

## Research governance policy

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Date effective from	December 2018
Date last amended	December 2018
Review date	December 2021

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## Introduction

1. Research governance can be defined as the broad range of regulations, principles and standards of good practice that ensure high quality research.
2. NICE staff undertake and commission research, and may support external research projects that are led by others. In addition, staff may be invited to be a research participant in external projects where NICE processes and methods are the subject of research.
3. The majority of NICE's research activity concerns methodological or translational research. NICE does not directly undertake clinical trials, and will not act as Sponsor for a clinical trial.
4. The aim of this policy is to ensure that NICE's research activities comply with national legislation and research governance policies. It:
  - Defines the roles and responsibilities of NICE staff involved in research and other activities;
  - Sets out NICE's research governance framework and describes the process by which it is implemented;
  - Provides information about relevant national legislation and policies that apply to research and other activities such as audits, service evaluation and literature reviews.
5. National legislation and research governance policies that relate specifically to clinical research have been re-interpreted and adapted for relevance to other types of research activity.
6. The policy has been structured to ensure the NICE governance requirements are proportionate to the risks involved with type of research being undertaken and the role of NICE and its staff.

## Scope

7. This policy applies to the following in their capacity of working at or for NICE (referred to hereafter as 'staff'):
  - all NICE employees (including staff on secondment to other organisations)
  - committee chairs and members and remunerated expert advisers
  - non-executive directors
  - agency workers and contractors on temporary contract or employed through an agency to work for NICE
  - secondees (those who are seconded to NICE from other organisations)

- individuals undertaking placements at NICE including interns

In some circumstances, the research governance policy of the host organisation may apply.

8. This policy applies to all types of research activities that NICE staff carries out and participates in, including those undertaken as part of a placement at NICE (referred to hereafter as 'research').
9. NICE does not directly undertake clinical trials and cannot act as a sponsor for clinical research. However, health technology assessment organisations will increasingly will be involved with primary evidence generation including facilitating collaborative research or real-world data collection activities. In such cases, NICE will not act as Sponsor for individual clinical studies and the research governance arrangements of another organisation, such as that conducting the research or data collection, will need to apply, within the principles set out in this policy.
10. NICE's process and methods manuals should ensure that research undertaken as part of guidance development meet the requirements of this policy, including requirements for the publication of protocols and outputs. For all other research activity, staff should ensure compliance by following the NICE research governance framework.

## **Responsibilities**

11. NICE's Science Policy & Research (SP&R) Programme is responsible for managing the NICE research governance policy, providing advice on its implementation and managing the research register (the central database recording detail of research activity in NICE).
12. SP&R is also responsible for ensuring NICE has access to expertise for ethical advice and ethical opinion on research projects, including whether good clinical or research practice training is required.
13. Senior Management Team (SMT)-level Directors are accountable for research activity within their own centre or directorate and are responsible for only approving research activities that demonstrate compliance with this policy.
14. Staff are responsible for ensuring that any research activities that they undertake meet the requirements of this policy. This includes responsibility for recording details of the research on NICE's research register and managing all correspondence with any external organisations that:
  - NICE commissions to conduct research;
  - NICE works with as a partner or co-applicant;

- request NICE staff to participate as a research subject;
  - request NICE to sit on an advisory group or provide a letter of support.
15. NICE has no responsibility for research projects that are undertaken by its staff that are not related to their role at NICE, for example research for MSc or PhD projects or research undertaken as part of an honorary position that they may hold. The governance arrangements for these activities need to meet the requirements of the organisation that is supervising the research. Any potential conflicts arising from such activity should be declared and staff should be aware of the NICE Standards of Business Code of Conduct regarding allocation of time. For all projects that are undertaken within a (non-NICE) academic portfolio, NICE staff must notify their line managers before publication and a disclaimer should be added that states that 'the findings and conclusions in the document are those of the author and not necessarily those of NICE'.

## **NICE Research Governance Framework**

### ***Requirements for all research activity***

16. The following requirements apply to all research activity, including:
  - NICE commissioning research;
  - NICE directly undertaking research;
  - NICE participating in someone else's research as a research subject;
  - NICE supporting someone else's research by sitting on an advisory group or providing a letter of support.

