Research governance policy

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<td>Date effective from</td>
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<td>Review date</td>
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**Scope**

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 agency to work for NICE
- secondees (those who are seconded to NICE from other organisations)
- individuals undertaking placements at NICE

**Review**

This policy will be reviewed every three years.

**Related policies**

- Data Protection
- Disciplinary
- Complaints
- Information governance
- Freedom of Information
- Placement
- Records management
- Risk management

**Summary**

1. Research governance can be defined as the broad range of regulations, principles and standards of good practice that ensure high quality research.
2. The aim of this policy is to ensure that research activities undertaken by NICE comply with national legislation and research governance policies. This policy applies to all types of research activities that NICE staff participate in and commission including those undertaken as part of a placement at NICE.

3. The NICE research governance policy:
   - Describes the relevant national legislation and policies that apply to research and other activities such as audits, service evaluation and literature reviews
   - Sets out the Institute’s research governance framework and describes the process by which it is implemented
   - Defines the roles and responsibilities of NICE staff involved in research and other activities. The primary focus of national legislation and research governance policies is to protect patients involved in clinical research. NICE’s current research remit does not extend to staff involvement in clinical research. As a consequence some of the existing legislation and practices have been re-interpreted and adapted.
   - Has been structured to ensure the NICE governance requirements are proportionate to the underlying risk associated with the proposed activity.

4. The type of governance arrangement required is dependent on the level of staff involvement and this policy describes the requirement in each case.

5. There are no additional governance requirements for any research undertaken as a routine part of guidance development activities that follows the relevant published process and methods manuals. For example a systematic review or field study.
6. NICE’s Science Policy & Research (SP&R) Programme is responsible for developing NICE’s research governance policy, providing advice on its implementation and managing the research register, the central database recording detail of research activity in NICE. The team is also responsible for managing a service level agreement with a third party which provides NICE with ethical advice and ethical opinion on research projects and whether good clinical or research practice training is required for specific projects.

7. The individual teams at NICE are responsible for ensuring that all research and other activities undertaken by their staff meet the requirements of this policy. This includes responsibility for all correspondence with any external organisations that:

   - NICE commissions to conduct research
   - NICE works with as a partner or co-applicant
   - request NICE to participate as a research subject, or

8. request NICE to provide a letter of support. 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 is held by the staff member. The governance arrangements 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 time¹.

Introduction

9. Most definitions of the term ‘research’ focus on the derivation of generalisable new knowledge through a process involving clearly defined questions and systematic and rigorous methods. The term is also used to refer to a broader range of related activities such as service evaluation, audit and literature reviews. Definitions have been developed by the National Research Ethics Service (Appendix A) to help researchers identify whether they need to submit the project for ethical opinion. In practice, it is often difficult to distinguish between projects in this way and the terms do not cover all of the activity undertaken at NICE, for example research involving analysis of secondary data and primary data collection through survey and interview methods.

10. 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 (please see Appendix B for examples of ‘high risk’ research activities). Research activities can also be resource-intensive and associated with opportunity costs. The research therefore needs to be appropriately managed to ensure it achieves its objectives.

11. In addition to the research activity related to the development of standards, guidance and advice, NICE staff undertake and commission research activities, and participate in external projects. These activities contribute to the development of processes and methods and support the continuous development of NICEs products and services. NICEs products, processes and methods are also the subject of research and staff are invited to take part in external projects.

12. In undertaking these activities NICE staff act in a range of capacities that are associated with different responsibilities that have practical and legal implications. Importantly, NICE and its staff
do not directly fund or undertake clinical trials and in this context NICE does not act in the capacity of a ‘sponsor’, of clinical research as defined by the Medicines for Human Use (Clinical Trials) Regulations 2004\(^2\) and national governance frameworks.

