ANTHONY NOLAN

Saving lives through stem cells

RESEARCH GOVERNANCE & INTEGRITY POLICY

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1 INTRODUCTION

1.1 Research is essential to unlock new ways to treat every patient. Anthony Nolan undertakes and funds research and may support external projects that are led by others.

1.2 Research can involve an element of risk, both in terms of return on investment (i.e. the new knowledge gained from the study might not warrant the monies, time and effort invested), and sometimes for the safety and well-being of the research participants. Appropriate governance of research is essential to safeguard the confidence in, and benefit from, quality research.

1.3 Research governance is the broad range of regulations, principles and standards of good practice that ensure compliance and continuously improve quality research. Governance helps research to meet high scientific and ethical standards, and have transparent decision-making processes, clear allocation of responsibilities and robust monitoring arrangements.

1.4 Research integrity is the conduct of research in ways that promote trust and confidence in all aspects of the research process. All research, throughout its whole lifecycle, as well as research environments and systems, should safeguard good research practice and research integrity.

1.5 The aim of this policy is to ensure Anthony Nolan's research activities comply with national legislation, responsible research conduct and research governance policies/guidance. It:

Defines the roles and responsibilities of Anthony Nolan staff and boards involved in research activities.

Sets out Anthony Nolan's Research Governance and Integrity Framework and describes the process by which it is implemented.

Outlines a framework to ensure that all aspects of research, from project proposals to publication and dissemination of results, are conducted, managed, and funded in accordance with good research practice.

Provides information about relevant national legislation and policies that apply to research.

2 PURPOSE

2.1 This document sets out the policy for the governance of research activity in Anthony Nolan. The principles and guidelines have been developed to ensure that all staff, investigators, and Anthony Nolan itself, conform to the requirements of research governance and good research practice.

2.2 There are many documents and resources that govern the conduct of research (see Section 8 and Appendix 9.1). The purpose of this policy is not to replicate the contents of

those documents but to describe the principles of the framework necessary for the management and conduct of research within Anthony Nolan.

2.3 This policy has been developed to ensure that it meets best practice and adheres to the relevant international and national regulations, standards, guidance, safeguards, and laws at all times.

2.4 The policy sets out Anthony Nolan's position on how researchers and research communities are expected to maintain good research conduct and support research integrity.

3 DEFINITIONS

3.1 Anthony Nolan adopts the best practices of the UK Policy Framework for Health and Social Care Research which defines research as:

> *The attempt to derive generalisable or transferable new (Including new knowledge about existing treatments or care) knowledge to answer or refine relevant questions with scientifically sound methods.*
>
> This excludes audits of practice and service evaluations. It includes activities that are carried out in preparation for or as a consequence of the interventional part (This means the part of the research where a change in treatment, care or other services is made for the purpose of the research. It does not refer to other methodological 'interventions', e.g. issuing a postal survey) of the research, such as screening potential participants for eligibility, obtaining participants' consent and publishing results. It also includes non-interventional health and social care research (i.e. projects that do not involve any change in standard treatment, care or other services), projects that aim to generate hypotheses, methodological research and descriptive research.
>
> Projects whose primary purpose is educational to the researcher, either in obtaining an educational qualification or in otherwise acquiring research skills, but which also fall into the definition of research, are in scope of this policy framework.

Activities that are not research according to this definition should not be presented as research and need not be conducted or managed in accordance with this framework. A decision tool that provides a definitive answer about whether a project counts as research under this policy framework is available at the HRA decisions tool. (See Appendix 9.2)

3.2 Research Integrity is about doing research that not only leads to findings and outcomes that people can trust, and have confidence in, but is carried out in an ethical manner with care and respect for those involved in the process. (UK Committee on Research Integrity, https://ukcori.org/wp-content/uploads/2023/02/UK-Committee-on-Research-Integrity-Strategic-Plan.pdf).

3.3 Research Misconduct: UKRIO defines misconduct in research as including, but not limited to:

a. Fabrication;
b. Falsification;
c. Misrepresentation of data and/or interests and/or involvement;
d. Plagiarism; and

e. Failures to follow accepted procedures or to exercise due care in carrying out responsibilities for:
   (i) avoiding unreasonable risk or harm to humans; animals used in research; and the environment; and
   (ii) the proper handling of privileged or private information on individuals collected during the research.

3.4 Researcher refers to any person who conducts research, including but not limited to as an employee; an independent contractor or consultant; research student; a visiting member of staff; or a member of staff on a joint clinical or honorary contract. It also includes a principal investigator for a research project in partnership with Anthony Nolan.

3.5 Sponsor: the individual or organisation that takes on responsibility for confirming there are proper arrangements to initiate, manage, monitor, and finance a project.