### **Developing the research proposal**

17. All NICE involvement in research activity must be approved by a SMT-level Director. The research proposal should be reviewed by the relevant Associate Director or Programme Director before submission to the SMT-level Director for approval.
18. Research proposals should also be reviewed by an individual with methodological or topic expertise (paragraphs 50-51) and consideration given as to whether service user/public involvement is required (paragraphs 52-53). Advice is available from NICE's SP&R team and Public Involvement Programme.
19. The individual's line manager must agree involvement in the research and ensure that the individual has the skills and capacity to provide the required input. The line manager should take into consideration the likely impact on the wider team and directorate.
20. Research activities may involve an element of risk, both in terms of return on investment and for the psychological and physical well-being of participants and the safety of researchers. Research activities can also be resource-intensive and associated with opportunity costs. The teams should consider any risks involved in the project and ensure that those risks are managed. This may include a discussion with the SP&R team, corporate office, or the Senior Management Team, depending on the nature and level of risk. If needed, a risk management plan and if appropriate, contractor management reporting templates and delivery indicators should be developed alongside the research proposal.
21. For projects involving NICE staff that require resourcing through an external budget, early advice from NICE's finance department should be obtained. This

is to ensure that all relevant staff time and overhead charges have been considered before the proposal is submitted to the research funder.

### **Research involving human participants**

22. For research that involves human participants a process of informed consent should be developed. The nature of the process will depend on the risks involved with the research and advice is available from NICE's SP&R team. Informed consent should be obtained through appropriate means for the participants involved. For example, it can be obtained via email in some circumstances such as interviews with professional colleagues.
23. All research projects involving human participants need to be considered by a person with the appropriate ethical expertise and staff should seek advice from the SP&R team in the first instance. Where appropriate, a favourable ethical opinion or notice of no ethical requirement should be obtained (Figure 1 and Appendix B). Due to the nature of the research activity undertaken at NICE it is anticipated that very few research projects will require review by an ethical committee. Activities such as audit and service evaluation may require ethical review if they involve the collection of personally identifiable data. NICE has access to advice and support for an ethical review application if it is necessary. This process is co-ordinated by the SP&R team ([researchgovernance@nice.org.uk](mailto:researchgovernance@nice.org.uk)).

### **Registering the research activity**

24. NICE has a central 'research register' where all research projects must be added as soon as they start. For some research activity, such as the participation in research where NICE and its activities are the subject, exemptions may be made if the research is low risk and the time and resource impact are minimal. Entries should be updated at least annually and when key milestones have been met. The NICE research register is accessible via the [SP&R pages](#) of the intranet. It is good practice to also submit details of research protocols to an appropriate external register (where applicable) (paragraph 56).

### **Information governance**

25. NICE's principles relating to transparency also apply to research activities. Therefore, unless there is a good reason not to do so, protocols and reports that do not contain confidential data should be made publicly available. All recorded information can be potentially disclosed under the Freedom of Information Act so it is important that sensitive information is kept to a minimum and held in accordance with the business need. Any potential sensitivity, for example personally identifiable data, should be identified at the research design stage and a management strategy developed. The NICE Corporate Office can provide advice.

26. The collection or management of data must comply with NICE's Information Governance policy and, if appropriate, NICE's Data Protection policy. Files and records should be maintained according to NICE's Records Management policy.
27. If a project uses data that has been obtained from a third party (for example NHS Digital), staff must ensure that they adhere to the terms of that data access. Advice can be obtained from NICE's Information Governance Manager or Caldicott Guardian via the Corporate office. Staff should also ensure that the terms and conditions of the data supply are fit for all of NICE's purposes. Advice can be obtained from Procurement.

### **Reporting research results**

28. The results of research activities should be reviewed by an individual with the appropriate methodological or subject matter expertise. Any publication of research outputs should be approved by the Associate Director and/or Programme Director to ensure that there is a senior sponsor for publication and appropriate interpretation and communication of results. This includes but is not limited to: journal articles, conference submissions, book chapters, and reports to be published on the NICE website or PubMed bookshelf.