**National legislation and policies**

13. Research governance requirements are defined by a range of national legislation and policies, professional codes and statements of practice. These are briefly summarised below. For further information please see:

- The NHS Health Research Authority website\(^3\)
- The Market Research Society (MRS) code of conduct.\(^4\)
- The Statement of Ethical Practice for the British Sociological Association\(^5\)
- The Economic and Social Research Council’s Research Ethics Framework\(^6\)
- Mental Capacity Act 2005\(^7\)
- Human Tissue Act 2004\(^8\)

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\(^3\) [http://www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/](http://www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/)

\(^4\) [https://www.mrs.org.uk/standards/code_of_conduct/](https://www.mrs.org.uk/standards/code_of_conduct/)

\(^5\) [http://www.britsoc.co.uk/about/equality/statement-of-ethical-practice.aspx](http://www.britsoc.co.uk/about/equality/statement-of-ethical-practice.aspx)

\(^6\) [http://www.esrc.ac.uk/about-esrc/information/research-ethics.aspx](http://www.esrc.ac.uk/about-esrc/information/research-ethics.aspx)


**Statutory responsibilities**

14. 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. NICE supports the purpose of the duty and is committed to providing an environment that supports the production of high quality research by its staff.

15. The Department of Health's (DH) Research Governance Framework for Health and Social Care (2005) defines the governance arrangements for all research within the remit of the Secretary of State for Health. This includes those activities undertaken in or by DH’s non-departmental public bodies and the NHS and social care agencies. The DH framework applies to the full range of research types, contexts and methods with the aim of promoting improvements in research quality. The framework describes legislation on clinical trials involving medicine and general principles of good practice for all types of research. The framework encompasses five domains: ethics; science; information; health, safety and employment; and finance.

16. The Market Research Society (MRS) is the professional organisation for market, social and opinion research and business intelligence, market analysis, customer insight and consultancy. All members of MRS must comply with the MRS Code of Conduct which provides a professional standards governance framework including legal and ethical requirements.

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Protecting research participants (ethics)

17. Research 'ethics' refers to the moral principles guiding all aspects of research, from its inception through to completion and publication of results and beyond.\(^\text{12}\)

18. The key ethical principles of research to be addressed are as follows:

- Research should be designed, reviewed and undertaken to ensure integrity, quality and transparency.
- Research staff and participants must normally be informed fully about the purpose, methods and intended possible uses of the research, what their participation in the research entails and what risks, if any, are involved.
- The confidentiality of information supplied by research participants and the anonymity of respondents must be respected.
- Research participants must take part voluntarily, free from any coercion.
- Harm to research participants and researchers must be avoided in all instances.
- The independence of research must be clear, and any conflicts of interest or partiality must be explicit.

19. Ethical review, , is one of a series of safeguards intended to protect all research participants and researchers. The requirements for research being undertaken in the NHS are set out in a series of documents and guidance that can be found on the website of the National Research Ethics Service (NRES).\(^\text{13}\). The ethical principles also apply to research that is being undertaken outside of the NHS.

\(^\text{12}\) [www.gold.ac.uk/media/ESRC_Re_Ethics_Frame_tcm6-11291.pdf](http://www.gold.ac.uk/media/ESRC_Re_Ethics_Frame_tcm6-11291.pdf)
for example in a university setting, and each institution is responsible for establishing appropriate mechanisms.

20. Within the NHS, all research that involves patients, their organs (under the provision of the Human Tissue Act (HTA)), or their data must have a favourable opinion from a NRES research ethics committee (REC) before it can begin. Not all non-clinical research or other activities such as audit and service evaluation will require full ethical review by NRES. However, all proposals need to be considered by an experienced individual to ensure that those that need a full ethical review are identified, for example those that involve collecting personally identifiable data.

21. Research within the social care setting may need to be reviewed by the Social Care Research Ethics Committee [http://www.scie.org.uk/research/ethics-committee/reviews.asp](http://www.scie.org.uk/research/ethics-committee/reviews.asp)

22. Ethical review is not required for the following activities because they involve data that are already in the public domain

- literature reviews
- Secondary analysis of existing anonymised data within the terms of the agreement under which those data were obtained or supplied.

Roles and responsibilities

23. The Department of Health’s (DH) Research Governance Framework for Health and Social Care (2005) and other legislation allocate governance responsibilities using specific terms for the main people and organisations involved in a project.

24. 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.

