Research Policy

POLICY STATEMENT

Metro South Health (MSH) is committed to conducting research that advances knowledge and innovation and enhances our ability to serve our community. MSH believes in conducting research with integrity, respect for participants, and in compliance with ethical and legislative standards.

In accordance with this commitment, the Research Policy establishes an overarching Research Policy Framework which sets out the standards and provides guidance for ethical and effective research and is designed to support and enhance the quality and impact of our research efforts. It does this by ensuring consistent, clear and detailed procedures, work instructions and supporting documents are in place, and publicly available, to inform and guide MSH researchers in the pursuit of research excellence.

SCOPE

This policy applies to all research activities conducted by MSH and all MSH employees (including visiting medical officers, visiting health professionals, students, volunteers and researchers) who propose to undertake research utilising MSH participants, data, employees and/or resources.

OUTCOME

The Research Policy aims to outline principles and expectations in conducting research within MSH or in collaboration with external entities. Effective implementation of this policy will:

- Establish a clear framework for conducting research within or in collaboration with MSH.
- Ensure the standards, procedures, and guidelines for ethical, efficient, and effective research are in place and ensure that all research activities are aligned with MSH strategic goals and values.
- Identify, outline and describe the values, principles and standards that govern the conduct of clinical research at MSH, set the expectations for research conduct and provide a reference for researchers, stakeholders, and decision-makers within MSH.
- Promote transparency and accountability, protect the rights of research participants, and ensure that the MSH's research activities are done with the highest standards of ethical conduct, in accordance with all relevant laws, regulations, and guidelines.
- Support the development of new knowledge and innovations and enhance MSH's reputation as a leader in research.
- Enable employees to understand their responsibilities to comply with quality standards and fulfill their responsibilities and obligations to research participants, MSH and the community, when conducting or sponsoring human research and clinical trials.

It is the responsibility of facilities, departments, divisions, clinicians, and researchers to be aware of and apply the principles and processes outlined within this policy and subsequent MSH research procedures in conjunction with other relevant guidelines, standards, general and specific legal obligations (statutory or otherwise) as in place from time-to-time. Failure to comply with this policy and related procedures may amount to research misconduct on the part of the responsible individual.

PRINCIPLES

The principles outlined below, research excellence, research support and research administration, guides the intent of all MSH research policy, processes, guidelines and practices. By following these standards and guidelines, we aim to conduct research that is rigorous, ethical, and impactful, and that contributes to the advancement of knowledge.

- MSH upholds the values of iCARE^2 (integrity, compassion, accountability, respect, engagement, and excellence) in partnering to deliver care for the MSH community, training the workforce for the future and researching and innovating delivery of health care our community.
- MSH is committed to ensuring that all human research conducted by MSH employees with patients and participants, including their data or biospecimens, is performed in compliance with legislation, regulation, codes, nationally recognised human research ethics and governance guidelines, and international standards.
- The Research Policy Framework ensures the availability of documents which help guide research excellence, research support (inclusive of the Clinical Research Facility and research biobanks) and research administration in MSH.

1. RESEARCH EXCELLENCE

MSH supports the implementation of procedures, work instructions, guidelines, and protocols which embeds research excellence and aids in the translation of new and innovative research into improved patient outcomes and best quality clinical care, in support of the MSH Research Strategy (as in place from time-to-time) (‘Research Strategy’).

When conducting or sponsoring research and/or utilising MSH participants, data, employees and/or resources, MSH and researchers must strive to achieve research excellence by upholding principles underpinned by the following elements; research integrity, quality, data and privacy, finance and business management and impact and translation.

