Monitoring of Approved Research Policy

Section 1 - Purpose

(1) The purpose of this Policy is to outline how approved research is monitored by the University and the University Review Bodies to support Research Governance (Research Governance Framework) and the responsible condcut of research (QUT Code for Responsible Conduct of Research).

Section 2 - Application

(2) Monitoring of approved research applies to all research projects undertaken by staff, researchers, students and visitors that requires review and approval from a University Review Body and/or other ethics review body.

Section 3 - Roles and Responsibilities

Position	Responsibility
Head of Research Portfolio	Responsible for ensuring that approved research is monitored. Approves clinical trials regulated by the Therapeutic Goods Administration (TGA) involving QUT investigators.
Executive Director, Office of Research Services	Manages sponsor responsibilities for clinical trials where QUT is the sponsor.
Director, Office of Research Ethics and Integrity	Oversees the conduct of QUT's monitoring obligations under the Australian Code, National Statement, Scientific Use Code and Good Clinical Practice (ICH/GCP).
Executive Director Health, Safety and Environment	Has responsibility for the implementation of health, safety and environment policies at QUT and, through the department's team of Health, Safety and Environment professionals, provides support to University Officers in meeting their due diligence duty under the legislation.
Research sponsors	Internal and external entities that provide funding or in-kind support to a QUT research project and include commercial companies, collaborative research groups and government entities. Responsible for ensuring that clinical trials are adequately monitored.
University Review Body	Committee responsibilities are described in the respective committee charters: 1. University Human Research Ethics Committee 2. University Animal Ethics Committee 3. University Biosafety Committee
Staff, students and visitors involved in research activities	Share responsibility and accountability for the University's research being conducted according to appropriate regulatory, ethical and scientific standards. Provide authorised QUT staff, University Review bodies and external regulators access to research related records.

Section 4 - Policy Principles

(3) Monitoring of research approved by a University Review Body is a component of QUT's Research Governance Framework and QUT's commitment to the Australian Code for the Responsible Conduct of Research (Australian Code),

the National Statement on the Ethical Conduct of Research (National Statement), Australian code for the care and use of animals for scientific purposes (Scientific Use Code) and the requirements of other external regulators.

(4) Monitoring of approved research is undertaken to assess that a project is being or has been conducted in the manner approved by a University Review Body and in accordance with institutional and regulatory requirements.

(5) Monitoring of approved research is conducted in accordance with the principles of QUT's Research Governance Framework.

(6) Procedures for monitoring approved research should foster education and promotion of ethically responsible research practices.

Section 5 - Obligations

(7) Research that is reviewed and approved by a University Review Body must comply with University policy and all relevant legislation and regulatory guidelines.

(8) Monitoring is the mechanism by which:

a. the University Review Body meets its obligations to monitor approved research;
b. the University meets its obligations to promote and support a high level of research governance practice and support responsible research conduct; and
c. the University meets its sponsor responsibilities for QUT sponsored clinical trials.

(9) All individuals conducting research associated with the University must maintain adequate records relating to their research and make these records available to authorised individuals and external regulators involved in the review and monitoring of their research and related activities.

Section 6 - Frequency and Duration

(10) The frequency and type of monitoring should reflect the degree of risk to research participants, animals and the environment and any regulatory requirements.

(11) Monitoring of approved research begins upon approval of the research and continues throughout the lifecycle of the research project, including the closure of the research project, communication of individual results and publication of outcomes.

Section 7 - Mechanisms

University Review Body

(12) The University Review Bodies monitor research to ensure responsible research practices and may delegate monitoring obligations to the Office of Research Ethics and Integrity for the purposes of coordinating and conducting monitoring activities.

(13) Monitoring will be undertaken in accordance with the University Review Body Standard Operating Procedures for monitoring approved research.

