to be processed via the full QAS research governance process.

Risk Analysis

Provide details of potential risks to participants and QAS in relation to involvement 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.

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.).

Also, outline how QAS will be involved in the review of study results and proposed presentations and publications. All reports, manuscripts and presentations **must be provided to QAS** prior to being made available in the public domain, with sufficient time to allow provision of feedback, and for the feedback to be incorporated. This includes conference abstract submissions, peer-reviewed journal publication submissions, presentations to symposiums, etc. QAS must be provided with advanced notice of media releases and/or aspects that may receive media attention in relation to research that includes reference to QAS or QAS data.

Potential Conflict of Interest

Please disclose to QAS 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.

Project Data

Please refer to, and complete, the QAS Variable List for projects requiring data (this can be found as Appendix 1 in the Application for Research form). Applications should clearly justify the reason each variable is required. Researchers should be aware that extraction of QAS data can be highly complex and time consuming. Only variables that are absolutely necessary should be requested.

Security Plan

Researchers will need to describe a security plan for the protection of the information provided by QAS. The Security Plan should specify the measures that will be taken to protect the information from misuse, loss or unauthorised access during the research project.

Retention and Disposal Plan

Researchers will need to outline their proposal for the retention and disposal of QAS data. Researchers should specify the period of retention of the data after the completion of the project, and the measures to be taken to secure the information during that retention period. The plan should also specify the date by which the information will be returned to QAS or destroyed by the researchers.

Progress Reports

Annual status reports are required for approved projects to notify QAS of progress, changes and milestones. Researchers will be required to submit an electronic report **every 12 months, or more frequently for projects of shorter duration,** following receipt of QAS data. A final report will be submitted on completion of the project. The QAS Research Project Status Report template can be found on our website https://ambulance.qld.gov.au/research.html.

Failure to submit reports can result in QAS approval for the project being withdrawn. Projects are approved for a period of 12 months initially, subject to receipt of a satisfactory annual report after one year. If the project is to continue beyond the initial approval period, a re-application or written request for an extension of time will be necessary.

APPENDIX A: Delegation Matrix

Data / Research Type	Approval
Low risk projects, such as: - Unidentified data available from existing sources (e.g. dARF, CAD etc.) - Identified Data for internal research projects - Expressions of interest for funding[1] - Draft publications (e.g. research articles, oral presentations, abstract submissions)[2] - QAS in-kind support, through ISRE, but no QAS data or paramedic input - Minor modifications to previously approved projects, where modification does not affect risk level.	Director, ISRE
Surveys / focus groups involving QAS staff Projects assessed at potential medium risk, such as: - Observational studies requiring Identified Data, such as data linkage studies - Proposals requiring Identified Data from the original source - Patient participation Projects assessed as high risk, for example: - Proposals involving a change in clinical or operational practice - Any request seeking the release of 'confidential information' (see page 5 for definitions)	Commissioner, QAS

1. Expressions of interest can be approved by the Director, ISRE and relevant Senior Executive, with the proviso that the final project (if funded) be subject to Commissioner endorsement.
2. Draft publications can be approved by the Director, ISRE and relevant Senior Executive, with the proviso that the final publication (if accepted) be subject to Commissioner endorsement.

APPENDIX B: QAS guidelines for recruitment of paramedics as research participants

There are many applications submitted annually to QAS requesting to survey/conduct focus groups with the paramedic workforce for research purposes. QAS 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 protocol, and particularly your draft paramedic survey/focus group plan, to QAS for approval.

Survey fatigue
Research has shown that repeated survey 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 ISRE Unit 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 QAS.

Ethics
Does your recruitment of paramedics comply with the principle of Justice according to the *National Statement on Ethical Conduct in Human Research (2007)?*

> *"Section 1.4: Justice - In research that is just: … (c) there is no unfair burden of participation in research on particular groups; …and (f) there is fair access to the benefits of 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 QAS and its paramedics?

Organisational responsibility
As an organisation and an employer, QAS 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?

Summary
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; and
- You have discussed your project with staff from the ISRE Unit 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.