PACE | Pathways to Antimicrobial Clinical Efficacy

Good Research Practice Policy

Principles and Guidelines

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Version History

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1	Baseline circulation	JPMB	09.07.2023
1.1	Update to reflect R&D Advisors approving in-vivo studies Added version history log	JPMB	11.03.2025

PACE Good Research Practice

Principles and Guidelines

Introduction

The PACE Programme ("PACE") is committed to uphold and promote the highest standards of scientific integrity and professional ethics in all research activities and expects that all PACE-funded research is conducted to the highest levels of integrity, clarity, and good management.

In alignment with this commitment, our Good Research Practice Policy provides a framework to ensure rigour, respect, responsibility, and reproducibility in research.

Researchers supported by PACE must adhere to the highest ethical standards and conform to requirements and guidance set out in this document and by national and international regulatory bodies, professional bodies, and local research ethics and governance frameworks.

Good research practice is essential to producing high-quality research, maintaining public trust, respecting the rights and dignity of research participants and the scientific community, and ensuring legal and ethical compliance.

The responsibility for promoting and delivering good research practice is shared by the whole research community. Researchers should strive for the highest achievable standards in the planning, conduct and reporting of their research and demonstrate integrity in their dealings with others. Research organisations should foster a culture which supports and embeds good research practice and aims to prevent research misconduct (as defined below).

Our commitment is inclusive of all academic and research staff, students, interns, visiting researchers, and other individuals engaged in research under the awarded grants.

This Policy encompasses diverse aspects of research, such as ethical considerations, data management, record-keeping, publication, and collaboration among others. It is designed to align with national and international standards of research conduct, and builds upon the foundational principles of honesty, transparency, accountability, and respect for evidence.

It includes both high-level principles and more detailed guidance to ensure the standards can be achieved in practice.

While this Policy provides a comprehensive guideline for maintaining the highest standards of research, it is also designed to foster a culture of continuous learning and improvement, and we encourage all members of our research community to integrate these principles into their daily practice.

Researchers and research organisations have a duty to ensure roles and responsibilities are clear, and that appropriate resources and skills are in place to deliver the research and maintain high standards of integrity, either by seeking access to training or developing collaborations with others with the necessary expertise.

The principles and guidelines outlined in this document are intended to complement not replace statutory or regulatory requirements and codes of conduct and ethical standards relating to specific professions, research areas or research environments and settings or the guidelines of other research funders.

Purpose

Aim of the Policy.

To ensure integrity, rigor and reproducibility in research conducted under the awarded grants.

Scope of the Policy.

The Policy applies to all research activities and people including students, staff, and any associated personnel who work on any project funded by the PACE Programme.

Principles of Good Research Conduct

The following principles outline PACE's expectations relating to the conduct of research. They should underpin all PACE-funded research. They apply to everyone involved in PACE-funded research, including researchers, research support staff, students, research managers, and administrators.

Excellence and Integrity

PACE is dedicated to excellence and high-ethical standards in the design, conduct, reporting, and exploitation of research. PACE expects all of those it supports to act with care and skill at all times in order to deliver high-quality science. Everyone involved in PACE-funded research must recognise and accept personal responsibility for the integrity of the research record, whether this is used as the basis for the further development of scientific knowledge, for improvements in healthcare, or the prevention of disease.

Honesty and Transparency

All of those involved in PACE-funded research should be honest in respect of their own actions and their responses to the actions of others. The research community must foster and support a culture of transparency and honesty which promotes good practice, recognises relevant interests or conflicts and deals with these openly and explicitly. This applies across the whole range of research activity, including:

- study and experimental design;
- generating, analysing and recording (including archiving) data;
- sharing data and materials;
- applying for funding;
- publishing findings;
- acknowledging the contributions of others and engaging in the peer review process; and
- reporting cases of suspected misconduct in a responsible and appropriate manner.

Procedures for reporting and investigating allegations of research misconduct (as defined below) should be clear, thorough, fair, constructive, conclusive, and timely, and shall provide details to MDC on request. Any remedial action should be promptly implemented.

Openness

PACE-funded researchers are expected to foster the exchange of ideas and to be as open as possible in discussing their work with other scientists and the public. Researchers must be open when conducting and communicating their research (subject to the terms and conditions of any research contracts and the protection of intellectual property and commercial exploitation).
This includes:

- the disclosure of any conflicts of interest;
- the reporting of research data collection methods;
- the analysis and interpretation of data;
- making all research findings widely available (including sharing negative results as appropriate);
- disseminating research in a way that will have the widest impact; and
- promoting public engagement/involvement in research.

Respect, ethics and professional standards

All research supported by PACE must respect and maintain the dignity, rights, safety and wellbeing of all involved, or who could be affected by it.

All researchers should be familiar with, and know how to access, the legal and ethical requirements relevant to their work. Researchers must ensure that they have the necessary skills and training to conduct their research.