### **Research misconduct**

29. Any allegations of research misconduct will be dealt with according to NICE's disciplinary policy and procedure.

### ***Additional requirements for particular types of research activity***

#### **Projects commissioned by NICE either funded directly or through a framework agreement**

30. All criteria under '*Requirements for all research activity*' of the research governance framework (paragraphs 16-28) must also be satisfied.
31. A number of projects, including research, service evaluation, audits and literature reviews are funded directly or commissioned to external providers through standard procurement processes. The entire project can be commissioned or only components. The NICE team/directorate that commissions the project is responsible for ensuring that the research activity is fit for purpose.
32. As the commissioner, NICE will not normally assume legal responsibility for the research. NICE must ensure that the legal and other relevant research responsibilities are transferred to the external organisation commissioned to carry out the research activity. The NICE team/directorate that commissions the research is responsible for ensuring that this is explicit in the terms and conditions of the contract established between NICE and the provider.



### **Externally funded projects where NICE staff are the lead applicant or co-applicant**

33. All criteria under '*Requirements for all research activity*' of the research governance framework (paragraphs 16-28) must also be satisfied.
34. The decision to be involved as a co-applicant should be based on the following considerations:
  - NICE has been given sufficient time to consider and respond to the request.
  - The proposal is methodologically robust and complies with the NICE research governance policy.
  - The aims and objectives of the project are likely to lead to information which will help shape the work of NICE.
  - The NICE staff members have the necessary skills.
  - Resource costs and time for NICE staff are costed into the proposal. The resource consequences of being involved in the project should ideally be at least neutral, but a negative resource consequence may be justified if there is sufficient overall benefit to NICE.
  - The project has appropriate disclosure and confidentiality agreements in place.
  - NICE can review results and comment on them before they are made available in public.
35. The employing organisation of the lead applicant will usually sign an agreement with the funding body, detailing the conditions of the grant. If a number of organisations and individuals are involved in a study, it is essential that clear agreements are reached about allocation of responsibilities and rights, including intellectual property rights, and that these are documented and enacted. All legal agreements for projects where NICE is the lead applicant or the co-applicant must be reviewed and approved by procurement before being signed.

### **Participation in projects undertaken by external organisations (including Universities) where NICE or its activities are the subject**

36. All criteria under '*Requirements for all research activity*' of the research governance framework (paragraphs 16-28) must be satisfied.
37. The decision to participate should be based on the following considerations:
  - The proposal is methodologically robust. This will require a review of the research proposal, and if appropriate, statement of ethical opinion.

- The aims and objectives of the project are likely to lead to information that will help shape the work of NICE.
- The investigators are of good standing and have a track record of delivering robust and ethical research.
- The support requirements, for example NICE staff time, have been established and agreed. Consideration should be given to capacity and if the project is likely to require significant support, costs should be recovered.
- The project has appropriate consent and disclosure agreements in place. Consent should be obtained individually from all NICE staff who take part in the research.
- NICE can review results and comment on them before they are made available in public.

**Projects where a NICE member of staff has been requested to sit on an advisory group or provide a letter of support for an external research project.**

38. All criteria under '*Requirements for all research activity*' of the research governance framework (paragraphs 16-28) must be satisfied.

39. This decision should be based on the following considerations:

- The research methods are reasonable. This will require a review of the research proposal, and if appropriate, statement of ethical opinion.
- The aims and objectives of the project are likely to lead to information which will help shape the work of NICE.
- The investigators are of good standing and have a track record of delivering robust and ethical research.
- For requests to sit on an advisory group, the ongoing support requirements, for example staff time, have been established and agreed.
- NICE has been given sufficient time to consider and respond to the request.

## **Review**

This policy will be reviewed every three years.

## **Related NICE policies**

- Data Protection
- Disciplinary
- Information governance

- Freedom of Information
- Records management

## Appendix A – National legislation and policies

40. The research governance requirements that apply to NICE staff undertaking research are defined by a range of national legislation and policies, professional codes and statements of practice. These are briefly summarised below.

### **Statutory responsibilities**

41. The [Health and Social Care Act 2012](#) outlines the Government's commitment to enhancing the contribution of research to health and social care, and the benefits of this activity to the wider economy. The Act places a statutory duty on the Secretary of State, NHS England, clinical commissioning groups (CCGs), local authorities and certain other organisations to have regard to the need to promote research within the NHS. For more information, see the Department of Health (DH) factsheet: '[Embedding research as a core function of the health service](#)'. NICE supports the aims of this statutory duty and is committed to providing an environment that supports the production of high quality research by its staff.
42. The NHS HRA [UK policy framework for health and social care research](#) sets out 15 principles of good practice in the management and conduct of health and social care research. It takes account of relevant legislation in the UK and applies to health and social care research that is:
- concerned with the protection and promotion of public health
  - undertaken in or by a UK Health Department, its non-Departmental public bodies or the NHS and social care providers
  - undertaken by NHS or social care staff using the resources of health and social care providers and any research undertaken within the health and social care systems that might have an impact on the quality of those services