25. The term 'sponsor' is defined by the Medicines for Human Use (Clinical Trials) Regulations 2004\(^\text{14}\). The Department of Health’s (DH) Research Governance Framework for Health and Social Care (2005) also uses the term in the context of all health and social care research. The designated sponsor(s) take legal responsibility for ensuring that any research complies with the appropriate legislation and policy (to include research governance, ethics and health and safety) and that the necessary insurance is in place. In practice, the sponsor is usually the employing organisation of the main researcher but the responsibilities can be transferred by mutual agreement, for example to an external research funder. The sponsor could also be individuals, or groups of individuals/organisations providing the responsibilities are explicitly allocated. The organisation that takes on the sponsorship of a project must ensure that the appropriate governance mechanisms are in place before the research begins.

26. The employing organisation of researchers is liable for the work of those employees and the management of any funds received under contract with a research funder. Other responsibilities include:

- Putting in place the protocols and to ensure that the relevant research governance framework is adhered to.

- Ensuring that researchers understand and discharge their responsibilities including providing training and supervision.

- Ensuring that studies are managed, monitored and reported according to the agreed protocol.

• Taking action if misconduct or fraud is suspected.

27. The person who takes overall responsibility for the design, conduct and reporting of the study and ensures it meets the requirements of the relevant governance framework is usually termed the principal, chief or main investigator. National research funders require a designated principal investigator and this role carries with it a set of legal and financial responsibilities. In general, these responsibilities are greater for clinical research due to the risks involved.

Research malpractice

28. 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. Under the (MRS) disciplinary regulations disciplinary action may be taken, including membership withdrawal, if a member is deemed guilty of unprofessional conduct. The organisation NHS Protect has overall responsibility for fraud and other unlawful activities within NHS.

Methodological review

29. 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

15 http://www.ukrio.org/
16 http://www.nhsbsa.nhs.uk/Protect.aspx
programme or a controversial or costly proposal. In others, for example a literature review, a colleague with appropriate expertise may suffice.

30. 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.

**Information governance**

31. Researchers must ensure the appropriate use and confidentiality of any information that is collected, particularly in circumstances where data are personally identifiable. Most organisations, including NICE, have an information governance policy that covers this requirement\(^\text{17}\).

32. Data collected in the course of the project must be retained for an appropriate period to support monitoring by regulatory and other authorities. Most organisations, including NICE, have a records management policy that covers this requirement\(^\text{18}\).

33. It is good research practice to ensure that the protocols are made available and any subsequent variations are transparent and explained. For this purpose international registers, for example the clinical trials register, ClinicalTrials.gov\(^\text{19}\), have been established for randomised controlled trials (RCTs) and other study designs. It is good practice to register systematic reviews on the international prospective register of systematic reviews (PROSPERO)\(^\text{20}\). For research in the social sciences and humanities consider the UK

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\(^\text{17}\) [http://intranet.nice.org.uk/NICEAndNicePeople/governance/informationgovernancenew.cfm](http://intranet.nice.org.uk/NICEAndNicePeople/governance/informationgovernancenew.cfm)

\(^\text{18}\) [http://intranet.nice.org.uk/NICEAndNicePeople/governance/recordsmanagement.cfm](http://intranet.nice.org.uk/NICEAndNicePeople/governance/recordsmanagement.cfm)

\(^\text{19}\) [http://clinicaltrials.gov/](http://clinicaltrials.gov/)

\(^\text{20}\) [http://www.crd.york.ac.uk/PROSPERO/](http://www.crd.york.ac.uk/PROSPERO/)
Data Archive\textsuperscript{21} 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.

34. In line with NHS organisations, NICE is required to have a Caldicott Guardian. This is a senior person who is responsible for protecting the confidentiality of patient and service-user information and enabling appropriate information-sharing\textsuperscript{22}. The Caldicott Guardian for NICE can be contacted through the corporate office (NICECorporateOffice@nice.org.uk)

**Involvement of service users or the public**

35. Relevant service users and carers, or their representative groups, should be involved wherever possible in the design, conduct, analysis and reporting of research. Not all research activities, for example literature reviews, may require this.

36. 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\textsuperscript{23}. The NIHR Central Commissioning Facility has established a Patient and Public Involvement (PPI) policy\textsuperscript{24}.

\textsuperscript{21} http://www.data-archive.ac.uk/
\textsuperscript{22} Health Service Circular: HSC 1999/012 and Local Authority Circular: LAC 2002/2.
\textsuperscript{23} http://www.invo.org.uk/
\textsuperscript{24} http://www.ccf.nihr.ac.uk/PPI/Pages/default.aspx
Expertise and Good Clinical Practice

37. 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.

