

Screening Programmes

Abdominal Aortic Aneurysm

NHS ABDOMINAL AORTIC ANEURYSM SCREENING PROGRAMME

RESEARCH IN ASSOCIATION WITH THE NAAASP

GUIDANCE FOR APPLICANTS

1. **Aim**

- 1.1. This document is a guide for healthcare professionals wishing to conduct research involving patients identified through the NHS Abdominal Aortic Aneurysm Screening Programme (NAAASP).
- 1.2. The document sets out clear rules of engagement for the conduct of research and the use of screening programme data.

2. **Background**

- 2.1. The NHS Abdominal Aortic Aneurysm Screening Programme (NAAASP) is designed to screen for asymptomatic aneurysms with a view to early detection and treatment in order to prevent rupture and death.
- 2.2. Data collection is an integral component of all screening programmes and it is recognised that a wealth of data will be available from screened patients, both in those found to have the condition being screened for and in those who do not have the condition.
- 2.3. Historically this data has not been used for research but there is a considerable potential for research to be performed using the data obtained for screening, or using further investigation modalities in the population attending for screening. The NAAASP offers a unique opportunity to allow academic and clinical institutions to undertake research involving this patient group thereby improving our knowledge of the clinical aspects of the condition and the pathophysiology behind aneurysm development and expansion.
- 2.4. It is essential that the research undertaken is of high quality protecting the safety of patients and researchers. Any research activity must be undertaken in line with current legislation and guidance.

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3. Fundamental Principles

3.1. There are some important principles which govern how the NAAASP engages with research activity.

- The primary function of the programme is to screen a defined population for AAA in a cost effective manner in order to reduce the mortality associated with this condition.
- An essential part of the screening programme is to ensure quality in the management of the condition of AAA.
- There are clear protocols for implementation of the screening programme and any research activity must not hinder the proper functioning of the programme. It is paramount that research considerations (such as the management of consent) do not dissuade people who would otherwise present for screening.
- Proposals for research activity need to take into account established legal, ethical, and patient confidentiality agreements.
- Any research activity must be undertaken in line with current legislation and guidance governing research undertaken in the NHS (Research Governance Framework for Health and Social Care (2005), the Data Protection Act 1998, the Human Tissue Act and the Medicines for Human Use (Clinical Trial) Regulations (2004).
- NAAASP and its officers and workforce are not funded to conduct research.

4. Types of Research Activity

4.1. The programme will consider requests relating to a variety of research related activities. The anticipated types of request are grouped into broad categories below, although this does not exclude requests which do not fall into these specific groups :

- Release of data
 - Demographic data
 - Clinical data
 - Person-identifiable data
 - Aggregate / anonymised data

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- Data on specific patients to support other research activities
- Endorsement of research topics eg those submitted to NIHR and other bodies prior to these being put out to competitive tender
- Permission to approach patients identified through the screening programme for the purposes of research activity
- Collaboration with projects at a local and national level which have been approved for funding by a peer-review process
- NAAASP “commissioned” research
- NIHR/HTA “commissioned” research

5. Relationships with other Institutions

5.1. The NAAASP will retain a basic independence from other institutions in relation to decision making with respect to research activity. However the programme will encourage interaction with other institutions which oversee research activity in the field of vascular disease e.g. NIHR, BHF, the Circulation Foundation and other grant funding bodies. This will allow the development of common aims and will help to avoid competing interests.

6. Application methods

6.1. Centres wishing to apply to the Screening Programme for research related activity should apply in writing to the Research Lead of the NAAASP, submitting (i) a completed application form, (ii) details of the research project plan and (iii) a brief CV of the lead applicant.

6.2. Informal discussions prior to submission of a formal application may be held with the Research Lead of the NAAASP.

6.3. Applications submitted without the relevant details will not be considered.

6.4. Requests will be examined initially by the Research Lead. If an application fulfils the criteria for consideration by the committee the application will be considered by all members of the research committee. In most circumstances this will be done without requiring a formal meeting of the committee. The Research Lead will seek to receive responses from the members of the research committee within a 2 week timeframe, allowing the Research Lead to respond to the applicant(s) within 6 weeks of a

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satisfactory application being received. Some applications will require further consideration at a formal meeting of the committee and any delays caused by such consideration will be conveyed to the applicant. The response of the committee to an application will be:

