

# Screening Programmes

## Abdominal Aortic Aneurysm

### NHS ABDOMINAL AORTIC ANEURYSM SCREENING PROGRAMME

#### TERMS OF REFERENCE FOR CONDUCTING RESEARCH

#### IN ASSOCIATION WITH THE NAAASP

#### 1. Aim

- 1.1. The aim of this document is to set out the framework whereby research may be undertaken involving the patients who are part of the NHS screening programme for the condition of abdominal aortic aneurysm.

#### 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 within a short period of time 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.

#### 3. The potential benefits of research

- 3.1. There are many gaps in our knowledge related to the growth, development and pathophysiology of aortic aneurysms. For that reason there are areas where we might

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reasonably improve the management of this condition with further knowledge. These include but are not limited to:

- The rates of aneurysm expansion
- Methods for measuring aneurysm size
- The optimal circumstances for intervention (including aneurysm size)
- The identification of risk factors for and the causes of aortic aneurysm formation
- Optimal screening schedules
- Risk factors for rupture of an AAA
- Identification of optimal patient group for screening (eg age, sex, ethnic groups)
- Fate of men with a large AAA unfit for intervention

3.2. It is important that the screening programme encourages well designed research in order to answer these questions and to inform and guide the programme in the future.

3.3. In addition there may be an opportunity to conduct research into other aspects of vascular disease in this patient group with a high risk of cardiovascular death.

3.4. There may also be opportunities for research in those who attend for screening but do not have an AAA, eg genetic and epidemiological studies.

#### 4. Fundamental Principles

4.1. There are some important principles which will 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

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paramount that research considerations (such as the management of consent) do not dissuade people who would otherwise present for screening.

- Research activity will 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.
- 4.2. As such it is unlikely that research will ever be a core component of the screening programme itself. Also individual institutions will have their own specific requirements in relation to research in this field. Some centres, for example, will have a track record in gene testing and therapy and will wish to pursue this type of research, whereas others may wish to investigate other aspects such as biochemical markers of aneurysm expansion, or epidemiological factors. A centrally driven research programme is therefore probably not appropriate, but if centres are to have access to the information and patient base available from the screening programme, clear rules of engagement and use of data need to be defined.

#### 5. Types of Research Activity

5.1. The programme will receive requests relating to a variety of research related activities. These types of request, and other potential research activities are grouped into broad categories below:

- Release of data
  - Demographic data
  - Clinical data
  - Person-identifiable data
  - Aggregate / anonymised data
  - Data on specific patients to support other research activities

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- 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 defined priorities for research
- NIHR/HTA defined research

#### 6. The Role of the NAAASP related to Research

- 6.1. Although research will not be a core component of the screening programme the NAAASP itself may wish to encourage research in order to answer a particular question within the programme. A good example of that would be the most appropriate technique for measuring aortic aneurysm size, or investigating methods to improve the uptake of screening.
- 6.2. The NAAASP may also wish to set priorities for research in order to assist research institutions and grant funding bodies in developing projects likely to be beneficial to the screening programme and the wider population.
- 6.3. The NAAASP will also from time to time undertake horizon scanning for new and emerging health technologies in relation to the management of AAA which may require evaluation and research.

#### 7. Defining Research

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

#### 8. Relationships with other Institutions

- 8.1. It is envisaged that NAAASP will retain a basic independence from other institutions in relation to decision making with respect to research activity. However it is logical that the programme should interact with other institutions which oversee research activity in the field of vascular disease. This is likely to include national (and international) bodies such as NIHR, BHF and the Circulation Foundation and specialist groups such as

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the Research Committee of the Vascular Society of Great Britain and Ireland and research committees of the BSIR, and VASGBI. It may also involve larger grant funding bodies. This will allow the development of common aims and will help to avoid competing interests.

#### 9. Research Committee

9.1. There will be a need for research related applications to the Screening Programme to be received, evaluated, and responded to. This may require some additional professional advice and may result in further correspondence with the applicant(s) for clarification of detail. If data release is required this may involve further work in obtaining, anonymising and cleaning data prior to release, this and other additional work for research purposes should be costed and these costs met by the researchers. These processes need to be conducted in a timely fashion and the outcome conveyed to the applicant with clear explanation of the reasons for the decision.

9.2. This will require a (small) research committee. Whilst much of the work might be done by email and telephone, there will be occasions when this committee will need to meet. Meetings of the committee should be arranged with regard to minimising cost and time commitment.

9.3. The committee will be responsible to the NAAASP via the Director of the Screening Programme

#### 9.4. Role of the Research Committee

- To discuss and agree the research framework for NAAASP (including this document)
- 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 assess the scientific value of each application and to ensure that studies are practical and feasible
- To determine which research applications will have access to persons invited as part of the NAAASP

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- 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.
- To maintain a database of all applications and their outcomes
- To respond to queries from funding bodies regarding applications which involve the use of NAAASP patients

#### 9.5. Constitution of the Research Committee

- The committee will be kept small for efficacy, and will comprise, as a minimum:
- Research Lead for the NAAASP
- Director of the NAAASP
- NAAASP Programme Manager
- Legal/information governance adviser (non-voting?)
- 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

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#### 10. Legal Issues

- 10.1. 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.
- 10.2. 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).
- 10.3. Any research applications involving the use of human tissue or organs must comply with the Human Tissue Act 2004
- 10.4. All applications when approved should be seen by the legal adviser for the programme prior to despatch.
- 10.5. 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
  - 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

#### 11. Ethical Issues

- 11.1. It will be a condition of acceptance of applications that relevant (local and/or national/international) ethics approvals will have been sought.

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- 11.2. 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).
- 11.3. Alternatively the committee may wish to raise these ethical issues with the NAAASP Implementation Group for further advice and clarification.

## 12. Good Clinical Practice in Research

- 12.1. 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](http://www.ich-global.org).
- 12.2. All research projects should conform to the code of practice for research as defined by the UK Research Integrity Office:

[UKRIO: Code of Practice for 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 programme.
- 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 will be received for release of data relating to AAA screened patients. The type of data requested is likely to fall into the following categories



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- 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
  - vi) Clinical and/or demographic data on specific patients to support other research activities
- 14.2. 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.

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#### 16. Application methods

- 16.1. 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.
- 16.2. Informal discussions prior to submission of a formal application may be held with the Research Lead of the NAAASP.
- 16.3. Requests submitted without the relevant details will not be considered.
- 16.4. 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 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
- 16.5. Any further correspondence relating to the application should be directed to the Research Lead.
- 16.6. Guidelines for applicants will be available from the Research Lead in due course.

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#### 17. Use of Data and Publications

- 17.1. 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.
- 17.2. Any publications or presentations arising out of research on AAA screened patients must not identify individuals or enable individuals to be identified.
- 17.3. Data may not be shared with or made available to any third party without the written permission of the NAAASP.
- 17.4. Data must be stored with proper safeguards to prevent unauthorised access.
- 17.5. 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.
- 17.6. 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.

#### 18. Criteria for Approval of Applications

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

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

#### 19. Progress Reporting

- 19.1. 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.
- 19.2. 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.

#### 20. Conflict of Interest

- 20.1. 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.
- 20.2. Members must declare any potential conflicts of interest or if their declaration of interests changes
- 20.3. In rare circumstances declarations of interest may highlight major conflicts of interest that might not be compatible with membership of the committee. The Chair of the committee and the Director of the NAAASP will determine whether the declared interest is compatible with continued membership of the committee.
- 20.4. An individual who is concerned about another individual's potential or actual conflict of interest should raise their concerns with the Chair.

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#### 21. Fees

- 21.1. NAAASP reserves 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.

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