South Central Ambulance Service
NHS Foundation Trust

# Getting approval for your research project in SCAS

SCAS is an innovative ambulance trust and we welcome the opportunity to be involved in research projects that offer potential to enhance the care of patients and support staff development. In order to ensure a smooth passage through the approvals process, it is strongly recommended that, you request a formal discussion with the research team to discuss your ideas and any practical considerations to ensure that your project is deliverable. Please request a formal discussion with a member of the team either our senior research paramedic Helen Pocock at helen.pocock@scas.nhs.uk or our research administrator Sarah Taylor at sarah.taylor@scas.nhs.uk.

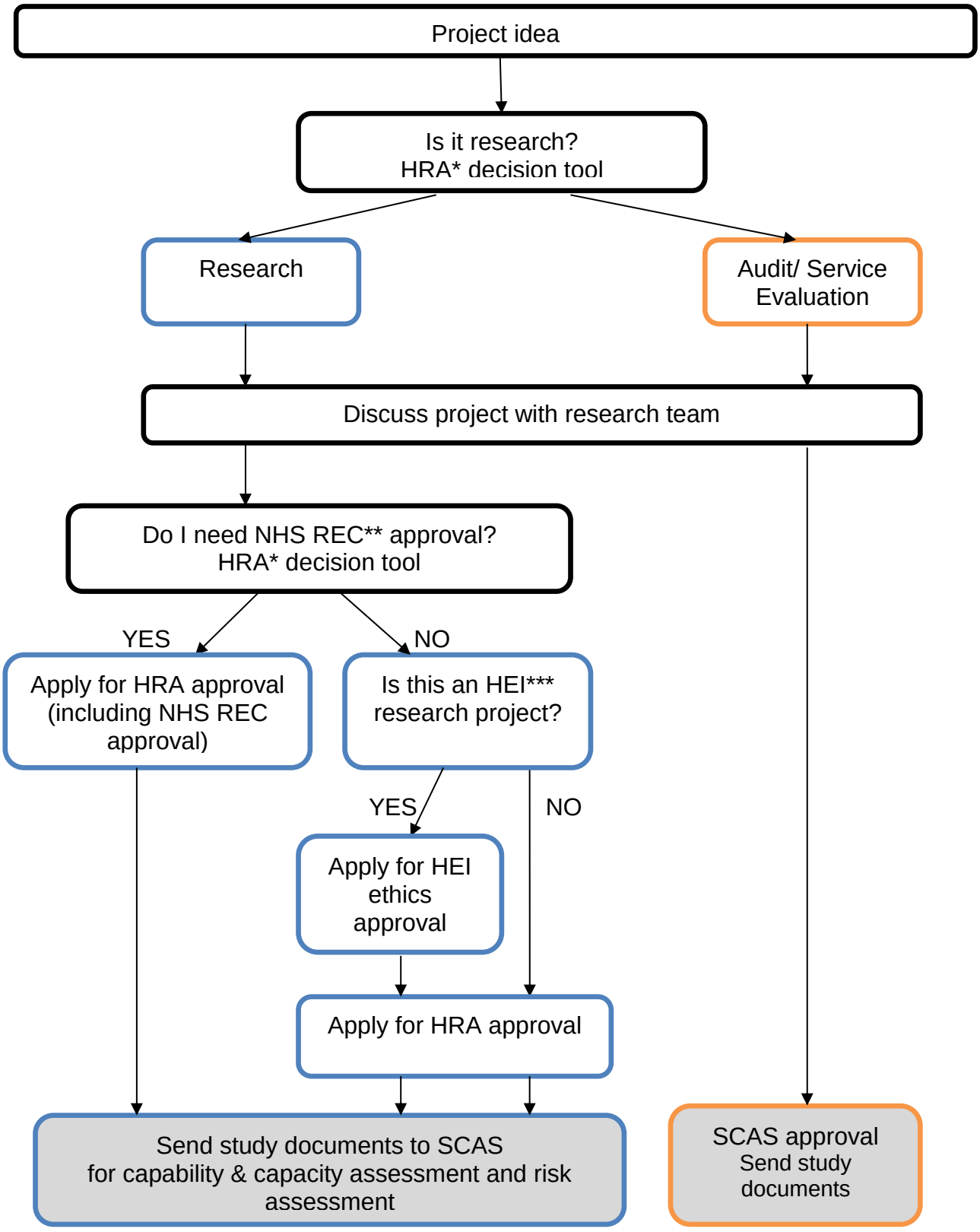
## Research Governance

Approval is granted by different bodies depending on whether your project is research or not. The Health Research Authority (HRA) leaflet 'Is my project research' available at http://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable_Oct2017-1.pdf will help to determine this if you are not sure (see appendix). The HRA provide an online decision tool, the results of which may be saved and printed/emailed by way of confirmation of the outcome. This is available at http://www.hra-decisiontools.org.uk/research/

