



UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

UNIVERSITY OF PRETORIA
Department of Research and Innovation

RESEARCH COMPLIANCE REGULATION

Document type: Regulation
Policy Category: Research

Document number: S 5103/23

TABLE OF CONTENTS

1. Purpose	2
2. Scope	2
3. Regulations	2
3.1. The University respects academic freedom and supports researchers.....	3
3.2. The University expects researchers to behave ethically.....	3
3.3. Research may be subject to approval by the University	6
3.4. Conduct compliant research.....	11
3.5. Respect intellectual property and intellectual property rights.....	12
3.6. Secure research data, research findings and intellectual property	14
3.7. Share, publish or reuse research data and research findings responsibly	15
3.8. Report research data management incidents.....	18
3.9. Act against research misconduct.....	20
4. Consequences of non-compliance	21
4.1. For the University.....	21
4.2. For researchers.....	21
4.3. For research participants or communities, and the environment.....	22
4.4. For animals	22
5. Definitions	22
6. Roles and responsibilities	26
7. Associated documents	28
8. Document metadata	28

1. Purpose

The purpose of the Research Compliance Regulation is to ensure that researchers and the University:

- conduct research ethically;
- protect the rights and interests of research participants, researchers, the University and society;
- conduct research effectively and efficiently;
- preserve and secure Research Data, research findings, and intellectual property (IP);
- ensure open access to Research Data when appropriate; and
- comply with all laws, regulations, codes, and contracts.

2. Scope

This Regulation applies to all research conducted at the University. Research is any activity aimed at generating or improving knowledge in any discipline (or across disciplines) through enquiry or systematic investigation.

This Regulation applies to academic, scientific and commercial research. It applies to research:

- by the University's students and staff (temporary and permanent);
- by affiliates, visiting research associates, contractors and collaborators who are subject to the University's policies by contract;
- conducted at Centres, Institutes, Units, Bureaus and any other recognisable structures of the University;
- when the University's infrastructure is used;
- that the University funds (in full or partially); and
- in which the University's students or staff are research participants.

3. Regulations

The University:

- respects academic freedom and supports researchers;
- expects that researchers behave ethically;
- approves and monitors research conducted at the University;
- conducts research that complies with the law and ethical norms;
- respects IP and IP rights;
- secures Research Data, findings, and IP;
- shares publishes or reuses research responsibly;
- reports Research Data management incidents; and
- acts against research misconduct.

3.1. The University respects academic freedom and supports researchers

The University must:

- respect academic freedom (freedom of inquiry); and
- support researchers by making its facilities, equipment and services reasonably available to researchers.

The University respects academic freedom and supports researchers by ensuring that researchers:

- are free to choose the subject of their research, to decide how research is conducted and to seek support for their research from any source;
- have access to information required for their research if providing such access is legal and does not violate any other rights (e.g., to personal or confidential information);
- have the right to disseminate their research results without oversight or alterations by external organisations unless that right has been conferred by law or agreed upon in a contract;
- have access to resources based on fairness, and educational and ethical merits (and not speculation on the political or social acceptability of research results); and
- have been trained in research ethics and compliance.

3.2. The University expects researchers to behave ethically

Researchers must:

- be accountable;
- be socially responsible;
- be fair;
- be beneficent;
- respect individual dignity and autonomy;
- be professional;
- avoid unfair discrimination; and
- avoid or declare conflicts of interest.

3.2.1. Accountability

Researchers are accountable to the University for their research. However, the University embraces the principle of ethical self-management. This means that researchers should accept responsibility for:

- the design, methodology and execution of their research;
- planning their research so that the findings will be credible and valid;
- reporting their findings and the limitations thereof so that their findings can be subjected to peer evaluation and be made available to the public; and
- pointing out alternative interpretations when applicable.

The University will:

- implement processes (e.g., the research ethics approval process) to help researchers comply with this Regulation;
- ensure that researchers, Supervisors, and research ethics committees are offered training on ethics and compliance; and
- monitor compliance with the University's policies and legal obligations, the quality of research, the ethical acceptability of research procedures, and the financial management of research-related funding. Researchers must cooperate during these reviews.

3.2.2. Social responsibility

Researchers must be attuned to the needs and problems of the international, national and local communities in which they conduct their research. They should address these needs and problems and contribute to developing prosperous, free and just communities.