38. 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.

39. The MRS Code of Practice states that researchers must ensure that their professional activities are conducted by persons with appropriate training, qualifications and experience\(^\text{25}\).

NICE Research Governance Framework

This section of the policy describes the research governance arrangements for research, audit, service evaluation and literature reviews.

40. The research governance arrangements have been developed to be proportionate to the risks involved with type of project being undertaken (Appendix A) and the role of NICE and its staff. The policy has been structured with the assumption that NICE staff do not participate in clinical research and NICE does not act as the sponsor of clinical research (For definition see Appendix D).

41. There are no additional research governance requirements for any research undertaken as part of guidance development that follows the relevant published process and methods manuals. This is because those processes and methods already meet the requirements of this policy including the publication of protocols and outputs on the NICE website.

42. For non-clinical projects undertaken internally, NICE acts as both the employing organisation and research sponsor, with staff sometimes acting as the principal investigator. Due to the lower risk associated with commissioning non-clinical research projects and undertaking activities defined as audit, market research, service evaluation and literature reviews, the existing national legislation and policies have been adapted for the purposes of the NICE Research Governance Policy. However it is good governance practice to identify any potential risks when projects are being planned. If any risks are identified, the teams/centres are responsible for notifying the corporate office and SP&R to ensure the appropriate arrangements are in place to manage those risks. This may include a discussion with the Senior Management Team.
43. NICE has both a Data Protection Policy\textsuperscript{26} and Information Governance policy\textsuperscript{27}. An appropriate data protection statement must be used whenever personal data is collected, for example on paper copies or online. This data should be kept confidential and protective marking used with secure arrangements for any data transfer. All data collected during a project must be retained for an appropriate period and securely destroyed when no longer required. Departmental information asset registers should include details of whether the team holds any research data.

44. The SP&R team at NICE are responsible for the Research Governance Framework and can provide advice on its interpretation. The responsibility for ensuring that any project meets the relevant governance requirements set out in this policy rests with the relevant Senior Management Team (SMT)-level Director.

\textbf{Essentials}

45. For research projects within the scope of this policy, the project proposal should be reviewed by the relevant Associate Director or Programme Director before submission to the SMT-level Director for approval. SMT should be notified of any atypical or high-risk research projects to ensure the necessary corporate governance mechanisms are followed.

46. Research proposals should also be reviewed by an individual with methodological expertise (paragraph 29) and consideration given as to whether service user/public participation is required (paragraph 36). Advice is available from NICE’s SP&R team and Public Involvement Programme.

\textsuperscript{26} http://intranet.nice.org.uk/media/EB2/42/DataProtectionPolicyApril2013.pdf
\textsuperscript{27} http://intranet.nice.org.uk/media/67A/6C/InformationGovernanceFinal.pdf
47. The individual’s line-manager must agree participation in the research and ensure that the individual/directorate has the skills/capacity to provide the required input.

48. The teams should consider any risks involved in the project, for example the collection of personally identifiable data or sensitive information and ensure that those risks are managed. For interviews, a process of informed consent should be developed and permission (without coercion) obtained for any recording of interviews. The nature of the process will depend on the risks involved with the research and advice is available from NICE’s SP&R Team. For example informed consent can be given via email in some circumstances such as interviews with professional colleagues.

49. Where appropriate, a favourable ethical opinion or notice of no ethical requirement should be obtained (Figure 2). Due to the non-clinical nature of the research activity undertaken at NICE it is anticipated that very few projects will require review by an ethical committee. However good research governance indicates that all ‘research’ projects involving human participants need to be considered by a person with the appropriate expertise. Activities such as audit and service evaluation may require ethical review if they involve the collection of personally identifiable data. NICE has established a service level agreement with an external organisation to provide 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).

50. For projects involving NICE staff that require resourcing through an external budget, early advice from NICE’s finance department²⁸

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²⁸ [http://intranet.nice.org.uk/NICEAndNicePeople/CentresDirectorates/planningandresources.cfm](http://intranet.nice.org.uk/NICEAndNicePeople/CentresDirectorates/planningandresources.cfm)
should be obtained to ensure that all relevant staff time and overhead charges have been considered.