### **Protecting research participants (ethics)**

43. Research ethics refers to the moral principles guiding all aspects of research, from its inception through to completion and publication of results and beyond.
44. The [Economic and Social Research Council \(ESRC\) framework for research ethics](#) sets out six key principles for ethical research:
- research should aim to maximise benefit for individuals and society and minimise risk and harm
  - the rights and dignity of individuals and groups should be respected
  - wherever possible, participation should be voluntary and appropriately informed

- research should be conducted with integrity and transparency
  - lines of responsibility and accountability should be clearly defined
  - independence of research should be maintained and where conflicts of interest cannot be avoided they should be made explicit.
45. Ethical review is one of a series of safeguards intended to protect research participants and researchers. The [HRA Research Ethics Service](#) reviews research proposals to protect the rights and safety of research participants and enables ethical research which is of potential benefit to science and society. Guidance about the [approvals and decisions that may be required](#) is available on the HRA website.
46. Within the NHS, all research that involves patients, their organs (under the provision of the Human Tissue Act), or their data must have a favourable opinion from the HRA before it can begin. Not all types of research (such as audit and service evaluation) may require full ethical review by the HRA. However, such research may still require proportionate review, for example if it involves collecting personally identifiable data. All proposals need to be considered by an experienced individual to ensure that those that need either a proportionate or full ethical review are identified.
47. Research within the social care setting may need to be reviewed by the [HRA Social Care Research Ethics Committee](#).

### ***Roles and responsibilities within a research project***

48. The NHS HRA [UK policy framework for health and social care research](#) and other legislation allocate governance responsibilities using specific terms for the main people and organisations involved in a research project. The roles most relevant to NICE's research activities are:
- **Sponsor:** the individual, company, institution or organisation, which takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the financing) for that research. The sponsor takes primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting. NICE cannot act in the capacity of 'sponsor' for clinical research.
  - **Principal Investigator (PI):** the individual responsible for the design, conduct and reporting of the research. NICE staff may take the role of PI where this is permitted by the funder of the research. Some funders, for example research councils, require the employer of the PI to have Independent Research Organisation status, which NICE does not have.

- **Employing organisation:** the employer of the PI. The employing organisation is liable for the work of the research team and the management of any funds received under contract with a research funder. This includes putting in place protocols and ensuring adherence to relevant research governance requirements.
- **Funder:** the organisation or group of organisations providing funding for the research project.

The HRA website provides further guidance on [roles and responsibilities within health research](#).

49. If a number of organisations and individuals are involved in an individual study, it is essential that clear agreements are reached about allocation of responsibilities and rights, and that these are documented and enacted. Whilst many agreements will relate to individual studies, it is possible to develop a framework agreement, to include allocation of responsibilities for studies that follow the same protocols.
50. For research projects undertaken internally, NICE acts as both the employing organisation and research sponsor, with staff sometimes acting as the principal investigator.

### ***Methodological review***

51. Good research governance includes independent peer review of proposals and findings, to include professional review, by experts in the relevant field. This ensures that all research undertaken is methodologically sound and the conclusions can be supported by the findings. The review arrangements should be in proportion to the scale of the research and the risks involved. For example, a panel of independent experts may be required for a new programme or a controversial or costly proposal. In others, for example a literature review, a colleague with appropriate expertise may suffice.
52. Research which duplicates other work unnecessarily, or which is not of sufficient quality to contribute something useful to existing knowledge, is unethical and a waste of resources. Therefore, before any major new research activity is undertaken, existing research should be identified and reviewed.

### ***Involvement of service users or the public***

53. The [NHS HRA UK policy framework for health and social care research](#) requires that patients, service users and the public are involved in the design, management, conduct, and dissemination of research unless otherwise justified. Not all research activities, for example literature reviews, may require this.

54. [INVOLVE](#) is an advisory group funded by the [National Institute for Health Research \(NIHR\)](#) which supports greater public involvement in the NHS, public health and social care research. [INVOLVE](#) has established the principle that the advisory bodies of any major research programmes funded by NIHR should normally have at least two consumer representatives. The NIHR Central Commissioning Facility has established a [Patient and Public Involvement \(PPI\) framework](#).