3.2.3. Fairness

The University must treat researchers fairly. For instance, the University must not discriminate unfairly between researchers when granting access to services, benefits, opportunities or facilities.

Researchers must treat individuals and communities involved in research activities fairly.

Researchers must ensure that:

- they recognise others for the IP that they contribute;
- engagement with communities is based on mutual agreement, that communities play a role in deciding the goals and benefits pursued in the research, and that the needs of the University and the community are considered;
- contributors share in commercial benefits (see the University's Intellectual Property Policy and the Intellectual Property Compliance Regulation);
- funds allocated for research are divided as agreed among participating institutions, faculties, and researchers;
- the results of the research are freely available to all, as long as this does not encroach on the rights of the University, funders, research participants, or others (e.g., privacy rights, rights to confidentiality or IP rights);
- community members have fair access to the benefits of the research and any burdens on the community are fairly distributed;
- research participants are representative of the entire South African community and are not selected unfairly from certain classes of persons, certain ethnic groups, or persons confined to institutions (unless the research is aimed at a specific group); and
- recruitment is fair and research participants are not unduly pressured to participate and have the right to withdraw with no consequences.

3.2.4. Beneficence (promotion of well-being and nonmaleficence)

Researchers must:

- assess and mitigate the potential for harm to individuals, communities, animals, other organisms, or the environment;
- aim to improve and promote the quality of life and well-being of humans, animals, and other organisms and benefit the environment;
- display sensitivity and responsiveness to the rights, welfare, and interests of all involved in research, including society, other researchers, and the University; and
- not perpetuate socio-political injustices and harm from the past.

3.2.5. Respect for individual dignity and autonomy

Researchers must respect individual dignity and autonomy by:

- giving research participants the information that they need to make informed decisions about their participation in the research; and
- accepting these decisions.

Researchers may not offer research participants incentives to influence or induce them to participate in their research. Covering the cost of participation or paying for the use of property or services is not considered an incentive.

Researchers must protect individuals who are incapable of making decisions (due to immaturity or incompetence due to developmental, mental or physical disorders or other circumstances that seriously limit the ability to make informed decisions).

3.2.6. Professionalism

Researchers must ensure that:

- they have or acquire the necessary academic, technical, and financial competence to conduct their research;
- their research or the research done under their supervision is accurate, valid, and credible;
- they apply best practices when they plan, implement and report their research;
- their work is their own;
- the procedures, theories, and data used during the research process are disclosed and reported to the academic community and the general public (unless there are legal or ethical reasons not to publish or report); and
- they maintain financial control over the allocation of research funds.

3.2.7. Refraining from unfair discrimination

Researchers must not directly or indirectly unfairly discriminate against someone on the grounds of race, gender, sexual orientation, pregnancy, marital status, family status, culture, language, ethnic or social origin, age, disability or medical condition, religion, conscience, or beliefs and birth.

Discrimination includes:

- withholding services, benefits, opportunities (e.g., the opportunity to participate in research) or facilities from a person on these grounds; or
- promoting a lack of respect or intolerance towards an individual or group.

Discrimination will only be tolerated if the discrimination is fair and in the interest of the person or community in question.

3.2.8. Conflicts of interest

Conflicts of interest arise when a researcher's private or personal interests conflict with their professional interest to such an extent that it undermines the integrity of the research. It is also unacceptable for clients or funders to compromise researchers' professionalism or integrity by interference or pressure.

Researchers must not abuse their position as researchers for personal gain; although they may have their own secondary interests, these interests must not compromise their objectivity.

Supervisors must ensure that their advice to researchers is not unduly influenced by personal gain or interests.

3.3. Research may be subject to approval by the University

Academic freedom is subject to legal and ethical limits. For certain types of research, researchers must obtain approval from the University before starting and ensure that they comply with the University's policies and legal obligations.

The following types of research must be submitted for approval via the PeopleSoft Ethics Application and Approval System:

- All research involving human participants (regardless of whether the information of the participants was collected anonymously or anonymised after collection) or the Personal Information of members of the public or other individuals or organisations.
- Research conducted by an external researcher (not registered at the University, employed by the University or contracted by the University) who wants to collect data from prospective students, current students, alumni, faculty and professional services staff members and other University stakeholders.
- All research involving animals or samples that originate from animals, including opportunistically collected samples or investigation around animal ownership, farming practices, animal use, animals on observation or working animals.
- Health Research.
- Research that involves the reuse (secondary use) of Research Data that contains the Personal Information of research participants, members of the public or other individuals or organisations.