4 SCOPE

4.1 The policy applies to the following in their capacity of working at or for Anthony Nolan:

All Anthony Nolan employees and their students (including staff on secondment to other organisations)

Individuals holding an honorary contract with Anthony Nolan

Any other individual undertaking research, or providing services for research, for or in partnership with Anthony Nolan

4.2 Research that is sponsored, hosted. conducted and managed by, or in partnership with, Anthony Nolan is governed by this policy. This includes research conducted by any person employed by Anthony Nolan or their students, and those external to Anthony Nolan wanting to undertake research within. This policy does not apply to research that Anthony Nolan provides a service to, for example where Anthony Nolan provides donor material to an external organisation for use in their research.

4.3 Anthony Nolan defines research as stated in Section 3.1. Research at Anthony Nolan must also support and align with the organisational and research strategies, and the Anthony Nolan charitable objects.

4.4 Researchers are expected to refer to Section 3.1 and 4.2 when determining whether a project should be defined as research for ethical and governance-related purposes. In some cases, the work will not conform to the above research definitions (3.1) but will however be subject to the terms of this policy.

4.5 There are some activities, although similar to research in some respects and sometimes referred to as ‘research’, that are not classed as research by Anthony Nolan and, therefore, are not subject to the provisions of this policy. The most common of these activities are Service Development and Audit.

4.6 This policy applies to all research employing any methodologies, regardless of funding mechanisms, including:

4.6.1 Externally funded research

4.6.2 Internally funded research: research for which Anthony Nolan facilities, staff time and/or allocated funding is provided and used.

4.6.3 A combination of externally and internally funded research

4.6.4 Research that is delivered in partnership with Anthony Nolan (AN may or may not receive funds for any service costs in relation to the partnership)

4.7 This policy applies to research being undertaken for undergraduate and postgraduate qualifications. For research projects that are not directly related to a staff member's role (e.g. PhD or MSc as part of an honorary position), the governance arrangements for these activities also need to meet the requirements of the organisation that is supervising the research.

5 ROLES AND RESPONSIBILITIES

5.1 Chief Medical and Scientific Officer is the senior person at Anthony Nolan who oversees the research principles and positions outlined in this policy.

5.2 Director of Quality and Regulation is the Named Person; the first point of contact for staff members, research participants and members of the public who want more information on matters of research integrity. The Director of Quality and Regulation is also the named point of contact for whistle-blowers or any other person wishing to raise concerns about the rigour or integrity of research in accordance with the concordat.

5.2.1 Details including the name and position of both the individual responsible for overseeing this Policy and the Named Person will be published on Anthony Nolan's website.

5.3 Research Office is responsible for:

5.3.1 Providing central oversight of research at Anthony Nolan.

5.3.2 Promoting and supporting researchers in the delivery of high-quality research, promoting good research practice and conduct, and building research capacity.

5.3.3 Providing advice and signposting on policies and procedures, insurance, indemnity cover, contract advice, legal advice, etc., as needed. In all cases where there is a lack of clarity regarding interpretation of policies, procedures and codes of practice, researchers should contact the Research Office for advice.

5.3.4 Coordinating the implementation of the Research Governance and Integrity Policy, working with other internal and external departments and personnel to achieve the objectives set out in this policy.

5.3.5 Management and administration of the Research Review Board.

5.3.6 Coordinating research project progress reporting (as per SOP DOC6816)

5.4 Research Governance function (Quality & Regulation department)

5.4.1 Authorship of, and assisting with implementation of, the Research Governance and Integrity Policy, working with other internal and external departments and personnel to achieve the objectives set out in this policy.

5.4.2 Ensuring the Research Governance and Integrity Policy is compliant with all applicable regulations and standards.

5.4.3 Providing advice and guidance, in collaboration with the Research Office, to support the development of high-quality research.

5.4.4 Monitoring that research undertaken in Anthony Nolan meets accepted standards of quality. Monitoring and supporting the implementation of research governance processes both within Anthony Nolan and/or as outsourced to any external provider.

5.4.5 Enabling Anthony Nolan's access to expertise for ethical and regulatory advice and opinion on research projects, including whether good clinical or research practice training is required.

5.5 Research Portfolio Group (RPG)

Cross organisational group enabling delivery of Anthony Nolan's research strategy by providing transparency, alignment, and opportunities for collaboration across all research projects.

5.5.1 Providing advice, guidance and feedback on research proposals or ideas and existing research projects from Anthony Nolan researchers.

5.5.2 Form part of a wider governance framework for research.

5.6 Research Review Board (RRB)

5.6.1 Providing independent and expert peer review for research proposals to be completely or partially funded (if appropriate) by Anthony Nolan and providing a recommendation on the suitability of the proposal.

5.6.2 Providing independent and expert peer review for long-term (5+ years) research projects and programmes, funded by Anthony Nolan, and providing a recommendation on the continued suitability and impact of the research.

5.6.3 Providing independent and expert advice for projects in partnership with Anthony Nolan.

5.7 Funding Decision Maker

5.7.1 Considering the recommendations of the RPG and RRB, the Chief Medical & Scientific Officer, in collaboration with the Senior Leadership Team, will make final decisions on the allocation of funding and resources to Anthony Nolan research projects.