51. The SP&R team maintains a central ‘research register’ that is accessible via the intranet. To facilitate cross-institute communication and meet the governance requirements relating to transparency details of all active research projects covered within the scope of this policy must be entered into the research register as soon as the project has started. Entries should be updated at least annually and when key milestones have been met. It is good practice to also submit details of clinical research protocols to an appropriate external register (where applicable)(paragraph 33).

52. NICEs 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 placed on the NICE website and/or incorporated into routine reporting activities. 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. ²⁹

53. If a project uses data that has been obtained from a third party (for example the Health and Social Care Information Centre (HSCIC)), staff must ensure that the terms of that data access are adhered to. For example such data usually cannot be shared with a third party unless by prior agreement. Advice can be obtained from NICEs Governance Manager or Caldicott Guardian via the Corporate office. ³⁰

²⁹ http://intranet.nice.org.uk/NICEAndNicePeople /CentresDirectorates/CorporateOffice .cfm
54. The results of research activities should be reviewed by an individual with the appropriate methodological expertise and discussed with the Associate Director and/or Programme Director prior to consideration for publication or submission to a journal. This is to ensure that there is a senior departmental sponsor for publication and appropriate interpretation and communication of results.

55. 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’.

56. Any allegations of research misconduct will be dealt with according to NICE’s disciplinary policy and procedure and may be referred to the appropriate professional body where applicable. E.g. Market Research Society.

Additional requirements

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

57. 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 is responsible for ensuring that the research activity is fit for purpose.

58. As the commissioner of the project NICE will not normally assume legal responsibility for the research project. Therefore the NICE commissioner must ensure that the legal and other relevant

http://intranet.nice.org.uk/HRAndStaffBenefits/NICEPoliciesAD.cfm
research responsibilities are transferred to the provider. The NICE team/directorate 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 principal investigator or co-applicant**

59. The employing organisation of the principal investigator is usually the sponsor of the project and takes on the legal and other responsibilities. The NICE applicant is required to ensure that these responsibilities are transferred to a partner organisation with the necessary infrastructure. This transfer should be agreed and documented.

60. The proposal to participate as a principal investigator or co-applicant must be approved by the SMT-level Director.

61. The decision to participate as a co-applicant should be based on the following considerations:

- 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.
- The resource consequences of participating in the project are, at a minimum, neutral.
- Time for NICE staff is costed into the proposal.
- 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.
Participation in projects undertaken by external organisations (including Universities)

62. For these projects, NICE and its activities is usually the subject of the research. The external organisation will be the sponsor of the project and takes on the legal and other responsibilities.

63. The proposal to participate must be considered by the team or department responsible for the area of NICEs work that is the proposed subject for the research and submitted to their SMT-level Director for approval.

64. 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. For advisory bodies, consent will need to be obtained individually from all members who take part in the research.
- NICE can review results and comment on them before they are made available in public.

Projects where NICE has been requested to provide a letter of support for an external research project

65. Letters of support are normally requested in order to help support an application for funding. The decision to provide a letter of support
or sit on an advisory group for an external research project must be approved by the SMT-level Director.

66. The decision of whether or not support is given should be based on the following considerations:

- The research methods are reasonable. This will require a review of the research proposal.
- 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.

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

67. The decision to sit on an advisory group for an external research project must be approved by the SMT-level Director.

68. 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.
- The ongoing support requirements, for example staff time, have been established and agreed.
Figure 1: NICE Research Governance Framework

Description of research governance arrangements at NICE for research, audit, service evaluation and literature reviews.

Is the type of project associated with risks? (see Appendix A: types of project)

Does the project involve human participants and potentially require research ethics review?