They must take appropriate steps to work within these legal and ethical frameworks to manage data and records appropriately, maintain confidentiality, and to minimise any adverse impact their work may have on people, animals and the natural environment; and to work with those with corporate responsibility within their organisations for meeting the requirements of the frameworks. Risks relating to the potential for research outcomes to be misused for harmful purposes must be recognised and managed.

Regulatory Compliance

Researchers are expected to make themselves aware of, and comply with, any legislation or regulations that govern their research. This includes, but is not limited to, regulations related to Data Protection, Clinical Trials and Human Tissue.

Guidelines and Standards

These guidelines and standards outline how the principles above should be applied within PACE-funded research and they apply to everyone involved in PACE-funded research.

Planning and conducting PACE-funded research

- Those planning and delivering PACE-funded research should have the necessary expertise, professional skills and experience to deliver the project proposed. This may include seeking specialist advice or securing access to expertise through collaboration.
- The rationale for the study and any subsequent modifications must be clearly documented within a well maintained system, for example in project proposals, contracts, protocol documents, laboratory notebooks, or as electronic records. All projects must be documented clearly, systematically and in a timely manner, including clear outcomes and end points, plans for statistical analysis, any ethical and regulatory approvals and any subsequent amendments. Key records or documents should be held in an accessible form. Any changes should be validated and recorded with appropriate version control by the researcher responsible, to establish the provenance of the study and protect intellectual property.
- PACE-funded research must adhere to current ethical standards, safety practices, relevant legal requirements, local policies of the researcher's organisation and other guidelines. Researchers should ensure they are aware of, and keep up to date with, all the regulatory, ethical and governance requirements that may apply to their area of research and are working with the teams and individuals within their organisations who have a responsibility to ensure that these requirements are adhered to within the organisations. All appropriate licences and permissions must be in place before the research starts and updated as necessary if plans change. The expectations and requirements of professional codes of conduct and standards, including arrangements for managing consent and information governance should be addressed in the planning and conduct of the study.
- Responsibilities for overseeing the scientific and ethical conduct of the study must be identified, allocated and agreed as the scientific plans are put into practice. This is especially important in projects involving patients, volunteers or confidential or identifiable data, tissue, biological samples and animals and in other complex, collaborative programmes.
- Research organisations should have appropriate research governance systems, in which roles are allocated to meet corporate/institutional and individual project responsibilities and are accepted and carried out within a sound research and project management framework. This may involve the identification of sponsors, appropriate and proportionate quality, risk management and monitoring systems, or the use of preferred project management processes or tools. When considering proportionate risks important aspects to consider include the impact on research delivery, supporting creativity, the credibility and robustness of results, and the risks involved in methods used in studies involving human participants.
- The proper use and maintenance of equipment and systems is an important element of the research process. Appropriate procedures should be in place and responsibilities assigned to ensure training and support for use, regular servicing and calibration of equipment by trained staff, appropriate records of calibration, servicing, faults, breakdowns and misuse.

Research Records

- All research data generated through PACE-funded research must be managed and curated effectively throughout its lifecycle, including archiving, to ensure integrity, security and quality and where possible to support new research and research data sharing to maximise the benefit and impact of PACE research funding. Records should be kept to enable understanding of what was done, how and why, and which allow the work to be assessed retrospectively and repeated if necessary.
- The principles, standards and technical processes for data management, retention and preservation will be determined by the area of science. Processes should be supported by appropriate data standards addressing confidentiality and information security, monitoring and quality assurance, data recovery and data management reviews where suitable.
- Research data (including images) should be recorded and retained. Retention periods should be informed by data management and quality assurance needs.
- It is essential to manage confidential identifiable data appropriately, including data associated with tissue and biological samples.
- Local procedures of the Researcher's organisation (for example, Standard Operating Procedures, protocols, etc) for all routine methods to be replicated across a study, together with associated risk assessments, should be documented systematically, in plain English and ideally in a standard format to ensure clarity, consistency, and accuracy. Where there is more than one approved technique for any given procedure within the organisation, clear records should be kept on which were used. Where procedures change, they should be version controlled and the current version should be available and readily accessible to all staff.
- Protocols for the use, calibration, and maintenance of equipment, together with associated risk assessments, must be clearly documented to ensure optimal performance and research data quality. Where protocols change, they should be version controlled and the current version should be available and readily accessible. Instructions for the safe shutdown of equipment in case of emergency should be readily accessible. Such quality assurance measures help demonstrate the robustness and validity of research data.