5.8 Anthony Nolan staff

5.8.1 Anthony Nolan and all researchers working within it are responsible for ensuring research is conducted in accordance with the principles and standards set out in this Policy.

5.8.2 Any research activities undertaken must meet the requirements of this policy. This includes responsibility for providing details of the research for Anthony Nolan's research portfolio.

5.8.3 Reporting any suspected research misconduct and other irresponsible research practices that undermine the trustworthiness of the research using the Procedure for the Investigation of Misconduct in Research (SOP DOC6767). Reporting potential instances of research misconduct to the Named Person in the first instance and following internal procedures set out in the SOP.

6 DETAILS OF THE RESEARCH GOVERNANCE AND INTEGRITY FRAMEWORK

Research Integrity and research misconduct

6.1 Anthony Nolan is strongly committed to fulfilling the principles of The Concordat To Support Research Integrity (revised October 2019) ("the concordat") in creating a comprehensive framework for responsible research conduct and its governance. The key commitments of the concordat apply to researchers, their employers and funding bodies alike.

6.2 In addition to the organisation's internal values and behaviours, Anthony Nolan is committed to the core elements of research integrity as follows:

- **honesty** in all aspects of research, including in the presentation of research goals, intentions and findings; in reporting on research methods and procedures; in gathering data; in using and acknowledging the work of other researchers; and in conveying valid interpretations and making justifiable claims based on research findings.

- **rigour**, in line with prevailing disciplinary norms and standards, and in performing research and using appropriate methods; in adhering to an agreed protocol where appropriate; in drawing interpretations and conclusions from the research; and in communicating the results.

- **transparency and open communication** in declaring potential competing interests; in the reporting of research data collection methods; in the analysis and interpretation of data; in making research findings widely available, which includes publishing or otherwise sharing negative or null results to recognise their value as part of the research process; and in presenting the work to other researchers and to the public.

- **care and respect** for all participants in research, and for the subjects, users and beneficiaries of research, including humans, animals, the environment and cultural objects. Those engaged with research must also show care and respect for the integrity of the research record.

- **accountability** of funders, employers and researchers to collectively create a research environment in which individuals and organisations are empowered and enabled to own the research process. Those engaged with research must also ensure that individuals and organisations are held to account when behaviour falls short of the standards set by this concordat.

6.3 These core elements of research integrity (Section 6.2) apply to all aspects of research, including the preparation and submission of grant and project proposals, and the publication and dissemination of findings.

6.4 Researchers must be able to exercise freedom in their academic choices and must also accept responsibility for the decisions that they make. Thus, the primary responsibility for ensuring that they act in accordance with these principles in all aspects of their research work, including expert/peer review, lies with the individual. Employers of researchers, funders of research and other organisations engaged with supporting research and researchers also have important roles to play.

6.5 Any allegations of research misconduct will be dealt with according to Anthony Nolan's Procedure for the Investigation of Misconduct in Research (SOP DOC 6767 – to be developed).

Requirements for all research activity

6.6 The following requirements apply to all research activity.

Development of a research proposal

6.7 Both Anthony Nolan and its researchers should ensure that any research projects being carried out are designed taking into consideration the basic scientific principles (Section 6.1).

6.8 A project of good scientific quality is one that uses an appropriate and rigorous method to answer a valid and specific question, taking any potential biases into consideration. Researchers have an obligation to design and conduct work to the highest possible standard, to ensure that the study is of sufficient quality to contribute something useful to existing knowledge.

6.9 All Anthony Nolan involvement in research activity must be reviewed by the Research Portfolio Group (RPG) and where appropriate the Research Review Board (RRB). A research proposal should be supported and reviewed by the relevant Research Office staff before submission to the RPG and RRB.

6.10 Consideration should be given as to whether patient and public involvement is required. Advice is available from the Research Office and Head of Patient Involvement.

6.11 The individual researcher'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.

6.12 The researcher and research teams should consider any risks involved in the proposed project and ensure that those risks are managed. If needed, a risk management plan should be developed alongside the research proposal.

6.13 For projects that require resourcing or working in partnership with an external funder or organisation, early advice should be obtained from the Research Office/Finance team. This is to ensure all relevant staff time and overhead charges have been considered before a proposal is submitted to the external funder.

Review of a research project

6.14 Good research governance includes independent expert/peer review of proposals and findings by experts in the relevant field to ensure all research is methodologically sound, the conclusions can be supported by the findings, and it meets ethical standards. The review arrangements should be in proportion to the scale of the research and the risks involved.

6.15 Research that duplicates other work unnecessarily, or which is not of sufficient quality to contribute something useful to existing knowledge, is unethical and a misuse of resources. Therefore, before any new research activity is undertaken, existing research should be identified and reviewed.