Research integrity	• Ethical conduct: Adherence to high ethical standards in the conduct of research, including obtaining informed consent from participants, protecting participant confidentiality and privacy, and ensuring the safety and well-being of participants. • Responsibility and accountability: Taking responsibility for the accuracy and integrity of research findings and being accountable for any errors or misconduct in research. • Supportive environment: MSH supports and promotes the highest standards of research. To that end, MSH has adopted the Australian Code for the Responsible Conduct of Research (‘the Code’) as the foundation

	document for the guidance of researchers in relation to their responsibilities. MSH researchers have a responsibility to ensure all their research activities are conducted with: o Honesty - conveying information truthfully. o Accuracy - avoiding research errors and reporting research findings precisely. o Objectivity - avoidance of inappropriate bias and presentation of research findings completely and impartially. • Investigation of research misconduct and complaints: Utilise fair and transparent research procedures and processes to investigate any reported breach of research integrity and/or research misconduct and research complaints. • Promoting trust in the scientific process: Ensure disclosed conflicts of interest are managed to ensure the integrity of the research process prior to ethical consideration and commencement of research in MSH.
Quality	• Scientific rigor: Conducting research with the highest standards of scientific rigor, including proper design, execution, and analysis of research studies. • Scope of practice: Ensuring all study personnel involved in research and clinical trials operate within their scope of practice. • Objectivity and independence: Ensuring objectivity and independence in the design, execution, and analysis of research studies, and avoiding conflicts of interest that may compromise the validity of research findings. • Evidence-based practice: Conducting research that is evidence-based and grounded in the best available scientific evidence. • Continuous improvement: Continuously improving the quality of research, through ongoing evaluation and refinement of research methods and processes. • Collaboration and peer review: Encouraging collaboration and peer review in research and seeking input and feedback from experts in the field to enhance the quality and impact of research efforts.
Data and privacy	• Data management: Proper management of research data, including data security and privacy, accurate record-keeping, secure storage and appropriate disposal of research data and ensuring the accuracy and validity of research findings. • Confidentiality: Ensuring the confidentiality of research data and protecting participant privacy and personal information. • Data security: Implementing appropriate measures to secure research data and prevent unauthorised access, use, or disclosure of research data. • Data privacy: Ensuring research data and results are managed appropriately, with proper consideration for data security and management.

	This includes obtaining informed consent from participants, protecting participant confidentiality and privacy, and ensuring the safety and well-being of participants. • Transparency and openness: Promoting transparency and openness in research and allowing for independent verification of research findings. • Compliance with Legislation and regulations: Uphold all guidelines for the collection, storage and use of research data, including data security and privacy. The intention is to protect the rights of participants ensuring their safety and well-being, and the integrity of research data.
Finance and business management	• Financial accountability: Ensuring financial accountability in the management of research funds, including transparent reporting of expenditures and financial results. • Budgeting and resource allocation: Developing and implementing appropriate budgeting and resource allocation processes to support research activities. • Effective contract management: Implementing effective contract management processes, including the negotiation and administration of research contracts and agreements. • Compliance with Legislation and regulations: Upholds all guidelines related to financial management, including but not limited to, tax laws, procurement regulations, and government funding regulations. • Continuous improvement: Continuously improving the financial and business management processes of research, through ongoing evaluation and refinement of methods and processes. • Stewardship: Responsible planning and management of resources and the efficient and appropriate use of financial and non-financial resources used in the conduct of research by ensuring: o the resources required to conduct research are appropriately identified and the availability of resources is confirmed prior to the commencement of research o research funds are appropriately costed to the research funding account/cost centre for both direct and indirect costs o utilisation of current information and technology to ensure good stewardship of research resources o research grant funds provided through the MSH Research Support Scheme (RSS) are dispersed in accordance with relevant procedures o all relevant approvals and agreements are in place prior to the commencement of research

	○ resources provided for research are used for their intended purpose and in accordance with relevant legislation, approvals and agreements and ○ the divestment of any resources that remain following the completion of the research is in accordance with relevant legislation, approvals, agreements and in the public interest.
Impact and translation	• Transparency and openness: Promoting transparency and openness in research, including the dissemination of research results, and allowing for independent verification of research findings. • Collaboration: Engaging with external organisations and individuals is encouraged and should be conducted in a manner that respects intellectual property rights and promotes the dissemination of research results. Provide guidance regarding the ownership and dissemination of research results, including patents and publications. • Partnership: Promoting collaboration and partnerships with stakeholders, including community organisations, government agencies, and industry partners, to enhance the quality, impact and translation of research. • Relevance: Conducting research that is relevant and responsive to the needs and priorities of society and aims to foster research that enhances patient care, challenges clinical practice and promotes innovative health service delivery. • Dissemination: Disseminating research findings and results to relevant stakeholders, including policymakers, practitioners, and the public. • Knowledge translation: Translating research findings into practical and accessible formats that can be used by stakeholders to inform decision-making and improve outcomes. • Evidence-based policy and practice: Advocating for evidence-based policy and practice and promoting the responsible use of research results to inform decision-making and improve outcomes.