Codes of conduct, ethics and professional standards

- All researchers involved in PACE-funded studies must be aware of, and adhere to, all legal requirements and relevant codes of conduct required by their employer, place of work and any professional bodies to which they, or members of their research teams belong.
- PACE-funded research must comply with all applicable legal and regulatory requirements relevant to the country where it is being conducted.
- PACE has high expectations for the design, conduct and reporting of medical research involving animals. NC3Rs* is a UK-based scientific organisation that works nationally and internationally with the research community. Their '3Rs' are the guiding principles in animal research and are defined as follows:
  - **Replacement** means that non-animal alternatives are used whenever possible.
  - **Reduction** means that numbers of animals are minimised whilst maintaining the robustness and reproducibility of data.
  - **Refinement** means that through exploitation of the latest *in vivo* technologies animal welfare is maintained, and any pain or distress is minimised.

  Within PACE implementation of the 3Rs (replacement, refinement and reduction) is essential to meet ethical standards and to obtain the best possible scientific results. PACE recipients must detail how they have considered replacing, reducing, and refining the use of animals in their research. The expectations PACE has with regard to responsibility in the use of animals in bioscience research is as described in the publication; Responsibility in the use of animals in bioscience research produced by the NC3Rs.
  - Experimentation on animals conducted within the UK must comply with Home Office legislation and all relevant regulatory requirements including approval from the appropriate local ethics committee (Local Animal Welfare and Ethical Review Body (LAWERB)). The use of live animals in research is regulated in the UK under the Animals (Scientific Procedures) Act 1986 (ASPA) (https://www.gov.uk/guidance/research-and-testing-using-animals).
  - Experimentation on animals conducted outside of the UK must abide by local legislation and regulation, whilst implementing NC3Rs standards. It is highly recommended that animal facilities with Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) accreditation are engaged. Similarly, accreditation from a recognised

Local Animal Welfare and Ethical Review Body (LAWERB) should be a priority. In all cases, animal facilities must meet an internationally recognised standard of animal welfare and husbandry.

To further enable and augment this, after funding is granted, PACE (via R&D advisor) reserve the right to review, critique and advise on plans, such that *in vivo* studies supported by PACE can only be initiated once agreed by the PACE R&D advisor. The intent is not to be obstructive, overly bureaucratic, or cause unnecessary delay, but to add even greater experience and insight to maximise the value and impact of data from animal studies.

*National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs): www.nc3rs.org.uk

Definition of research misconduct and poor research practice

Research misconduct includes, but is not limited to:

- **Fabrication** (making up results, other outputs (for example, artefacts) or aspects of research, including documentation and participant consent, and presenting and/or recording them as if they were real) when proposing, carrying out or reporting the results of research;
- **Falsification** (the inappropriate manipulation and/or selection of research processes, materials, equipment, data, imagery and/or consents) when proposing, carrying out or reporting the results of research;
- **Plagiarism** (using other people's ideas, intellectual property, or work (written or otherwise) without appropriate acknowledgement or permission);
- **Failure to meet legal, ethical and professional obligations**, for example:
    i. Not observing legal, ethical and other requirements for human research participants, animal subjects, human organs or tissue used in research, or for the protection of the environment.
    ii. Breach of duty of care for humans involved in research whether deliberately, recklessly or by gross negligence, including failure to obtain appropriate informed consent.
    iii. Misuse of personal data, including inappropriate disclosures of the identity of research participants and other breaches of confidentiality
    iv. Improper conduct in peer review of research proposals, results or manuscripts submitted for publication. This includes failure to disclose conflicts of interest; inadequate disclosure of clearly limited competence; misappropriation of the content of material; and breach of confidentiality or abuse of material provided in confidence for peer review purposes.
    v. Misuse of research funds, equipment or premises.
    vi. Mismanagement or inadequate preservation of data and/or primary materials where this could have a significant impact on the research or research outputs.
    vii. Deliberately preventing the publication of research, for example by withholding data or by inappropriately withholding permissions.
- **Misrepresentation**:
    i. Misrepresentation of data, including suppression of relevant results/data or knowingly, recklessly or by gross negligence, presenting a flawed interpretation of data.
    ii. Misrepresentation of involvement, including inappropriate claims to authorship or attribution of work and denial of authorship/attribution to persons who have made an appropriate contribution.
    iii. Misrepresentation of interests, including failure to declare competing interests of researchers or funders of a study.
    iv. Misrepresentation of qualifications, experience and/or credentials.
    v. Undisclosed duplication of publication (self-plagiarism), including undisclosed duplicate submission of manuscripts for publication
- **Improper dealing with allegations of research misconduct**: failure to address possible infringements, such as attempts to cover up misconduct and reprisals against whistle-blowers, or failing to adhere appropriately to agreed procedures in the investigation of alleged research misconduct accepted as a condition of funding. PACE requires organisations receiving PACE funding to have appropriate processes for addressing allegations of misconduct. The process for reporting concerns and making formal allegations must be clear and accessible. Processes for investigating allegations must be thorough, fair, constructive, conclusive and timely.