- Approval
- Rejection
- Request for further information
- Conditional approval based on modifications recommended by the committee

6.5. Any further correspondence relating to the application should be directed to the Research Lead.

7. Criteria for Approval of Applications

7.1. Applications for well constructed research with appropriate ethics approval will be supported wherever possible.

7.2. Projects must be relevant to patients enrolling in the NAAASP and must conform to the requirements outlined in this document. Projects are unlikely to be supported in the following circumstances:

- The research is not relevant to vascular disease, AAA, the screened population, or screening programmes
- The research may impede the effective operation of the screening programme
- Information on how personal information will be used and protected is insufficient or does not conform to policy and/or regulatory requirements
- There is a conflict with the legal obligations of the screening programme
- There are unanswered ethical issues which relate to the screening programme, or ethics approval has not been obtained
- The proposal includes plans to use NAAASP IT systems for research data collection

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- The proposal uses time that is funded for the delivery of the local screening programme for research data collection / analysis

8. Research Committee

8.1. Research applications will be considered by the Research Committee as outlined in section 7. The roles of the committee in this process are outlined below

8.2. Role of the Research Committee

- To review research-related applications to the NAAASP
- To seek appropriate professional advice on applications where required
- To produce recommendations for action following consideration of applications
- To ensure studies included in applications relate to important and valid research questions
- To ensure that studies are practical and feasible
- To protect the primary function of the screening programme as defined in section 4, 'Fundamental Principles', by identifying potential adverse effects of the research/application on the effective functioning of the screening programme and balancing these with the potential benefits of research
- To assess possible areas of duplication with other projects and to provide liaison between research groups considering similar projects
- To ensure that regulatory and ethical issues in relation to the screening programme have been identified and addressed
- To ensure that the NAAASP is informed of research outcomes in a timely manner, so that the translation of new beneficial practice(s) is not hindered.

8.3. Constitution of the Research Committee

The committee will comprise, as a minimum:

- Research Lead for the NAAASP

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- Director of the NAAASP
- NAAASP Programme Manager
- Legal/information governance adviser
- Three appointed members eg

Member of NIHR

Chairman of Research Committee of VSGBI

Member on national grant funding body eg MRC, Wellcome, BHF

- Lay person

9. Legal Issues

9.1. The screening programme has legally binding contracts with several other institutions in order to ensure delivery of the programme. The programme is also bound by the Data Protection Acts, the National Health Service Act 2006 and other regulations and policy relating to the personal information collected as part of the programme.

9.2. It is essential that any research activity, or release of data for research purposes, complies with all relevant legal and regulatory requirements. Any uncertainty in relation to legal issues arising from applications to the research committee will be clarified by the committee's legal adviser prior to any response to the applicant(s).

9.3. Any research applications involving the use of human tissue or organs must comply with the Human Tissue Act 2004

9.4. All applications when approved should be seen by the legal adviser for the programme prior to despatch.

9.5. Current contracts in place are:

- Contract between NHS Connecting for Health and Gloucestershire Hospitals NHS Foundation Trust (on behalf of NAAASP) for the delivery of NAAASP Screening Subject Population Index – contract not finalised but under negotiation

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- Contract between Northgate Information Solutions (UK) Ltd and Gloucestershire Hospitals NHS Foundation Trust (on behalf of NAAASP) for the delivery of a national screening and referral software solution
- Contract between The Vascular Society of Great Britain and Ireland and Gloucestershire Hospitals NHS Foundation Trust (on behalf of NAAASP) for developments to and use of the National Vascular Database for AAA surgery and outcomes
- Contract between The Vascular Society of Great Britain and Ireland and Dr Foster Ltd for the development of extensions to the National Vascular Database for AAA surgery and outcomes

10. Ethical Issues

- 10.1. It will be a condition of acceptance of applications that relevant (local and/or national) ethics approvals will have been sought.
- 10.2. In situations where applications raise additional ethical issues specific to NAAASP which have not have been considered elsewhere, the research committee may decide to reject applications or to require further ethics approval from the applicant(s).
- 10.3. Alternatively the committee may wish to raise these ethical issues with the NAAASP Implementation Group for further advice and clarification.

