National Ambulance Service

Research Committee Terms of Reference

January 2015

1. Purpose

- Ensure that research projects are appropriate to National Ambulance Service (NAS)
- Ensure appropriate research governance procedures are applied to research projects
- Evaluate the risk associated with the research proposals for the organisation
- Promote and support high quality/relevant research within NAS and the wider health sector
- Ensure compliance with research agreement documents.
- Ensure NAS access to study data in advance of publication particularly that affecting clinical or operational management of the service.
- NAS research committee to approve all publications involving NAS staff or data in advance of submission for publication
- Ensure NAS representation as co-investigator on all NAS associated projects
- Ensure NAS acknowledgement in publications/presentations of NAS associated research

2. Responsibility of the Committee

- Assess proposed research proposals (internal and external).
- Monitor progress of research projects.
- Ensure that all research projects adhere to NAS procedures and guidelines.
- Influence the future direction of NAS research projects / topics through the identification and promotion of NAS priority areas.
- Manage research misconduct claims and the remedial action for supported claims.

3. Membership

1. A/Prof Conor Deasy (Chair), Deputy Medical Director, National Ambulance Service (NAS)
2. David Hennelly, National Clinical Development Manager, NAS
3. David Willis, Quality, Safety and Risk Manager, NAS
4. Ciaran McCullagh, Irish Ambulance Representative Council (IARC)
5. Shane Knox, Assistant Chief Ambulance Officer, National Ambulance Service College (NASC)
6. Anthony Byrne, Educational Competency Assurance Officer National Ambulance Service
7. Siobhan Masterson, Out-of-Hospital Cardiac Arrest Register
8. Orla Curtis and Emily Mahon, Administrative and Business Support, NAS

National Ambulance Service

Research Committee

Guideline for Applicants

January 2015

1. Purpose

This guideline is designed to help you provide the information that is used by NAS to prioritise NAS participation in pre-hospital research projects**.**

The purpose of this guideline is to set out the criteria by which NAS assesses proposals to conduct research by NAS staff or external parties in conjunction with NAS. Individuals considering the development of research proposals are requested to first liaise with a member of the NAS Research Committee who, if appropriate, will support them in completing the Research Application Form which is available upon request from NAS.Research@hse.ie.

NAS 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.

NAS encourages collaborative research projects. It is expected that at least one approved NAS employee is included as a co-investigator for projects requiring significant use of NAS data and/or staff. NAS may choose to nominate an appropriate staff member if required to support the project.

It is highly recommended that prior to formulating and submitting a research proposal, researchers contact NAS to discuss the proposed protocol. This will help to reduce delays in the application process, which can be caused by incomplete or inappropriate applications (in particular regarding the use of staff time/resources). Please contact: **Chair Research Committee A/Prof Conor Deasy, Consultant in Emergency Medicine, Deputy Medical Director of NAS** Email: conor.deasy@hse.ie **Or** NAS.Research@hse.ie

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.

All project applications will be reviewed and subject to approval by the NAS Research Committee. Comments and opinions from external sources may also be considered.

NAS will assess projects based on the following criteria:

1. The benefits and knowledge arising from the research.
2. How the research fits with NAS strategic direction.
3. Operational impacts to NAS
4. Existence of funding/potential funding for the research
5. Credentials or technical competence of the researchers
6. Risk to NAS in relation to conducting the research
7. Ethics Committees' approval (if applicable)

In general, NAS 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 or are likely to require significant increases in the training requirements or work-load of ambulance personnel
- 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).

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

2. Advice and Instructions to Applicants

The research application form and guidelines are modified and updated on occasion. Please ensure you contact NAS.Research@hse.ie prior to making a new application to ensure that you are using the latest version of the form.

The research application form is the prime source of information available to the NAS 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 and 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 assists you in ensuring that all relevant documents are included in your application. Applicants must include the completed checklist with your application.

3. Funding Submissions or Expressions of Interest for Funding

Funding applications and expressions of interest (EOI) that require NAS participation and/or data, require sign-off by the Research Committee prior to submission to the funding body. Once funded, final project applications are required to be processed via the full NAS research governance pathway using the NAS research proposal format.

4. Progress Reports

Annual status reports are required for approved projects. Researchers will be requested via e-mail to submit a report every 12 months using a Progress and Final Report Form. Reports are required to be submitted to NAS electronically within 4 weeks of request.