## HRA approval

If your project is research, the HRA tool will tell you whether NHS Research Ethics Committee (REC) approval is also needed. This can be accessed at http://www.hra-decisiontools.org.uk/ethics/. In any case, only a single application needs to be made to the HRA. This brings together the independent ethical opinion by a Research Ethics Committee (REC) and the assessment of governance and legal compliance is undertaken by HRA staff. Prior to applying for approval it is expected that you will have discussed the project with the SCAS research team. Once all approvals have been granted please ensure that all study documentation is sent to Sarah Taylor at sarah.taylor@scas.nhs.uk if it is audit or service evaluation, HRA approval is not necessary; however, SCAS approval is still required.

A flow chart of this process is provided below:




*HRA = Health Research Authority
** NHS REC = NHS Research Ethics Committee
***HEI = Higher Education Institution

**Audit & Service Evaluation**

The committee responsible for reviewing and approving audit and service evaluation projects in SCAS is the Clinical Review Group (CRG) which meets once every two months. The project will be presented to the Clinical Review Group by the Research Team. Be sure to allow enough time for the Research Team to review your project and submit it for inclusion on the agenda. There is no opportunity for additional review of projects between meetings

Please send the following documents, as soon as they are available, to Sarah Taylor Research Administrator via sarah.taylor@scas.nhs.uk

- One-page summary of project
- Audit/Service Evaluation Protocol
- Data required and likely data sources
- Information Governance solutions – how data will be transferred & stored

You will be notified of the outcome in writing within 7 days of the publication of the minutes.

**Research**

Please send the following documents to Sarah Taylor Research Administrator at sarah.taylor@scas.nhs.uk

- Research protocol & amendments
- Participant Information Sheet(s)
- Consent form
- Ethics approval letter (from NHS Ethics Committee or HEI Ethics Committee)
- HRA Approval initial assessment letter (or HRA Approval if no initial assessment letter is issued)

Include in your email the project title, a brief description of the project and how you would like to involve the ambulance service e.g. staff interviews, survey of key individuals, observation of clinical practice etc.

**HRA Capability & Capacity Assessment**

Prior to engagement in the research project SCAS are required to conduct a Capability & Capacity Assessment. It would be helpful if you could address the following themes in your request:

- Access/permission requirements for patients in other NHS organisations or non-NHS orgs
- Impact of study on workload and patient care (additional to standard care)
- Time requirements for training delivery
- Information Governance requirements – data storage & transfer

We will aim to provide confirmation within 30 calendar days of receiving your request.

## Appendix

**Differentiating clinical audit, service evaluation, research and usual practice/surveillance work in public health**

| RESEARCH | SERVICE EVALUATION* | CLINICAL AUDIT | SURVEILLANCE | USUAL PRACTICE (in public health) |
|---|---|---|---|---|
| The attempt to derive generalizable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them. | Designed and conducted solely to define or judge current care. | Designed and conducted to produce information to inform delivery of best care. | Designed to manage outbreak and help the public by identifying and understanding risks associated. | Designed to investigate outbreak or incident to help in disease control and prevention. |
| Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology. | Designed to answer: "What standard does this service achieve?" | Designed to answer: "Does this service reach a predetermined standard?" | Designed to answer: "What is the cause of this outbreak?" | Designed to answer: "What is the cause of this outbreak?" and treat. |
| Addresses clearly defined questions, aims and objectives. | Measures current service without reference to a standard. | Measures against a standard. | Systematic, statistical methods to allow timely public health action. | Systematic, statistical methods may be used. |
| Quantitative research – may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced. | Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference. | Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference. | May involve collecting personal data and samples with the intent to manage the incident. | Any choice of treatment is based on clinical best evidence or professional consensus. |
| Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care. | Usually involves analysis of existing data but may include administration of interview or questionnaire. | Usually involves analysis of existing data but may include administration of simple interview or questionnaire. | May involve analysis of existing data or administration of interview or questionnaire to those exposed. | May involve administration of interview or questionnaire to those exposed. |
| Quantitative research – study design may involve allocating patients to intervention groups. Qualitative research – uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications. | No allocation to intervention: the health professional and patient have chosen intervention before service evaluation. | No allocation to intervention: the health professional and patient have chosen intervention before audit. | Does not involve an intervention. | May involve allocation to control group to assess risk and identify source of incident but treatment unaffected. |
| May involve randomisation. | No randomisation. | No randomisation. | No randomisation. | May involve randomisation but not for treatment. |
| Normally requires REC review. Refer to www.nres.npsa.nhs.uk/applications/apply/ for more information. | Does not require REC review. | Does not require REC review. | Does not require REC review. | Does not require REC review. |

* Service development and quality improvement may fall into this category.