2. RESEARCH SUPPORT

MSH has a role in providing a platform to support and facilitate a broad range of research, in an ethical and collaborative way, which meets the needs of clinicians and researchers whilst ensuring that all research conducted within MSH facilities, or involving MSH personnel, is conducted in a safe and responsible manner with the appropriate use of resources. MSH aims to provide research support by upholding principles underpinned by the following elements:

- Accessibility: Providing research support services that are accessible and available to researchers.
- Tailored support: Offering tailored support services to meet the specific needs and requirements of researchers and research projects.

- Capacity building: Building the capacity of researchers through training and professional development opportunities, and providing; access to specialised expertise and resources, advice, training and education.
- Build research capability: Increase the ability to retain and attract high quality health and medical researchers.
- Open and transparent communication: Encouraging open and transparent communication between researchers and research support services and promoting the sharing of information and best practices.
- Continuous improvement: Continuously improving the quality and effectiveness of research support services, through ongoing evaluation and refinement of methods and processes.

3. RESEARCH ADMINISTRATION

MSH promotes the consideration of ethical implications of research and the appropriate review of research in accordance with national frameworks. MSH ensures all ethical implications (including scientific considerations) are considered and appropriate action is taken to ensure that research is conducted in an ethical and scientifically robust manner by upholding principles underpinned by the following elements:

- Knowledge of Legislative requirements: Maintaining a comprehensive understanding of relevant regulations, laws, and guidelines related to research (i.e. National Statement) and providing guidance and support to researchers in complying with these requirements. Advise on common law obligations which may arise from the relationships between institutions, researchers, and participants, while contractual arrangements may impose further obligations.
- Operate the MSH Human Research Ethics Committee (HREC): Maintain certification by the National Health and Medical Research Council (NHMRC) to operate a health service HREC to review both the ethical and scientific validity of proposed research in MSH.
- Ethical review: Ensuring all research projects undertaken in MSH or involving MSH participants and/or resources all submitted for ethical review and approval:
    - All research involving human participants (incorporating research that involves information about human participants) must be reviewed and approved by a public health service based HREC that is certified by the NHMRC.
    - All research involving Genetically Modified Organisms (GMO) must be conducted in accordance with the National Framework of Ethical Principles in Gene Technology 2012 and reviewed and approved by an accredited Institutional Biosafety Committee (IBC).
- Research governance review: For research projects, ensure research governance review is undertaken, including Site-specific Assessment (SSA) of each research project. Site-specific authorisation includes contractual and financial management of research and research authorisation by the relevant authority
- Compliance monitoring: Undertake monitoring research activities to ensure compliance with relevant regulations, laws, and guidelines related to research pertaining to informed consent, confidentiality and protection of human participants. It also includes requirements when collaborating with external organisations and individuals including joint research projects and data sharing.

- Risk assessment: Conducting regular risk assessments to identify potential compliance issues and implement appropriate risk mitigation strategies.
- Transparency and openness: Promoting transparency and openness in research administration and allowing for independent verification of research compliance.
- Continuous improvement: Continuously improving the quality and effectiveness of research administration services, through ongoing evaluation and refinement of methods and processes.
- Minimise duplication: Ensuring all efforts are undertaken to minimise duplication of HREC review of research and legal review of research agreements for multi-centre research across Queensland.
- Streamline processes: Seek to engage with the MSH research community to facilitate, where possible, parallel HREC and Site-Specific Assessment (SSA) processes to enable timely review and approval of research projects.
- Valid and accurate research activity reporting: Achieve consistent research ethics and governance procedures and processes that facilitate research which allows for valid and accurate research activity reporting.