5. Research Application Form

The research application form comprises of twenty-five headings that must be completed in full. Below is an overview of the information required when completing your application.

1) Full Project Title

Give the full technical or scientific project title

2) Relationship To Other Projects

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 project that is sub-component of another project will usually have been flagged in the original application. 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.

3) Type of Research Study

Indicate the category that best fits the application. Please indicate if the project is a student project (e.g. forms part or all of an Honours, Masters 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 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.

4) Purpose of Research Study

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

5) Research Objectives

Clearly specify all the research objectives.

6) Benefit to NAS

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

7) Study Description

The description of the project must be easily understood by NAS staff. Provide a brief description of key aspects of the project including major phases. You should also identify and summarise key issues that the project raises. The study description should be no more than one page in length.

8) 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 NAS and/or ethics 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.

Note: A project time-line with associated milestones must be submitted as part of the detailed project proposal.

9) Project Summary

Indicate participant/intervention information as applicable to the project.

10) Data Collection Methodology

Provide details of proposed data collection methodology. Applications should clearly justify the reason each variable is required. Researchers should be aware that extraction of NAS data can be highly complex and time consuming. Only variables that are absolutely necessary should be requested. Data extraction may take some time following final approval of a project.

Please fully justify the need to use NAS staff time, in particular via the administration of a survey. Researchers are requested to be cognisant of the fact that NAS 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 NAS staff.

11) Data Collection Details

Provide details of data collection including:

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

Note: NAS will only provide identified data if it is essential to the research methodology and if appropriate ethics approval is granted.

12) NAS Personnel

Indicate exactly what will be required of NAS personnel. Paramedic participation time should be clearly summarised in the table provided. NAS requests that an NAS staff member be included as a co-investigator for most projects. In general, the Research Committee can nominate the most appropriate NAS 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 NAS Research Governance Framework.

13) Training

Provide details of training requirements for NAS personnel that would be required for the study. This could include briefing of relevant NAS staff regarding study methodology. Training may be required for any aspect of the project, for example, to use a piece of equipment, to fill out data collection forms or to randomise patients etc.

14) Project Proposal

Attach a detailed project proposal. Complete the checklist to indicate where specific information may be found in the protocol. If a particular element is not included because it is not applicable to the project, tick the "not applicable" box for that element.

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, including scientific description of experimental procedures, surveys and questionnaires, recruitment strategies and other relevant information. Please provide sufficient detail to enable NAS 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, if any. 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 (when applicable).
8. Sample size/ power calculation (when applicable).
9. Statistical or other analyses. To ensure rigorous research design, seek professional advice from a clinical epidemiologist or bio-statistician.
10. Project time line. Attach a Gantt chart describing the proposed project time line and associated tasks and milestones.

15) Financial Costs

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

16) Source of Funding

Please disclose the source of funding including internal funding where applicable.
Note: 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.

17) Ethics Committee

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

NAS will not provide final approval for a project until the Ethics Committee(s) approval certification is received. Projects which have been amended after Ethics Committee(s)

approval will need to be re-submitted in order for the amended protocol to receive Ethics Committee(s) approval.

Please ensure that there are no discrepancies between the protocol approved by the HREC(s) and the protocol submitted to NAS. This could cause significant delays in obtaining approval.

18) Risk Analysis

Provide details of potential risks to participants and NAS 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.

19) Adverse or Unforeseen Events

Explain the monitoring, reporting and other procedures set up to manage serious adverse events and unforeseen events. Adverse events include all adverse events that are related to or possibly related to the project. Adverse events may relate to the participants or to unintended events in relation to information. Where applicable (in particular for interventional projects) an adverse event monitoring committee will need to be established. All adverse events must be reported in writing to NAS.

20) Ownership of Results

Describe the proposed ownership of study results in particular in relation to NAS. *Note: it is a requirement of most projects to have an NAS 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 NAS staff member as a co-investigator.*

21) Review of Results

Describe how NAS will be involved in the review of study results and proposed presentations and publications. Proposed publications should be sent to the NAS co-investigator for review prior to submission to conference organisers or journal editors.

22) Method of presentation of results

Describe the proposed method of publication of results (e.g. conference presentations, study summary for participants, peer reviewed journals, PhD thesis etc).