- Any other research that is subject to approval according to the approval procedures of the relevant faculty, a research ethics committee or by law.

Depending on the type of research and how it is funded, the approval process may have several steps that are outlined below. Researchers must:

- ensure that the Innovation and Contracts Management Office or Enterprises University of Pretoria (Pty) Ltd (Enterprises UP) concludes a research contract with external organisations or external researchers;
- develop a research proposal;
- perform an assessment in accordance with the Protection of Personal Information Act 4 of 2013 (POPIA);
- obtain approval from the Survey Coordinating Committee; and
- obtain ethics approval from a research ethics committee(s), the Animal Ethics Committee or any other approvals prescribed by the relevant faculty or by law.

3.3.1. Conclude a research contract with external organisations or external researchers

The University must conclude a research contract with any outside organisation or outside researchers if they commission or fund research (in whole or in part).

The University distinguishes between commercial contract research and other contract research.

Commercial contract research must be conducted through Enterprises UP. The researcher must obtain permission from the relevant head of department, dean or both before commencing the research. The following are examples of when contract research is commercial in nature:

- the research has a clear commercial intent and focus;
- the recipient of the research outcomes will be leveraging the outcomes for commercial gain (e.g., clinical trials, analytical services, feasibility studies, proof of concept, prototype development);
- the research was the result of Enterprises UP's own commercial endeavours and exploits;
- a proposal must be submitted to the client via a tender process, quotation or other formal supply chain management process;
- the research will be done at commercial rates without any contribution or subsidy from the University.

The specific entity that will handle a contract will be determined through consultation between the principal investigator, the Executive Manager of Enterprises UP and the Head: Innovation and Contracts Management.

Intellectual Property generated by both commercial and non-commercial contract research must be managed in accordance with the University's Intellectual Property Policy and Intellectual Property Compliance Regulation.

All other research contracts for non-commercial contract research must be concluded with the University and the contract must be approved by the Innovation and Contracts Management Division of the University and the relevant head of department, dean or both.

The research contracts for non-commercial research must comply with the University's Guideline on Research Contracts (as approved by the Executive) and must contain provisions on:

- a budget that reflects the scope of the work that the University employee will undertake and the infrastructure, services and support funding that the University will provide;
- how costs incurred by the University will be recovered;
- the ownership of the IP used in and created by the research;
- confidentiality;
- data protection (if the Research Data will contain identifiable personal information); and
- publication or sharing of Research Data, research findings or other IP.

Contract research must be distinguished from consulting contracts and outside work:

<p>Consulting:</p> <p>Consulting occurs when a researcher makes their expertise available to an outside organisation for commission. Unlike research, the primary purpose of consulting is not to generate new knowledge, but to provide advice and expertise to solve problems.</p>	<p>The researcher must obtain the University's permission to use its infrastructure, staff or students and conclude an agreement via Enterprises UP.</p> <p>Researchers can obtain permission from the relevant head of department, dean or both.</p>
<p>Outside work:</p> <p>Outside work occurs when an employee works for their own interest outside the course and scope of their employment at the University without using the University's infrastructure, staff or students.</p>	<p>The researcher must obtain the University's permission to do outside work but does not need to conclude an agreement with the University or with Enterprises UP.</p> <p>Researchers can obtain permission from their line manager and Human Resources.</p>

The University has established a Contract Research and Consulting Committee to:

- consider requests to waive the University's cost recovery fee for contract research; and
- to make a final decision when there is a dispute about whether the research is commercial contract research or consulting.

This committee is comprised of the following individuals:

- Vice-Principal: Research, Innovation and Postgraduate Education (chairperson).
- Senior Director: Research and Innovation.
- Director of Finance.
- Executive Director: Finance.
- Chief Executive Officer of Enterprises UP.

The committee will convene every three (3) months or as necessary and any meeting shall be requested via the Department of Research and Innovation.

3.3.2. Develop a research proposal

Researchers must develop a research proposal for all types of research that is subject to the University's approval (as described in clause 3.3).