RELATED AND SUPPORTING DOCUMENTS

Legislation and other Authority	**Legislation** • *Australia's Foreign Relations (State and Territory Arrangements) Act 2020 (Cth)* • *Australian Radiation Protection and Nuclear Safety Act 1998 (Cth)* • *Australian Research Council Act 2001 (Cth)* • *Copyright Act 1968 (Cth)* • *Coroners Act 2003 (Qld)* • *Crime and Corruption Act 2001 (Qld)* • *Criminal Code Act 1899 (Qld)* • *Defence Trade Controls Act 2012 (Cth)* • *Designs Act 2003 (Cth)* • *Epidemiological Studies (Confidentiality) Act 1981 (Cth)* • *Financial Accountability Act 2009 (Qld)* • *Gene Technology (Licence Charges) Act 2000 (Cth)* • *Gene Technology (Queensland) Act 2016 (Qld)* • *Gene Technology Act 2000 (Cth)* • *Guardianship and Administration Act 2000 (Qld)* • *Hospital and Health Boards Act 2011 (Qld)* • *Hospital Foundations Act 2018 (Qld)* • *Human Rights Act 2019 (Qld)* • *Industrial Relations Act 1999 (Qld)* • *Information Privacy Act 2009 (Qld)* • *Mental Health Act 2016 (Qld)* • *National Health and Medical Research Council Act 1992 (Cth)*

	• *Patents Act 1990 (Cth)*
	• *Powers of Attorney Act 1998 (Qld)*
	• *Privacy Act 1988 (Cth)*
	• *Prohibition of Human Cloning for Reproduction Act 2002 (Cth)*
	• *Public Governance, Performance and Accountability Act 2013 (Cth)*
	• *Public Health Act 2005 (Qld)*
	• *Public Interest Disclosures Act 2010 (Qld)*
	• *Public Records Act 2002 (Qld)*
	• *Public Sector Ethics Act 1994 (Qld)*
	• *Public Service Act 2008 (Qld)*
	• *Research Involving Human Embryos Act 2002 (Cth)*
	• *Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003 (Qld)*
	• *Security Legislation Amendment (Critical Infrastructure Protection) Act 2022*
	• *Statutory Bodies Financial Arrangements Act 1982 (Qld)*
	• *Therapeutic Goods Act 1989 (Cth)*
	• *Trade Marks Act 1995 (Cth)*
	• *Transplantation and Anatomy Act 1979 (Qld)*
	• *Work Health and Safety Act 2011 (Qld)*
	Regulations
	• Epidemiological Studies (Confidentiality) Regulations 2018 (Cth)
	• Financial Accountability Regulation 2009 (Qld)
	• Financial and Performance Management Standard 2009 (Qld)
	• Gene Technology Regulations 2001 (Cth)
	• Hospital and Health Boards Regulation 2012 (Qld)
	• Hospitals Foundation Regulation 2015 (Qld)
	• Information Privacy Regulation 2009 (Qld)
	• Public Health Regulation 2018 (Qld)
	• Statutory Bodies Financial Arrangements Regulation 2007 (Qld)
	• Therapeutic Goods (Medical Devices) Regulations 2002 (Cth)
	• Therapeutic Goods Regulations 1990 (Cth)
	• Transplantation and Anatomy Regulation 2004 (Qld)
	National Health and Medical Research Council (NHMRC)
	• Administering Institutions
	• Australian code for the care and use of animals for scientific purposes 8th edition 2013 (updated 2021)
	• Australian Code for the Responsible Conduct of Research, (2007) (Updated 2018)
	• Australian Code for the Responsible Conduct of Human Research supporting guides:
	  ○ Authorship
	  ○ Collaborative research
	  ○ Disclosure of interests and management of conflicts of interest