6.16 The RPG and RRB processes contribute to the review arrangements required by 6.15 and 6.16, including review by independent individuals with methodological or topic expertise.

Registering the research activity

6.17 Anthony Nolan has a central Research Portfolio where all research projects are to be added when they are approved. The Research Portfolio is maintained and managed by the Research Office.

6.18 All entries in the Research Portfolio should be updated when key milestones have been met, and at least annually (as per SOP DOC6816 – to be developed).

6.19 It is also good practice to submit details of finalised research protocols to an appropriate external register, where applicable (for example, registering clinical trials).

Research involving human participants

6.20 All medical research involving human subjects (human tissue or data) will be compliant with The World Medical Association (WMA) Declaration of Helsinki which sets out a statement of the ethical principles for human experimentation.

6.21 The dignity, rights, safety, and wellbeing of participants must be the primary consideration in any research study involving human participants. Research should be initiated and continued only if the anticipated benefits justify the risks involved.

6.22 A process of informed consent should be developed. The nature of the process will depend on the risks involved with the research and informed consent should be obtained through appropriate means for the participants involved. Advice is available from Research Governance and the Research Office.

6.23 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 Research Governance team and the Research Office.

6.24 Where appropriate, a favourable ethical opinion or a notice of no ethical requirements should be obtained. Due to the nature of the research activity undertaken at Anthony Nolan, it is anticipated that not all projects will require review by an ethical committee.

6.25 When conducting, or collaborating in, research in other countries, Anthony Nolan and its researchers based in the UK should comply with the legal and ethical requirements existing in the UK and in the countries where the research is conducted. Similarly, organisations and researchers based abroad who participate in UK hosted research

projects should comply with the legal and ethical requirements existing in the UK as well as those of their own country.

Research involving animals

6.26 Researchers should refer to the Anthony Nolan policy on animal testing. Anthony Nolan does not conduct animal research, nor does it fund animal research in other institutes.

6.27 As a member of the Association of Medical Research Charities (AMRC), Anthony Nolan supports and endorses the AMRC position statement on the use of animals in research.

6.28 When research requires animal testing, and where there is no alternative available, Anthony Nolan researchers can work in collaboration with other institutions to ensure the in vivo validity of their research.

6.29 Researchers should consider, at an early stage in the design of any research involving animals, the opportunities for reduction, replacement and refinement of animal involvement (the three Rs), and should animals be considered necessary for a research study, the research will comply with the law and regulations set under the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 (ASPA 2012). The animal testing in collaborative projects cannot be funded by Anthony Nolan.

Information Governance

6.30 Anthony Nolan's researchers must ensure that personal data is collected, used, stored, and managed in accordance with the law and regulation and the internal policies set out within Anthony Nolan's own Data Protection policy.

All researchers must include any new research involving the processing of personal data in Anthony Nolan's Records of Processing Activities (ROPA), which is achieved by completing a Processing Activity Questionnaire (PAQ).

Unless there is good reason not to do so, protocols and reports that do not contain confidential data should be made publicly available. Any potential sensitivity, e.g., personally identifiable data, should be identified at the research design stage and a risk management strategy developed. For those research activities implying a potential high risk to the rights and freedoms of individuals, for example, due to the sensitivity or volume of data processed, a Data Protection Impact Assessment (DPIA) must be completed. The Anthony Nolan Data Privacy team can provide guidance.

6.31 All research will comply with the obligations in accordance with the Data Protection Act (2018) and the UK General Data Protection Regulation (as amended or re-enacted from time to time)

6.32 Researchers must comply with Anthony Nolan's Privacy Policy, when conducting research at Anthony Nolan.

6.33 If a project uses data that has been obtained from a third party, staff must adhere to the terms of that data access as imposed by the third party. Staff should also ensure that the terms and conditions of the data supply are fit for all of Anthony Nolan's purposes.

Record keeping

6.34 All research project information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification. All data shall be stored according to recognised good practice and/or Ethics Committee guidelines.

6.35 Records of all participants' informed consent and carers'/relatives' assent, and all appropriate research records should be stored and made available when requested by Anthony Nolan and other authorised agents, where applicable (such as the MHRA).

6.36 External funders and collaborators may have additional stipulations with regards to retention of records from research studies that will need to be adhered to.

Reporting research results

6.37 All researchers are encouraged to publish their work and to make the work open to critical review through accepted scientific and professional channels. Researchers are encouraged to draw up a plan for disseminating their findings during the design phase of the project.

6.38 Researchers must ensure authorship and other publication credit accurately reflects the relative scientific or professional contribution of the individuals involved. No person who fulfils the criteria for authorship should be excluded from the submitted work, and no person who does not fulfil the criteria should be listed as author. Researchers should be aware that anyone listed as an author of any work should be prepared to take public responsibility for that work and ensure its accuracy and be able to identify their contribution to it.

6.39 Researchers must clearly acknowledge all sources used in their research and seek permission from any individuals if a significant amount of their work has been used in the publication.