23) Authorship

Describe what will be offered to NAS in terms of authorship for publications resulting from the study. NAS 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, NAS should receive appropriate recognition. NAS will generally not approve projects where authorship is not offered to an NAS co-investigator.

24) Research Experience

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

25) Potential Conflict of Interest

Please disclose to NAS 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.

6. Governance Process

The Research Committee will assess the likely risk of a project. Consideration will be given to the following:

- Project funding
- Ethics approvals
- NAS co-investigator(s)
- Resource allocation and endorsement
- Track record of investigators
- Project methodology
- Risk (operational, clinical, privacy, reputation)

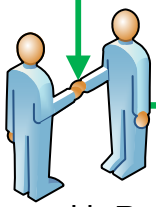
7. Summary

It is highly recommended that prior to formulating and submitting a research proposal, researchers contact the Research Committee to discuss the proposed protocol. Please contact: conor.deasy@hse.ie or NAS.Research@hse.ie

National Ambulance Service Research Committee Application Process

Applicant considers research topic and reviews research policy

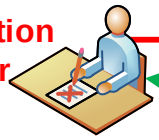
- Discuss with Supervisor / Collaborator / Third Level Institution ☑
- Perform Literature Review ☑
- Draft provisional / outline study protocol ☑
- Discuss with Research Committee representative ☑



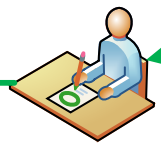
Initial contact with Research Committee (A/Prof. Conor Deasy), conor.deasy@hse.ie to discuss possible topic and consider research direction

Applicant will complete the Research Application Form and forward to Research.NAS@hse.ie

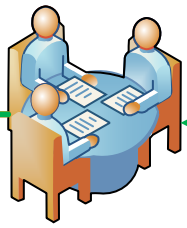
Incomplete application form returned for amendments



Initial submission will be checked in line with the standards and guidelines prior to NAS Research Committee receiving application



Submitted to Research Committee



Research Committee will review application

Rejected

Approved with conditions

Approved

Applicant is informed of Committees decision

National Ambulance Service Research Application Form

Date	Click here to enter a date.
Full Title	Click here to enter text.
Brief Title	Click here to enter text.
Version	Click here to enter text.
Submitted By	Click here to enter text.

Date Received	Click here to enter a date.
Date Reviewed	Click here to enter a date.

Please complete the Research Application Form and forward by either email or by post to:

NAS Research Committee
Address: Ambulance HQ, Midland Regional Hospital Tullamore, Co. Offaly
Tel: 057-9358167

Email: NAS.Research@hse.ie

Applications will be acknowledged within 5 working days. If acknowledgement is not received within this timeframe, contact 057-9358167.

Researcher/Investigator Name:
Click here to enter text.
Title/Grade/Position:
Click here to enter text.
Academic Institution/Company:
Click here to enter text.
Address:
Click here to enter text.
Mobile:
Click here to enter text.
Email:
Click here to enter text.
Fax:
Click here to enter text.

PROPOSAL INFORMATION

1. Full Project Title:

2. Relationship to other projects

Indicate whether the project is:

☐ A new stand-alone project
☐ A sub-component of a previously approved project
☐ Related to other previously approved projects (e.g. a follow-up study)

If the project is a sub-component of, or in any way related to, a previously approved project, provide details here:

3. Type of research study

☐ Randomised controlled trial
☐ Clinical trial
☐ Prospective cohort (or case review)
☐ Retrospective cohort (or case review)
☐ Case control study
☐ Case cross over study
☐ Cross sectional study
☐ Other (specify)_ Click here to enter text.

Is the project considered to be quality assurance?

☐ Yes ☐ No

Is the project a student project?

☐ Yes ☐ No

If *Yes*, indicate the qualification:

☐ Undergraduate degree
☐ Honours degree
☐ Masters degree
☐ PhD
☐ Other (specify)_ Click here to enter text.

Is the project a feasibility study for a larger project?

☐ Yes ☐ No

If *Yes*, please provide a brief description of the larger intended study

Click here to enter text.

4. Purpose of the research study

Click here to enter text.

5. Research Objectives

Click here to enter text.

6. Provide a description of how the research may be of benefit to the NAS

Click here to enter text.