Does the project meet all the requirements in the ‘Essential’ Section of the policy? (paragraphs 45 to 56)

Are there any ‘Additional Requirements’ associated with the project? (paragraphs 57 to 68)

Complete the data submission form for the research register

Update the research register annually and on project completion
Figure 2 Process for seeking ethical review of a project

NICE staff contact SP&R for advice about whether project needs ethical review

SP&R identify whether ethical advice may be required from external provider to determine if review is required (up to 10 working days)

Ethical advice is not required

Ethical advice is required

SP&R liaise with external provider

Provider determines if project requires ethical review (up to 2 working days)

Ethical review is not required

Ethical review is required

SP&R feedback outcome to NICE staff

NICE staff apply for ethical approval with support of SP&R team and provider

Ethical approval not given

NICE staff do not proceed with project – but may revise proposal and repeat the above process as required

Ethical approval given

NICE staff proceed with project and submit details to the research register

NICE staff proceed with project and submit details to the research register
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<tr>
<th>Research</th>
<th>Service Evaluation</th>
<th>Audit</th>
<th>Literature Review</th>
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<tr>
<td>The attempt to derive generalisable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.</td>
<td>Designed and conducted solely to define or judge current care service or product.</td>
<td>Designed and conducted to produce information to inform delivery of best care.</td>
<td>Designed and conducted to produce information on current practice and to manage outbreaks</td>
</tr>
<tr>
<td>Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.</td>
<td>Designed to answer: “What standard does this service achieve?”</td>
<td>Designed to answer: “Does this service reach a Predetermined standard?”</td>
<td>Designed to answer: “What is currently known about this service? Or What is the current practice?” Or What is the cause of this outbreak?</td>
</tr>
<tr>
<td>Addresses clearly defined questions, aims and objectives.</td>
<td>Measures current service without reference to a standard.</td>
<td>Measures against a standard.</td>
<td>Determines current practice and utilises systematic statistical measures</td>
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<td>Quantitative research – may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced.</td>
<td>Involves an intervention/service in use.</td>
<td>Involves an intervention/service in use.</td>
<td>May involve an intervention/service</td>
</tr>
<tr>
<td>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.</td>
<td>Usually involves analysis of existing data but may include administration of interview or questionnaire.</td>
<td>Usually involves analysis of existing data but may include administration of simple interview or questionnaire.</td>
<td>May involve analysis of existing anonymised data. Does not involve interviews or questionnaires</td>
</tr>
<tr>
<td>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.</td>
<td>The intervention/service to be evaluated is identified prior to the service evaluation.</td>
<td>The intervention/service to be evaluated is identified prior to the audit.</td>
<td>No allocation to intervention OR might not involve an intervention</td>
</tr>
<tr>
<td>May involve randomisation.</td>
<td>No randomisation.</td>
<td>No randomisation.</td>
<td>No randomisation</td>
</tr>
<tr>
<td>Requires ethical opinion</td>
<td>May require ethical opinion</td>
<td>May require ethical opinion outside the NHS</td>
<td>Does not usually require ethical opinion</td>
</tr>
</tbody>
</table>

*Table taken from NRES – Defining Research Leaflet April 2013
Appendix A – Project type definitions

**Research**

- Research projects can be defined as those ‘Projects that attempt to derive generalisable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them’[^31].
- Within the NHS, no study classified as ‘research’ that involves patients, their organs, or their data may begin until it has a favourable opinion from NRES or the Social Care REC. Not all types of research conducted in the NHS will require full ethical review but all ‘research’ proposals should be considered by an experienced individual to ensure that those that need an ethical review are identified. Research conducted outside of the NHS and involving human participants should also be considered for whether it requires research ethical review.

**Service Evaluation**

- Service evaluation projects, including service development and quality improvement projects, can be defined as a project which is ‘designed and conducted solely to define or judge current care’[^32]. For NICE, this could also include evaluations of the services it provides to NICE staff, stakeholders and external audiences. These projects are designed to answer “What standard does this service achieve?” and measures current service without reference to a standard. These projects usually do not need an ethical opinion, however if these projects involve collecting personally identifiable data, then there may be a need to obtain a favourable ethical opinion.

**Audit**

- Audit can be defined as a project which is ‘designed and conducted to produce information to inform delivery of best care’[^33]. These projects usually do not need an ethical opinion through NRES, although they may involve data collection via surveys and require ethical review through alternative arrangements. In the NHS Multi-centre audits where data is collated off-site may need a favourable ethical opinion by NRES to ensure data confidentiality when data is transferred across sites.