Research Sponsorship/Funding

6.40 Anthony Nolan adopts the definitions from the UK Policy Framework for Health & Social Care Research for the responsibilities of the Funder and the Sponsor (paragraphs 9.9 and 9.10 of the framework respectively).

6.41 All staff employed by, or under contract with, Anthony Nolan can request that Anthony Nolan acts as Sponsor for their research project. Sponsorship is awarded at the discretion of Anthony Nolan following a risk assessment of the proposed study and full review of the study management arrangements.

6.42 Research undertaken in part or whole to fulfil a qualification from a higher education institute should ordinarily be sponsored by that institute.

Insurance and Indemnity

6.43 In most circumstances, formal Anthony Nolan approval of research will secure insurance/indemnity for liability and harm. Projects involving human participants may be subject to additional review and approval to confirm insurance and indemnity cover.

Health and Safety

6.44 Researchers will ensure that any risks that could impact on the health and safety of those involved in research, whether researchers, research subjects, patients, participants, or others, are assessed and effectively managed to reduce the risk of injury or harm or ill health to themselves, the wider community or environment, in accordance with Anthony Nolan's Risk Management policy and applicable risk registers. If an applicable divisional or project risk register does not exist, one should be created.

6.45 Researchers within Anthony Nolan must refer to Anthony Nolan's Health and Safety Policy (DOC3784) when designing their research.

Patient, Service User, Community, and Public Involvement

6.46 In this section, the terms 'public' and 'people' include patients, people with lived experience, whether they are current patients or not, services users, carers and loved ones, donors of tissue, cells and data and other interested members of the public.

6.47 Anthony Nolan strongly supports the principle that the public should be involved in decision-making regarding research strategy, policy and activity. Researchers should aim to involve the public throughout the design, conduct, data collection, analysis and dissemination of the research.

6.48 Anthony Nolan endorses the AMRC position statement on the importance of public involvement in medical research. Involvement signifies an active partnership in which the public meaningfully contribute to and collaborate in all aspects and stages of research.

6.49 Researchers are encouraged to consult the Research Office and the Head of Patient Involvement as well as external resources such as PPI (Patient and Public Involvement) resources for applicants to NIHR research programmes | NIHR and UK Standards for Public Involvement , to help direct efforts in public participation.

Equity, Diversity and Inclusion

6.50 Anthony Nolan encourages an inclusive environment that celebrates our diversity and where everyone can bring their own unique contribution.

6.51 Researchers are expected to make equity, diversity and inclusion (EDI) considerations throughout the design, conduct, data collection, analysis and dissemination of any research. The EDI team should be contacted for guidance.

6.52 All research must be conducted in line with Anthony Nolan's organisational EDI strategy, policies and processes.

Environmental Sustainability

6.53 All research must be conducted in line with Anthony Nolan's Environmental Sustainability Policy.

6.54 Researchers are expected to consider environmental sustainability when designing, developing, and running research projects, accounting for reduction, reuse, and

recycling where possible. The Environmental Sustainability Lead can provide guidance, if needed.

6.55 When working with external suppliers, collaborators, or other external parties, researchers should aim to work towards Anthony Nolan's sustainability requirements with them.

Conflicts of Interest

6.56 Researchers are expected to recognise, declare, and manage appropriately any real or potential conflicts of interest either of a financial or other nature. Researchers should refer to Anthony Nolan's relevant declarations for staff and volunteers or for suppliers or potential suppliers.

6.57 Anthony Nolan must ensure all researchers have access and comply with any policies regarding conflicts of interest.

6.58 Conflicts of interest should be risk assessed before decisions are made regarding the continuation of the research. Research should not proceed if the conflict is likely to invalidate or severely compromise its integrity, however, if the conflict can be appropriately mitigated through declarations and/or special safeguards relating to the conduct and reporting of the research, it should still be allowed to be carried out.

Intellectual Property

6.59 It is the usual practice for Anthony Nolan to own any intellectual property (IP) arising from research developed by its employees and students unless otherwise specifically agreed. The position otherwise for any other relationship depends on the contractual arrangement in place. Refer to the IP policy DOC6815 – to be developed.

6.60 Researchers should consider the potential of the IP arising from their research and take reasonable measures to protect any such IP. Protection of IP within individual research activities should be included in associated contracts, agreements, and documents for those same activities.

Financial Management

6.61 Anthony Nolan and the researchers collectively have a responsibility to ensure the good financial management of research projects. The Research Office will provide support to determine costs and resourcing requirements in collaboration with the researcher.

6.62 Any funding for research purposes should be transparent. All research funding must be managed in full compliance with the funders terms and conditions, and other relevant policies.

6.63 Income generated from research belongs to Anthony Nolan. Under no circumstances may a researcher retain any research monies as a payment outside of their Anthony Nolan contract, e.g. as a personal gift from the company, nor may any monies be paid into an external account, e.g. a building society account.