	○ Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research, 2018 ○ Management of data and information in research ○ Peer review ○ Publication and dissemination of research ○ Research Integrity Advisors ○ Supervision • Competencies for Australian Academic Clinical Trials (2018) • Data Safety Monitoring Boards (DSMBs) (2018) • Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and Communities: Guideline for research and stakeholders (2018) • Ethical consideration in Quality Assurance and Evaluation Activities 2014 • Framework for Monitoring: Guidance for the National Approach to Single Ethical Review for Multi-centre Research 2012 • Good Practice Process for Site Assessment and Authorisation Phases of Clinical Trial Research Governance. Version 2.3. September 2016. National Health and Medical Research Council, Canberra, Australia • Guidelines to Promote the Wellbeing of Animals Used for Scientific Purposes, 2008 • Medical Genetic Testing: Biobanks (2010) • Medical Genetic Testing: Information for health professionals (2010) • National Certification Handbook, 2012 • National Statement on Ethical Conduct in Human Research (2007) - Updated 2018 (as amended from time to time) • NHMRC Certification Handbook, National Certification Scheme of Institutional Processes related to the Ethical Review of Multi-centre Research 2012 • NHMRC ethical issues and resources • Payment of participants in research: information for researchers, HRECs and other ethics review bodies (2019) • Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods (2018) • Research Governance Handbook: Guidance for national approach to single ethical review December 2011 • Risk-based Management and Monitoring of Clinical Trials involving Therapeutic Goods (2018) • Safety monitoring and reporting in clinical trials involving therapeutic goods (2016) • Statement on consumer and community involvement in health and medical research (2016) **Therapeutic Goods Administration** • Australian Clinical Trial Handbook: Guidance on conducting clinical trials in Australian using “unapproved” therapeutic goods (2020) • Clinical Trials • Good Clinical Practice (GCP) Inspections Program • Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) (2016)

	• Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (CPMP/ICH/377/95) 2000 • Pharmacovigilance responsibilities of medicine sponsors: Australian recommendations and requirements (2018) • Special Access Scheme (SAS) and Authorised Prescriber (AP) **Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)** • Code for Radiation Protection in Planned Exposure Situations (2020) • Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005) • Fundamentals for Protection Against Ionising Radiation (2014) • Guide for Radiation Protection in Existing Exposure Situations (2017) • Radiofrequency Electromagnetic Energy and Health: Research Needs **National** • National Principles for Teletrials in Australia • National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia **Queensland** • General Retention and Disposal Schedule • Health Sector (Clinical Records) Retention and Disposal Schedule • Health Sector (Corporate Records) Retention and Disposal Schedule • Information security policy [IS18:2018] • Public Service Code of Conduct • Queensland Procurement Policy (QPP) 2021 **Department of Health** • Health Service Directive: Research Ethics and Governance Directive QH-HSD-035:2013 • My health, Queensland's future: Advancing health 2026 • Queensland Advancing Health Research 2026 • Queensland Health Clinical Research Fellowships • Queensland Public Sector Health System Multi-Site Research Collaboration Agreement Standard Terms • Research involving patients who are unable to give consent Policy Statement (April 2018) • Research Management Guideline: external funding and infrastructure support QH-GDL-013-1:2022 • Research Management Policy QH-POL-013:2022 • Research Management Standard QH-IMP-013:1:2022 • Standard Operating Procedures for Queensland Health HREC Administrators • Standard Operating Procedures for Queensland Health RGOs **Other** • ACSC Information Security Manual (ISM) • AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (2020)

	• Australasian Tele-Trial Model Access to Clinical trials closer to home using tele-health • Australia's Cyber Security Strategy 2020 • Clinical investigations of medical devices for human subjects – Good Clinical Practice ISO 14155:2020 • CONSORT Statement for Clinical Trials • Guidelines for Good Pharmacoepidemiology Practices (GPP) 2015 • Medical Technology Association of Australia (MTAA): Clinical Investigations Research Agreements (CIRA) • Medicines Australia: Clinical Trials Research Agreements • Medicines Australia: Indemnity and Compensation Guidelines • Office of the Gene Technology Regulator: National Framework of Ethical Principles in Gene Technology 2012 • Office of the Information Commissioner: All agencies - Use or disclosure for public interest research • Queensland Biotechnology Code of Ethics **Metro South Health** • Finance Management Practice Manual (FMPM) • PR2016-66 Conflict of Interest Procedure • PL2014-38 Management of Conflict of Interest Policy • Metro South Health – SERTA Committee Business Rules • Metro South Health Research Strategy 2019-2024 • PL2018-62 Risk Management Policy • PR2018-97 Risk Management Procedure

