

Research Review Board – Terms of Reference

Anthony Nolan launched their research strategy in 2024, *Unlocking New Ways To Treat Every Patient*. Through this strategy the aim is to expand and enhance the research that is delivered in pursuit of Anthony Nolan’s charitable objectives. To support this, Anthony Nolan has established a Research Review Board (RRB) to assess and provide expert review of new research proposals and research projects that have been running for more than five years.

For new research proposals, the purpose of the RRB is to provide a recommendation on the suitability of the proposed research, taking into account the factors set out in these terms of reference. For long-term research projects, running for >5 years, the RRB is to provide a recommendation on the continued suitability and planned future impact of the project. The RRB will not make business decisions, for example allocation of funds or requests for additional headcount but instead will focus on assessing the quality of research proposals and projects.

Definitions and Responsibilities

Applicant	A researcher who wishes to conduct research at Anthony Nolan, which may be either externally or internally funded, who has submitted a research proposal for review by the RRB.
Chair	Facilitate the meetings of the RRB ensuring that for all research proposals reviewed by the RRB, a consensus is reached that is acceptable to the full membership.
Non-voting Participant	Participants of the research review process who will provide insight, knowledge and comments on the research proposals but will not be asked to vote on the outcome.
Research	As defined in the Research Governance and Integrity Policy. New study proposals and research projects that have been running for more than five years that meet this definition, and are funded by Anthony Nolan, are to be reviewed by the RRB.
Research Office	Provide central oversight of research at Anthony Nolan. Manage and administer the RRB; responsible for the general running and set up of the RRB meetings, for the distribution of documents to the members and ensuring the membership is inducted to the review process.
Research Portfolio Group (RPG)	Enable delivery of Anthony Nolan’s research strategy by providing transparency, alignment, and collaboration across all

	research projects. All research proposals will have been discussed by the RPG before they are submitted to the RRB.
Long-term research projects	Research projects, funded by Anthony Nolan, that have been running for 5 or more years.
Research proposals	New research projects that have not yet started. These projects will be funded by Anthony Nolan and will require RRB recommendation before being initiated.

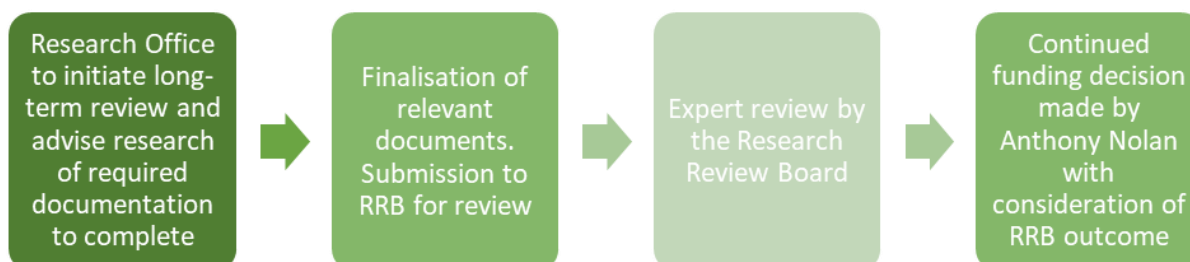
Summary of RRB Review Process

The Research Office will manage and coordinate the expert review process for all research proposals and long-term research projects, including conducting an initial check prior to circulation for RRB review, to ensure all required documentation is available. Before research proposals are circulated to the RRB for consideration, they will have been discussed by the Research Portfolio Group (RPG), to check that the proposed research aligns with the organisational and research aims and fits within the Anthony Nolan research portfolio.

For new research proposals, the following process will be followed prior to initiation of the project:



For long-term research projects, the following process will be followed approximately every five years:



RRB Review Criteria

The RRB will focus on the following criteria when reviewing a research proposal;

1. **Alignment with Anthony Nolan's Research Strategy** research proposals and long-term research projects will be assessed for their alignment with the Anthony Nolan Research Strategy and priority areas identified by Anthony Nolan.
2. **Quality of the research**– the research aims will be reviewed; the study design and the scientific merit will be assessed considering the originality and quality of the study design, and competitiveness and relevance within the field of research. The RRB should review the importance of the research question(s), and the appropriateness of the methodology outlined to answer the research question(s).
3. **Feasibility/Appropriateness of resources** – project teams must have the adequate skills and resources in place to complete the research, and projects must have a clearly defined budget and outline for use of resources. The RRB will review the adequacy of the resources, budget, and timelines.
4. **Likelihood to generate future Impact** – research must have a clearly defined impact and benefit on patients and/or donors with the potential to contribute to scientific understanding and/or advance clinical practice.

The RRB members are encouraged to comment on any strengths of the research proposals and long-terms projects, as well as suggesting areas for improvement or development.

Research Study Documentation

The following documentation for a research proposal will be provided to RRB members:

- A completed Research Proposal Form, which will include a lay summary that will be used publicly by Anthony Nolan (for e.g. posted on the website) if the research proposal is approved
- Protocol and other supporting documents (for example, information sheets, consent forms, or additional budget information), where appropriate

The following documentation for long-term research projects will be provided to the RRB members in advance of an RRB meeting:

- A completed Project Review Form, which will include a lay summary, details on the project over the previous 5+ years, and information of future plans/direction.

- Protocol and other supporting documents (for example, information sheets, consent forms, or additional budget information), where appropriate.

An initial check will be completed by the Research Office prior to an application being circulated to the RRB membership, including the completeness of the application, and supporting documents. The documents will be circulated by the Research Office at least one week in advance of a RRB meeting.