**Literature Reviews**

- Literature reviews and the use of anonymous data sets already in the public domain do not require an ethical opinion. A literature review is a text written by someone to consider the critical points of current knowledge including substantive findings, as well as theoretical and methodological contributions to a particular topic. Literature reviews are secondary sources, and as such, do not report any new or original

[^31]: [http://www.nres.nhs.uk/applications/is-your-project-research/](http://www.nres.nhs.uk/applications/is-your-project-research/)
[^32]: [http://www.nres.nhs.uk/applications/is-your-project-research/](http://www.nres.nhs.uk/applications/is-your-project-research/)
[^33]: [www.nice.org.uk/media/796/23/BestPracticeClinicalAudit.pdf](www.nice.org.uk/media/796/23/BestPracticeClinicalAudit.pdf)
experimental work. These projects are designed and conducted to produce information on current practice and are designed to answer “What is currently known about this topic?” They do not require an ethical opinion.
Appendix B – High risk research

Research may be defined as high risk which involves the following:

- Particularly vulnerable participants
- Infants and children under 18 years of age;
- People with physiological and/or psychological impairments and/or learning difficulties;
- People dependent on the protection or under the control/influence of others (e.g. children, pupils, people in care, young offenders, prisoners);
- Relatives of sick people (e.g. parents of sick children);
- People who may only have a basic or elementary knowledge of English.

Highly sensitive topics

- Race, ethnicity, political opinion, religious beliefs/other beliefs of a similar nature, physical or mental health or condition, sexual life;
- Abuse (child, adult); nudity; obesity;
- People affected by conflict situations (e.g. ethnic, religious, tribal conflicts/wars).
- Covert observation
## Appendix C - Version Control Sheet

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Author</th>
<th>Replaces</th>
<th>Comment</th>
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<tr>
<td>1.1</td>
<td>October 2013</td>
<td>Sarah Garner</td>
<td>July 2013</td>
<td>Minor amendments for clarification following staff briefings. Updated diagrams.</td>
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<tr>
<td>1.2</td>
<td>August 2014</td>
<td>Sarah Garner</td>
<td>October 2013</td>
<td>Minor amendments for clarification following implementation.</td>
</tr>
<tr>
<td>1.3</td>
<td>June 2015</td>
<td>Ian Wall</td>
<td>August 2014</td>
<td>Replaced references to 'R&amp;D' team with 'SP&amp;R', in line with the change in team name</td>
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</tbody>
</table>
Appendix D – Glossary

Caldicott Guardian - A Caldicott Guardian is a senior person responsible for protecting the confidentiality of a patient and service-user information and enabling appropriate information-sharing. Each NHS organisation including the Department of Health and associated agencies is required to have a Caldicott Guardian.

Clinical Trials Registration – A process of logging details of a clinical trial to ensure that essential details are made public from its inception, rather than publication many years later.

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.

**Good Clinical Practice (GCP) training** – GCP is the standard and guidelines that all research must be conducted to. Researchers of high risk clinical trials must have completed GCP training to ensure they are best prepared to carry out their duties.

**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.

**Low risk research** - Research where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily lives of the general population or during the performance of routine physical or psychological examinations or tests.

**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.

**Peer Review** - The evaluation of work by one or more people of similar competence to the producers of the work (peers). It constitutes a form of self-regulation by qualified members of a profession within the relevant field.

**PROSPERO** - PROSPERO is an international database of prospectively registered systematic reviews in health and social care. Key features from the review protocol are recorded and maintained as a permanent record. PROSPERO aims to provide a comprehensive listing of systematic reviews registered at inception to help avoid unplanned duplication and enable comparison of reported review findings with what was planned in the protocol.
**Protocol / Proposal** - a document written by a researcher that provides a description of the proposed project.

**Research ‘ethics’** – Research ethics refers to the moral principles guiding all aspects of research, from its inception through to completion and publication of results and beyond.

**Research Governance** - the broad range of regulations, principles and standards of good practice that exist to achieve, and continuously improve, research quality across all aspects of healthcare in the UK and worldwide.

**Research Register** – the central database which records projects falling within NICEs Research Governance policy.

**Risk (in the context of research)** - The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. See Appendix B for a list of examples of high risk research topics.

**Sponsor** - A Sponsor is the organisation legally responsible for a project's administration and management. 'Sponsor' does not mean the same as 'funder'