University

(14) The University is responsible for ensuring research is conducted responsibly, ethically and with integrity. To achieve this the University exercises appropriate quality control and risk management of approved research, including compliance with the following processes throughout a project's duration.

a. Health, Safety and Environment;
b. Contracts and Legal Instruments Management;
c. Indemnity and insurance;
d. Finance (Budgets and Grants);
e. Management of Research Data and Primary Materials;
f. Conflicts of Interest;
g. Responsible research practices;
h. Trade Controls for Goods, Software, Technology and Services.

(15) The University may request monitoring of an approved research project in consultation with the University Review Body unless there are actions or risks associated with the research that can be dealt with under another mechanism i.e. health and safety, fraud and corruption, misconduct.

(16) Where the University is the sponsor of an approved research project (e.g. clinical trial), it is responsible for implementing and maintaining quality assurance and quality control systems to ensure that the research is conducted and data are generated, documented (recorded), and reported in compliance with the protocol, good clinical practice and relevant regulatory compliance.

Researcher

(17) Chief Investigators are ultimately responsible for ensuring appropriate procedures for monitoring are in place, providing reports, maintaining records and taking prompt actions in response to unexpected adverse events, risk and emergencies.

Section 8 - Coordination and Efficiency

(18) Monitoring of approved research must be undertaken in a coordinated approach that minimises duplication and unnecessary disruption to the day to day activities of the University.

(19) Where approved research is being conducted under the auspices of QUT and includes additional institutions, the University Review Body in collaboration with the Office of Research Ethics and Integrity will make reasonable arrangements to ensure appropriate monitoring occurs.

(20) Where a University Review Body does not review and approve a research project as the lead Committee, it will not have a monitoring role with respect to that project and cannot accept the delegation of responsibility from an institution to perform such a role, unless otherwise stipulated (e.g. via a collaborative or inter-institutional agreement).

Section 9 - Reporting

University Review Body

(21) The University Review Body must notify the Chief Investigator of the outcomes of any monitoring process. The University Review Body reports its monitoring of approved research activities annually to the University Research Committee.

University

(22) Reports on monitoring activities conducted by the University may be provided to the relevant University Review Body, for endorsement and where necessary assistance in addressing recommendations.

(23) Investigators are informed of the outcomes of any monitoring activities and provided the opportunity to comment.

(24) As sponsor the University must notify the Chief investigator of the outcomes of all monitoring processes and report to the Therapeutic Goods Administration and other relevant parties any findings that could adversely affect the safety of participants, impact the conduct of the trial or alter the University Human Research Ethics Committee approval to continue the trial.

Researcher

(25) Researchers must report any adverse events or unexpected outcomes and must notify the University Review Body promptly.

(26) Researchers must provide reports to the relevant University Review Body and the University in accordance with reporting requirements.

(27) For QUT sponsored clinical trials Chief Investigators must report to the sponsor representative all significant safety issues, serious adverse events, protocol deviations and any other reporting requirements as outlined in the protocol.

Section 10 - Definitions

Term	Definition
Approved Research	Means a project reviewed and approved by a University Review Body and/or other ethics review body.
Chief Investigator	Is defined in Management of Research Data and Primary Materials Policy.
External Regulators	Includes (but not limited to) the National Health and Medical Research Council (NHMRC), the Australian Research Council (ARC), the Therapeutic Goods Administration (TGA), the Queensland Department of Agriculture and Fisheries (DAF), the Office of Gene Technology Regulator (OGTR), Defence Export Control Office (DECO), Department of Foreign Affairs and Trade (DFAT) and the Department of Agriculture Water and the Environment (DAWE).
Lead Committee	Is defined as the committee who is allocated to undertake review and approval of a research project.
Monitoring	Is defined in Research Governance Framework.
Sponsor (as defined in Integrated Addendum to ICH E6(R1)	Guideline for Good Clinical Practice ICH E6(R2)) an individual, company, institution, or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial.
University Review Body	Means the University Biosafety Committee, University Animal Ethics Committee, University Human Research Ethics Committee and other human ethics review bodies approved by the University, e.g. review of low risk human research.

Section 11 - Delegations

(28) Refer to Register of Authorities and Delegations (VC165) (QUT staff access only).

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