7. Outline description of the study

Click here to enter text.

8. Outline of proposed study time frame

a. Duration (months):

Click here to enter text.

b. Anticipated commencement date:

Click here to enter a date.

c. Anticipated completion date:

Click here to enter a date.

9. Project summary

Does the project involve:

- ☐ Participants
- ☐ Paramedics/APs/EMTs
- ☐ Patients
- ☐ Other staff
- ☐ Collection, use or disclosure of NAS data
- ☐ Drug or device trial

10. Data collection

Does the data collection for the project involve:

☐ Survey(s)
☐ Retrieval of Patient Care Records
☐ Interviews / focus groups
☐ Additional collection of study specific data (e.g. a study form to be completed by paramedics and / or patients)
☐ Other data collection methods (specify)_ Click here to enter text.

11. Provide details of data collection. How many records will be collected and/or participants will be involved? Specify the information that will be collected, used or disclosed.

Click here to enter text.

12. Provide a detailed statement of what would be required of NAS personnel.

Click here to enter text.

13. Detailed Project Proposal

Every application must be accompanied by a detailed proposal. Attachments should include brochures / pamphlets, questionnaires or surveys and any other relevant documents. Ensure that all attachments are page numbered throughout. Please consult the guidelines regarding the type of information that should be included in the detailed proposal.

Project checklist

Major proposal components	Page and / or section number in the proposal	Not applicable
Literature review	Click here to enter text.	☐
Rationale for project	Click here to enter text.	☐
Hypothesis research questions	Click here to enter text.	☐
Aims	Click here to enter text.	☐
Methodology	Click here to enter text.	☐
Inclusion / exclusion criteria	Click here to enter text.	☐
Randomisation procedures	Click here to enter text.	☐
Sample size / power calculation	Click here to enter text.	☐
Statistical or other analyses	Click here to enter text.	☐
Project timeline (Gantt chart)	Click here to enter text.	☐

14. Analysis of likely financial costs for project

Attach a project budget to this application, which provides NAS specific information.

15. Source of study funding

How will this study be funded? List all sources of funds (e.g. grants, commercial sponsorship, organisational / departmental funds)

Source	Amount (€)	Status of funds	
		Application pending	Funds available
Click here to enter text.	Click here to enter text.	☐	☐
Click here to enter text.	Click here to enter text.	☐	☐
Click here to enter text.	Click here to enter text.	☐	☐
Click here to enter text.	Click here to enter text.	☐	☐

16. Do the funds presently available or applied for cover all requirements to conduct the project?

☐ Yes ☐ No

If No, explain how the shortfall will be met or dealt with

Click here to enter text.

17. Describe the ethical considerations specific to NAS

Click here to enter text.

18. Provide details of the Ethics Committee(s) that have or will review the protocol (Please attach a copy of the study ethics approval certificate from the relevant HREC(s))

Click here to enter text.

19. Provide a risk analysis of potential risks and how these would be mitigated

Click here to enter text.

20. Adverse or unforseen events

What procedures are in place to manage, monitor and report adverse and unforseen events?

Click here to enter text.

21. Describe the proposed ownership of the study results

Click here to enter text.

22. Describe how NAS will be involved in the review of study results and proposed presentations and/or publications

Click here to enter text.

23. Describe the method(s) of presentation of study findings and the proposed method of publication of study results

Click here to enter text.

24. Please state what will be offered to the NAS in terms of authorship and recognition in proposed presentations and/or publications

Click here to enter text.

25. Potential conflict of interest

Do any researchers have any financial interests in this research or its outcomes, or any relevant affiliations?

☐ Yes ☐ No

Click here to enter text.

If *Yes,* give details

Application Checklist

Please satisfy each of the following before submitting the application. Failure to do so will delay review of the application. Include a copy of this checklist (completed and signed) with the application.

Project Title

Click here to enter text.

Have you answered all the relevant questions in the application?	☐
Have you attached a detailed project proposal?	☐
Have you included all questionnaires or surveys to be used?	☐
Have you calculated the paramedic/NAS time required?	☐
Have you included a detailed project budget?	☐
Have you declared all potential conflicts of interest?	☐
Are all pages (including attachments) numbered in the footer?	☐

Name of Researcher/Investigator Click here to enter text.

Signature:_____

Date: Click here to enter a date.