Standards	• National Clinical Trials Governance Framework
	• National Safety and Quality Health Service (NSQHS) Standards 2nd Ed.
	  ○ Standard 1 – Clinical Governance
	  ○ Standard 2 – Partnering with Consumers

Supporting documents	• MSH and Directorate policy documents aligned to the Research Policy • Supporting documents aligned to the Research Policy

DEFINITIONS

Term	Definition
Ethical review	Ethical review of research refers to the process of evaluating research protocols to ensure that they meet established ethical standards for conducting research with human subjects. The primary purpose of ethical review is to protect the rights and welfare of research participants, while also ensuring that the research is conducted in a scientifically valid and responsible manner.
Monitoring	Research monitoring refers to the process of tracking and reviewing a research study's progress to ensure that the study is conducted according to the protocol and ethical standards. The monitoring process can help to identify and address issues that arise during the study, such as deviations from the protocol, noncompliance with ethical standards, or problems with data collection.

Term	Definition
Research Policy Framework	A all policy and supporting document aligned to MSH research practices.
Policy framework documents	Policy documents include policies, procedures, work instructions and guidelines – PR2013-01 Policy Document Management Procedure.
Quality	Quality standards in research refer to the criteria used to evaluate the quality and validity of research studies. These standards are important to ensure that research studies are conducted in a rigorous and transparent manner, and that the findings can be trusted and used to inform decision-making.
Research	Clinical research - A type of scientific research that is conducted with human participants to understand, diagnose, prevent, or treat medical conditions or diseases. It involves the study of human biology, physiology, pharmacology, and psychology, among other disciplines, in order to improve our understanding of health and disease. Clinical research can take many forms, including observational studies, randomised controlled trials, and retrospective analyses of patient data. In some cases, clinical research involves testing new drugs, medical devices, or other interventions in human subjects to evaluate their safety and efficacy. Clinical research is typically conducted in a controlled environment, such as a hospital, and is overseen by a team of researchers, including physicians, nurses, and other healthcare professionals. The goal of clinical research is to generate new knowledge that can improve patient outcomes, inform clinical practice, and advance medical science. Non-clinical research - The concept of research is broad and includes the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative
Research excellence	MSH has committed to go beyond compliance, to a culture of excellence in clinical services – our research endeavours are an integral part of that commitment. MSH is committed to the highest standards of ethical conduct, quality and management in research.
Research governance review	Research governance/site-specific authorisation includes contractual and financial management of research and research authorisation by the relevant authority.
Sponsor	A sponsor is an individual, organisation, or company that takes responsibility for initiating, managing, and financing a research project or clinical trial. The sponsor is typically the organisation that has developed the new drug, medical device, or other intervention being tested in the project.

HUMAN RIGHTS ACT 2019

Metro South Hospital and Health Service is committed to respecting, protecting and promoting human rights. Under the *Human Rights Act 2019*, Metro South Health has an obligation to act and make decisions in a way that is compatible with human rights and, when making a decision, to give proper consideration to human rights. When making a decision about research, decision-makers must comply with that obligation. Further information about the *Human Rights Act 2019* is available at: https://www.forgov.qld.gov.au/humanrights.

POLICY DETAILS

Policy Name	Research Policy
Policy Number	PL2023-92
Current Version	1.0
Keywords	Research, ethics, protocol, governance, site specific assessment, research excellence, quality management system
Executive Sponsor	Chief, People, Engagement and Research Officer, MSH
Endorsing Committee	Executive Strategic Governance Committee
Approving Authority	Health Service Chief Executive (HSCE)
Document Author	Manager, Research Development, Metro South Research
Next Review Date	May 2026

REVIEW HISTORY

Version	Approval date	Effective from	Authority	Comment
1.0	26/05/2023	12/06/2023	HSCE	The Metro South Research Policy supersedes the following policies: • Research Management Policy PL2017/55 • Research Biorepositories Policy PL2021-83 • Clinical Research Facility Policy PL2017/53 All procedures aligned to the above-mentioned superseded policies are now incorporated under the Research Policy until such a time that they are reviewed and published.