Conflict of Interest

All members of the RRB must consider if there are any conflicts of interest, in line with Anthony Nolan's conflicts of interest policy, before assessing any research proposal or long-term research project. The purpose of this is to ensure that members identify and declare any situation in which their personal or professional interests, or duties which they owe to another body, influence (or appear to influence) their decision making.

In order to document their consideration of actual or potential conflicts of interest, each Member will be asked to complete a Conflicts-of-Interest form in advance of considering and/or discussing any research proposal or long-term research project.

Any potential conflicts of interest will be reviewed by the Chair who will determine the appropriate action. If the Chair has a conflict of interest, then this will be considered by the Deputy Chair. The Chair (or, Deputy Chair, as applicable) shall decide whether the Member should:

- Refrain from voting on acceptability of the research;
- Refrain from participating in the discussion and assessment of the research
- Withdraw from the meeting during the discussion and voting
- Participate in the discussion and vote as the potential conflict of interest is not deemed to be prohibitive or harmful to participation in the review.

All decisions will be documented for transparency purposes. If a member is unable to vote due to conflict-of-interest, all efforts will be made to replace that member to ensure quorum is met for each review.

Membership

Members of the RRB will include a range of internal and external individuals with relevant skills and expertise to ensure there is sufficient expert review and independence in the decision-making process. The members of the RRB are as follows:

Non-voting Members/Attendees

- Chief Medical and Scientific Officer, Chair
- Deput Chair (TBC)

- Representative from Research Office, Administrator
- Expert advisors may be invited to attend on an adhoc basis [who may be external or internal]
- Applicant [invited to attend and present their application]

Voting Members are appointed based on their professional and personal experience and should be independent from Anthony Nolan research. Voting members will include people invited from the following communities:

- Clinical experts within field of haematopoietic cell transplantation and/or cell therapy
- Clinical Nurse Specialists or allied health professional
- Researcher/scientist (including but not limited to Cell and Gene Therapies, Transplant, HLA, Bioinformatics, Immunotherapy, Haematology, Behavioural and Social Science)
- Patients and family members
- Donors

Members will not serve for a period of longer than 6 years in total. Initial membership will be for a period of 3 years with the option to extend this for a further 3 years. Members will have to wait for 3 years before re-joining if they have served a six-year term. During the 2nd or 5th year of appointment, recruitment to fill the position will commence.

Roles of the membership (members may be assigned more than one role):

- Chair - this person will facilitate the meetings of the RRB, their role is to ensure that for all research proposals assessed during the RRB meeting a consensus is reached that is acceptable to all RRB members.
- Deputy Chair - fulfils the role of the Chair in their absence.
- Member - These people will have sight of the applications in advance of meetings. Their role on the RRB is to represent their community, and to comment and vote on the applications during RRB meetings.
- Administrator - this person is responsible for the general running and set up of RRB meetings, the distribution of documents to members and the recording the minutes during the meetings.
- Expert Advisors - these individuals will be identified as and when required and will provide advice on any aspect of the request.

Acknowledgement: before participating as a member of the RRB, each member shall sign and return an RRB Member Acknowledgement to the Research Office. If a member has not signed an RRB Member Acknowledgement, they will not be provided with the research proposal and shall not be permitted to attend meetings of the RRB

In the event that an external expert is invited to attend an RRB meeting or assess a research proposal, they shall be required to sign an RRB Member Acknowledgement (or equivalent).

Quorum

Five voting members and the Chair (or Deputy Chair) shall constitute a full quorum for the Anthony Nolan RRB. If the Chair (or Deputy Chair) considers there are insufficient expertise to cover all the criteria, then any decision made by the RRB will be considered provisional.

Voting

The RRB members will vote on whether, based on the above Review Criteria, they recommend the proposed research be considered for funding and resource allocation by Anthony Nolan. Once the research proposal has been considered and discussed within the RRB, members will vote. Each Member has one vote. There are three possible outcomes for an application:

Recommend – the research meets the RRB review criteria and no changes are needed to the documentation or project parameters. The proposed research will be put forward for funding and resource decisions, or recommended for funding to continue. Improvements or future developments may be suggested but these are not required for the RRB outcome to be valid.

Recommend with conditions – conditions are to be met prior to the RRB recommendation being valid. The applicant will be responsible for responding to and implementing, where applicable, the RRB's conditions. Changes may be needed to some documents with regards to wording or formatting, or to project parameters and objectives. If a research proposal/project receives this outcome, the RRB will decide whether, once any amendments have been made, the revised research can be reviewed outside of an RRB or whether it must be considered again at a future RRB meeting. The proposed research can be put forward for funding and resource on the condition that all conditions are met prior to funding allocation.

Not recommended – the project is not suitable for Anthony Nolan and does not meet all RRB review criteria.

The Chair/Deputy Chair will facilitate the voting process by asking members to indicate which of the three outcomes they consider suitable for the research based on their expertise. Most

votes will inform the outcome decision. If there is no clear majority for a specific outcome, the Chair will endeavour to achieve a consensus in the decision outcome by attempting to address the points raised. In the case of research proposals which are “Recommended with Conditions”, the Chair will also ask members to consider if any proposed amendments to the research can be approved outside of the RRB.

Final recommendation from the RRB will be dependent on the Applicant responding in a timely fashion to any further clarification requests arising from the RRB.

Applicants will be informed of the RRB’s decision within 10 business days of the relevant meeting.

Decisions will be formally recorded in the minutes of each RRB meeting and an outcomes letter that will be provided to the applicant.

Feedback

Where possible, feedback will be provided to Applicants in written format. This will include comments from written reviewers and the RRB. Feedback should not contain any identifiable information about the reviewer or any member of the RRB. If comments seem overly critical or likely to cause offence, they should be discussed with the Chair to decide if the feedback will be given, or if the wording can be adjusted, whilst ensuring that any points of constructive criticism remain clear.