6.64 Anthony Nolan is committed to upholding the principles of the concordat to support researchers, specifically around training opportunities and career development. Anthony Nolan will endeavour to provide and facilitate training opportunities for members of staff

carrying out research, these will include time off their normal duties to take courses, participate in conferences and other accredited academic forums.

6.65 Researchers should undergo training to carry out their duties and to develop their knowledge and skills throughout their career, repeating training where necessary to ensure that skills are kept up to date. They should identify needs for training when they arise and report them to their line manager during the appraisal process.

Additional requirements for particular types of research activity

Projects commissioned by Anthony Nolan

6.66 All criteria under 'Requirements for all research activity' of the research governance framework (Paragraph 6.6) must also be satisfied.

6.67 The Anthony Nolan team that commissions the project is responsible for ensuring that the research activity is fit for purpose.

6.68 Projects to be commissioned should be submitted to the RPG with reasoning on:

- why the project is being commissioned, including why it can't be covered by Anthony Nolan resources,
- how Anthony Nolan will benefit from the commission and
- how the process will be managed to ensure legal and other research responsibilities are clearly defined and contracted, including authorship and publication.

Externally funded research where Anthony Nolan staff are the lead or co-applicant

6.69 All criteria under 'Requirements for all research activity' of the research governance framework (Paragraph 6.6) must also be satisfied.

6.70 All externally funded research should be submitted, at least, to the RPG prior to funding application submission.

6.71 The decision to be involved as an applicant for external funding should be based on the following considerations:

- The proposal is methodologically robust and complies with this policy.
- The aims and objectives of the project are likely to lead to information which will help deliver the work and strategy of Anthony Nolan.
- The Anthony Nolan staff members have the necessary skills.
- Resource costs and time for Anthony Nolan 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.
- The project has appropriate disclosure and confidentiality agreements in place.

- Anthony Nolan can review results and comment on them before they are made available in public.

6.72 Anthony Nolan, as the employer of the 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 must be reviewed by the Legal team before being signed.

7 PROCEDURES FOR FOLLOWING THE RESEARCH GOVERNANCE AND INTEGRITY FRAMEWORK

7.1 Anthony Nolan will provide the following procedures, tools, and training to enable compliance with this Policy:

- SOPs, documents and templates (See Section 8)

- Training and education in regulations governing relevant areas of research through staff development, individual researcher training, e-learning, and external training providers.

- Monitoring of research projects in accordance with Anthony Nolan monitoring and auditing procedures. All studies registered on the Anthony Nolan Research Portfolio will be risk assessed for monitoring and eligible for audits.

- Support of and engagement with internal and external audits and inspections of projects in all areas of research, for example the Association of Medical Research Charities (AMRC) and any audits associated with grant funding.

8 RELATED POLICIES AND DOCUMENTS (SOP'S TO BE DEVELOPED)

- Research Project Proposal form
- Terms of Reference for the RPG and RRB
- Procedure for the Investigation of Research Misconduct (SOP DOC6767)
- Progress Reporting for Research (SOP DOC6816)
- IP Policy (DOC6815)
- Current Anthony Nolan Research Strategy (available on our website)

9 APPENDICES

Appendix 1: National regulations, legislation, and policies

The research governance and integrity requirements that apply to Anthony Nolan staff undertaking research are defined by a range of national regulations, legislation, policies, and professional codes of practice. These are include some of the below.

9.1 Statutory Responsibilities

The Human Tissue (Quality and Safety for Human Application) Regulations 2007Data Protection Act 2018 (General Data Protection Regulation): Introduced to protect individual's rights regarding the access to and use of their personal information. The Act is designed to ensure that the inappropriate use of data does not lead to any unnecessary harm or distress in individuals. The Data Protection Act 2018 is the UK's implementation of the General Data Protection Regulation (GDPR).

Mental Capacity Act 2005: Designed to empower and protect vulnerable people who cannot make their own decisions. Research involving incapacitated or potentially incapacitated subjects must comply with the Act.

Medicines for Human Use (Clinical Trial) Regulations (2004)

9.2 AMRC Position Statements

As a registered full member of the AMRC, Anthony Nolan commits to meet and comply with the necessary requirements, including publishing a research strategy, following the principles of expert review, and publicly endorsing the position statements:

AMRC Guidance on implementing the principles of expert review. Published: March 2024

AMRC position statement on the importance of involvement in medical research. Published: Dec 2022

AMRC position statement on the use of animals in research. Updated: Sep 2020

9.3 Expertise and Good Clinical Practice

UK Framework for Health and Social Care Research (Department of Health, 2017) Sets requirements and recommended guidelines for hosting, conducting, and managing research; it defines the roles and responsibilities of individuals and organisations and sets good practice standards.

World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects

International Conference of Harmonisation's Guideline Good Clinical Practice

UK Research Integrity Office Code of Practice for Research. Designed to encourage good conduct in research and help prevent mistakes and misconduct.