### ***Information governance***

55. Researchers must ensure the appropriate use and confidentiality of any information that is collected. Adhering to NICE's information governance policy will ensure compliance with legal and other requirements for good information governance. In particular, personally identifiable data must be treated in accordance with the General [Data Protection Regulation 2016/679](#) and NICE's data protection policy.
56. Data collected in the course of the project must be retained for an appropriate period to support monitoring by regulatory and other authorities. NICE's records management policy covers this requirement.
57. It is good research practice to ensure that the protocols are made available and any subsequent variations are transparent and explained. Systematic reviews can be registered on the international prospective register of systematic reviews ([PROSPERO](#)) or Systematic Review Data Repository ([SRDR](#)). For research in the social sciences and humanities, consider the [UK Data Archive](#). The outcomes of research should also be made openly available irrespective of whether they are positive or negative. This may be through publication and/or other means appropriate to the type of research activity. Information should be presented in a format understandable to the public.

### ***Expertise and Good Clinical Practice***

58. All those involved in research activities should ensure that they, and those they manage, have the necessary experience for the role they are undertaking in relation to the project.
59. Good Clinical Practice (GCP) training is mandatory for all NHS staff involved in experimental research, for example studies involving healthcare interventions. It is also recommended for staff involved in all other types of research activities that require ethical review.
60. The [Market Research Society](#) (MRS) is the professional organisation for market, social and opinion research and business intelligence, market analysis, customer insight and consultancy. NICE follows the [MRS Code of Conduct](#)

which provides a professional standards governance framework, including legal and ethical requirements, for these types of research.