11. Good Clinical Practice

- 11.1. All research projects should conform to international ethical and scientific quality standards defined by the International Conference on Harmonisation Good Clinical Practice Guidelines (ICH GCP) www.ich-global.org .
- 11.2. All research projects should conform to the code of practice for research as defined by the UK Research Integrity Office:

http://www.ukrio.org/sites/ukrio2/the_programme_of_work/code_of_practice_for_research.cfm

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12. Defining Research

The difference between research, clinical audit, service evaluation and usual practice/surveillance work is defined in a document on the National Research Ethics Service Website: www.nres.npsa.nhs.uk/applications/apply/is-your-project-research

13. Consent

- 13.1. In patients who are invited to attend for screening consent is currently obtained to use anonymised / aggregate data for research linked to abdominal aortic aneurysms or screening programmes.
- 13.2. Consent is also requested to contact patients to ask if they will allow the use of personal information for research purposes.
- 13.3. Research applicants requiring the use of personal information will need to make it clear why personal information will be required, how this will contribute to the proposed research, and why the research cannot be performed without personal information.
- 13.4. The methods to be used for contacting patients (including the full wording of any initial communication with the patient) and the information that will be requested must be included as part of the research application.

14. Release of Data

- 14.1. Requests for release of data relating to AAA screened patients will fall into the following categories.
 - i) Anonymised aggregate clinical data
 - ii) Anonymised clinical and/or demographic data at individual patient level
 - iii) Pseudonymised clinical and/or demographic data allowing further analysis in order to identify candidate lists of patients who have given consent to be contacted for further research
 - iv) Contact information allowing patients having provided relevant consent to be contacted for the purposes of research
 - v) Clinical and/or demographic data at individual patient level for patients meeting specific criteria

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- vi) Clinical and/or demographic data on specific patients to support other research activities
- 14.2. Applicants should note that categories (i) to (iv) above may be approved, but categories (v) and (vi) are not allowable within the current governance framework of the screening programme.

15. Collecting Data on Screened Patients

- 15.1. Additional data for the purpose of research may be collected by local screening programmes and vascular units on screened patients subject to the normal processes and approvals for ethics, data protection, and consent.
- 15.2. The NAAASP software solution may not be used for the purposes of collecting such additional data, though patient identifiers within the NAAASP software solution may be linked to other databases subject to approval from the NAAASP research committee.
- 15.3. Individuals from local screening programmes wishing to collect additional data for this purpose must not do this in time that is funded for the delivery of the local screening programme.
- 15.4. It may be decided at a national level to extend the AAA Screening Dataset for projects deemed to be in the national interest, but this would require additional approval from NAAASP, and identified funding.

16. Use of Data and Publications

- 16.1. Data released by the NAAASP for the purposes of research described in this document may be used in professional presentations. It is a condition of release of this data that any such presentation acknowledges the NAAASP as the source of the data.
- 16.2. Any publications or presentations arising out of research on AAA screened patients must not identify individuals or enable individuals to be identified.
- 16.3. Data may not be shared with or made available to any third party without the written permission of the NAAASP.
- 16.4. Data must be stored with proper safeguards to prevent unauthorised access.

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- 16.5. Publications arising out of research conducted with approval of or in association with the NAAASP must acknowledge the source of data and the role of the NAAASP.
- 16.6. Proposed publications which have involved data from the screening programme should be seen by the NAAASP Research Committee prior to submission. If, in exceptional circumstances, the Research Committee considers the submission unfit for publication due to the research methodology being defective, the data incomplete, or the conclusions unreliable, then the Committee reserves the right to block the publication.

17. Progress Reporting

- 17.1. Centres which have involved the NAAASP in a local, regional, or national research study will be expected to provide the Research Committee with an annual summary of progress of the project. This should be a brief report (1 side of A4) detailing the stage of research achieved.
- 17.2. Applicants having sought and obtained the collaboration of the NAAASP for a research grant application should inform the programme of the outcome of the grant application.

18. Conflict of Interest

- 18.1. There may be occasions when a researcher proposes research that overlaps with research being considered by one of the members of the Research Committee. In such instances that member of the committee will declare his conflict of interest and will take no further part in the review process and the application will be considered by the rest of the committee (with external expertise if required). The Committee may wish to recommend collaboration between the applicant and the committee member if appropriate.

19. Fees

- 19.1. NAAASP reserve the right to charge reasonable administrative fees for filtering or extracting data released to support research projects. A list of charges will be available which may be used within applications for research grants, subject to the permission of the NAAASP research committee.