9.4 Research Ethics

Research ethics refers to the moral principles guiding all aspects of research, from the idea stage through to completion and publication of results, where applicable.

NHS Research Ethics Service and Research Ethics Committees (RECs) review research proposals to protect the rights and safety of research participants and enable 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.

Health Research Authority (HRA) Approval: If your project involves the NHS in England a favourable opinion from the HRA may be needed before it can begin. Not all types or research 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.

Confidentiality Advisory Group (CAG) advises on both research and non-research uses of confidential patient information without consent.

Gene Therapy Advisory Committee (GTAC) must be applied to if an application is for the approval of a gene therapy clinical trial.

Integrated Research Application System (IRAS) should be used to apply for permission and approvals (including regulatory and ethical) for health and social care research in the UK. IRAS Help is a useful tool for all application queries.

9.5 Patient and Public Involvement and Engagement

UK Framework for Health and Social Care Research (Department of Health, 2017) 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.

NIHR Briefing Notes on Public Involvement

NIHR Centre for Engagement and Dissemination – (to be set up) https://www.nihr.ac.uk/news/nihr-launches-new-centre-for-engagement-and-dissemination/24576

PPI (Patient and Public Involvement) resources for applicants to NIHR research programmes | NIHR

UK Standards for Public Involvement

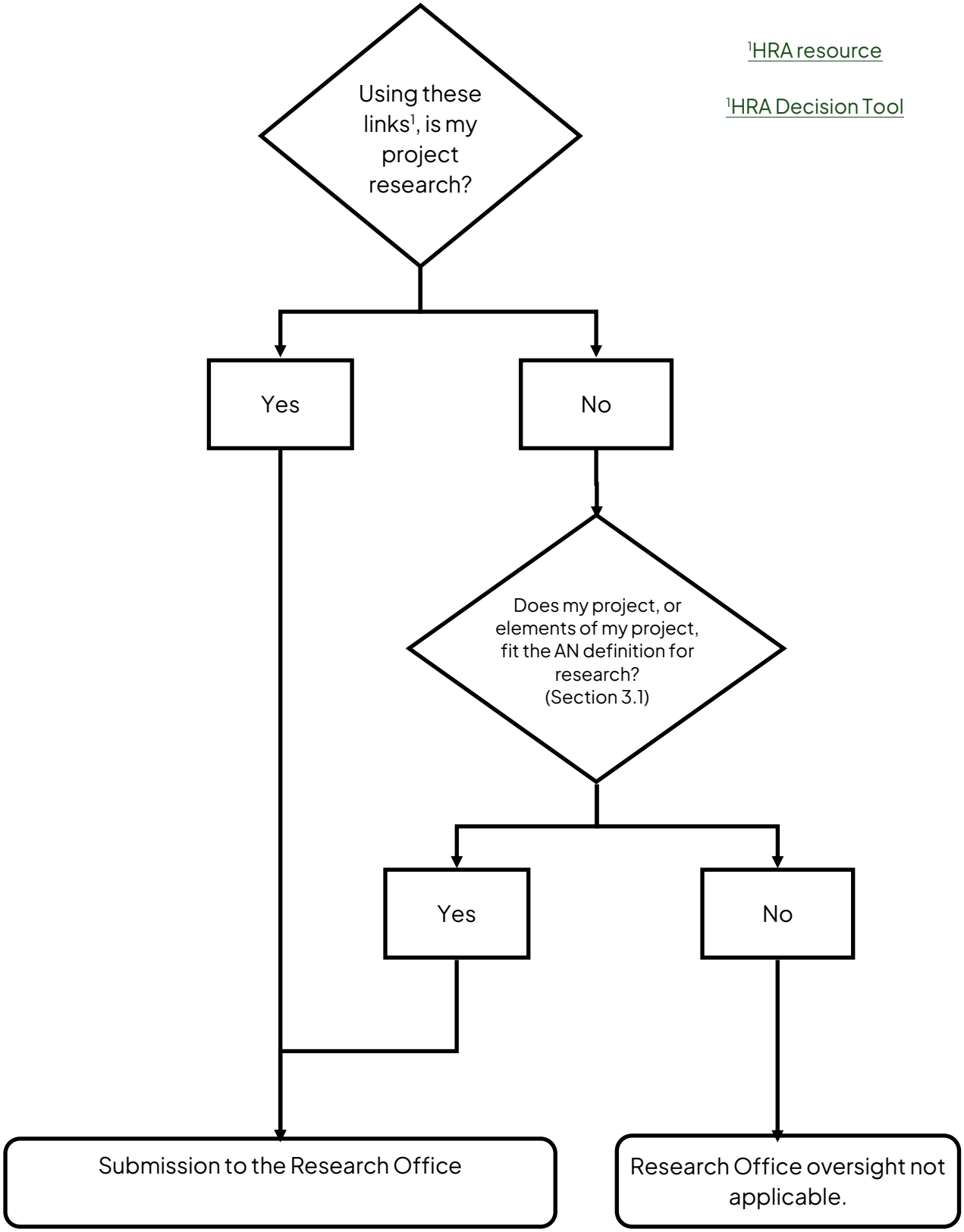
9.6 Research Malpractice

The Concordat to Support Research Integrity, Universities UK 2019. Anthony Nolan are not signatories for the Concordat but as outlined in this policy, Anthony Nolan is committed to fulfilling the principles of the Concordat.