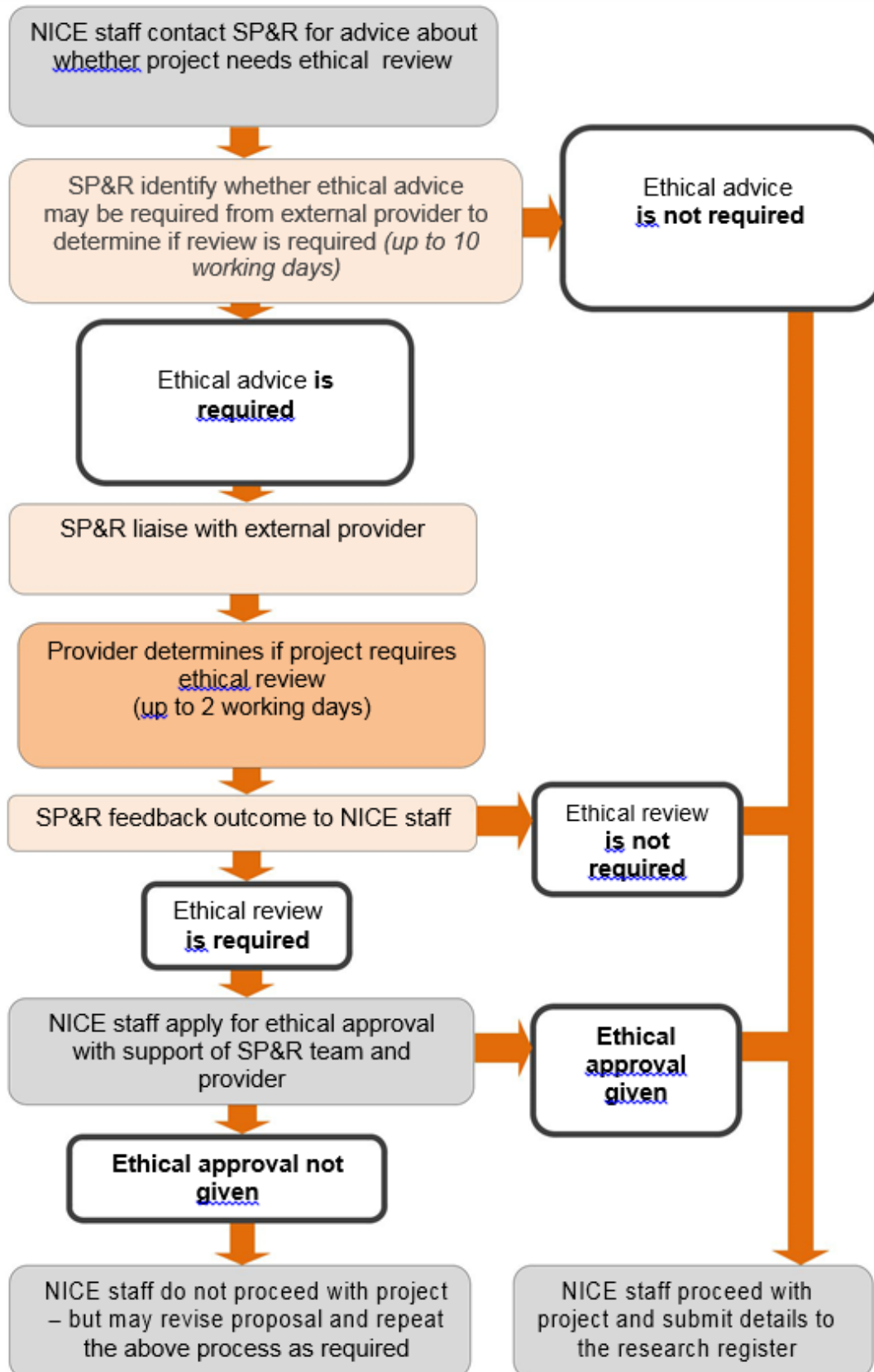
### ***Research malpractice***

61. There have been a number of instances where the results of research activities have been falsified for personal or financial gain. The [UK Research Integrity Office](#) is an independent body that provides expert advice and guidance about the conduct of research. Research misconduct is addressed through a number of mechanisms. Professional groups are subject to disciplinary action by their professional bodies. The organisation [NHS Counter Fraud Authority](#) has overall responsibility for fraud and other unlawful activities within NHS.



## Appendix B - Ethical review: process and key terms

Figure 1: Process for seeking ethical review of a project



**Ethical approval** – Once reviewed by an ethics committee and a research project is deemed to have minimised risk to participants and is ethical, approval will be given by the committee and a letter sent to the lead researcher confirming this.

**Ethical advice** – Prior to any approval, ethical advice maybe sought from an ethics expert about any potential ethical issues associated with a research project and any relevant approvals that maybe required for a research project.

**Ethics Committee** - a committee that has been formally designated to approve, monitor, and review biomedical and behavioural research involving humans. They often conduct some form of risk-benefit analysis in an attempt to determine whether or not research should be done.

They can consist of up to 18 members, a proportion of which are lay (broadly, this means their main professional interest is not in a research area, nor are they a registered healthcare professional). The number one priority of Ethics Committee's is to protect human subjects from physical or psychological harm. Within the NHS, ethics committees are referred to as Research Ethics Committees (RECs) and outside of the NHS can be known as Institutional Review Boards (IRB), Ethical Review Boards or Committees for the Protection of Human Subjects.

**Ethical opinion** – Once a research project has been reviewed by an ethics committee, an ethical opinion will be given. This can be approval for the project to go ahead, conditional approval whereby minor alterations will be requested before approval will be given or the project maybe rejected if it is considered to be unethical.

**Ethical review** – The process whereby an ethics committee assess any ethical issues associated with a research project prior to giving their approval.

**Informed Consent** - a legal procedure to ensure that a patient, client, and research participants are aware of all the potential risks and costs involved in a treatment or procedure. The elements of informed consent include informing the client of the nature of the treatment, possible alternative treatments, and the potential risks and benefits of the treatment. In order for informed consent to be considered valid, the client must be competent and the consent should be given voluntarily.

**No ethical requirement** – A project that doesn't have ethical issues is deemed to have no ethical requirement and therefore does not require any ethical approval prior to commencement. Initial ethical advice should be sought in order to determine this status.

## Appendix C - Version Control Sheet

Version	Date	Author	Replaces	Comment
1.1	October 2013	Sarah Garner	July 2013	Minor amendments for clarification following staff briefings. Updated diagrams.
1.2	August 2014	Sarah Garner	October 2013	Minor amendments for clarification following implementation.
1.3	June 2015	Ian Wall	August 2014	Replaced references to 'R&D' team with 'SP&R', in line with the change in team name
2.0	December 2018	Pall Jonsson	June 2015	Updated references for national legislation, policy and best practice Greater clarification of NICE's research remit Reorganisation of the document structure to make it easier for staff to use General format improvements, in line with the NICE style guide