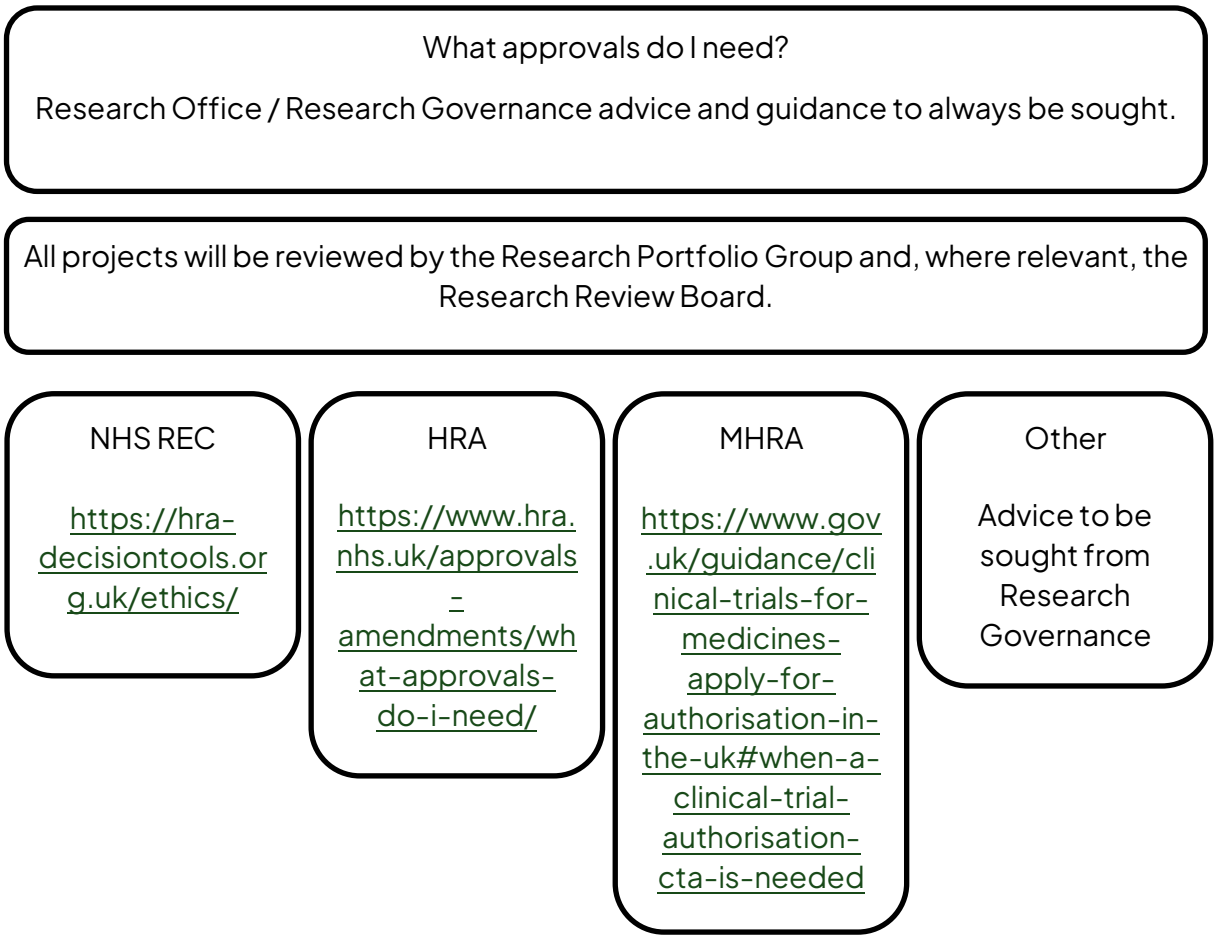
UKRIO Procedure for the Investigation of Research Misconduct, version 2.0, 10 March 2023. Anthony Nolan's Procedure for the Investigation of Research Misconduct (SOP DOC6767) is adapted from this document.

Appendix 2: Project approval requirements

9.7 Diagram 1: Flowchart to determine whether an Anthony Nolan project should be submitted to the Research Office for support and oversight.



9.7.1 Diagram 2: What approvals are needed for a research project?



10 DOCUMENT HISTORY

Document review and approvals

Name (can be an individual or a committee)	Role	Date of Review/ Approval	Version	Comments
Senior Leadership Team	-	March 2025	v001	