A guideline for research proposals is available on the PeopleSoft Ethics Application and Approval System. For assistance with the research proposal, researchers may also approach their Supervisor, principal investigator, Deputy Dean or designated faculty member.

3.3.3. Perform a Protection of Personal Information self-assessment

To ensure that the University complies with the POPIA Code of Conduct for Research, researchers must perform a POPIA self-assessment for all research involving human research participants, members of the public or other individuals or organisations to determine:

- whether the research is subject to POPIA;
- whether the research is inherently high risk in terms of POPIA; and
- whether the research complies with POPIA.
-

The POPIA self-assessment form part of the PeopleSoft Ethics Application and Approval System.

If the research is inherently high risk, the Research Data Management Committee must :

- confirm that a POPIA self-assessment was performed;
- monitor that research data is pseudonymised unless there is a compelling reason why it is not feasible or appropriate; and
- request that researchers confirm periodically that they have implemented their Research Proposal (including a Research Data management plan) as approved.

3.3.4. Obtain approval from the Survey Coordinating Committee

If a researcher is going to gather Research Data by surveying the University's students or staff, the researcher must obtain approval from the Survey Coordinating Committee. See the definition of 'Survey' in the Definitions section.

Remember that this approval is in addition to obtaining approval for the research from a research ethics committee or faculty (discussed in 3.3.5).

For more information about this and other Surveys, see the Survey Policy.

3.3.5. Obtain approval from a research ethics committee or faculty

Each research ethics committee and faculty must create a written procedure and accompanying guidelines that set out:

- what type of research requires approval;
- who must approve the research (e.g., a research ethics committee or faculty committee);
- the additional requirements for approval (e.g., compliance with guidelines on the use of animals in research and education or guidelines for research involving human participants);
- the process that must be followed (e.g., the PeopleSoft Ethics Application and Approval System or another process); and
- where research administration documentation (such as research proposals and records of decisions made during the approval process) will be stored (e.g., the PeopleSoft Ethics Application and Approval System or the Graduate Research Management System).

All procedures and guidelines will be housed on the University's Research Resources page. Research ethics committees and faculties must ensure the procedures and guidelines are updated from time to time.

3.3.6. Obtain approval from the Animal Ethics Committee

The Animal Ethics Committee is a university-level ethics committee and consists of members from Veterinary Science, Health Sciences and NAS. The Animal Ethics Committee is accredited by the National Health Research Ethics Council of the Department of Health. Applications are referred to the Animal Ethics Committee by the respective Faculty committee once they have approved the project. No project falling under the mandate of the Animal Ethics Committee may commence until full approval has been received.

All research or training (including undergraduate and postgraduate modules) using animals or animal-derived samples (even if stored) must attain approval from the AEC. All Projects must comply with the requirements of the South African National Standard for the care and use of animals for scientific purposes (SANS10386).

3.4. Conduct compliant research

When conducting their research, researchers must:

- follow their approved research proposal or approve material changes in cases where approval of the research proposal was required in terms of 3.3.5;
- comply with this and other University policies, procedures and templates;
- comply with all laws, regulations, codes and other binding rules; and
- comply with any research contracts.

The Department of Research and Innovation must ensure that:

- the research contracts that the University is a party to are reviewed by the Innovation and Contracts Management Office, and researchers are aware of their obligations; and
- researchers receive sufficient guidance and training to perform their responsibilities and comply with all laws, regulations, codes and other binding rules.

3.4.1. Follow the approved research proposal

Researchers must follow their approved research proposal (if one was required). If there are material changes to their research, researchers must approve changes in cases where approval was required in terms of 3.3.5.

3.4.2. Comply with all binding rules

The University's policies and procedures are designed to ensure that researchers comply with:

Research-related legislation	For example: <ul style="list-style-type: none">• the National Health Act 61 of 2003;• the Animal Protection Act 71 of 1962; and• the Veterinary and Paraveterinary Professions Act 19 of 1982.
IP-related legislation	For example, the Intellectual Property Rights from Publicly Financed Research and Development Act 51 of 2008.
Ethical codes	For example: <ul style="list-style-type: none">• the Department of Health Ethics in Health Research: Principles, Processes and Structures; and• the South African National Standard: The care and use of animals for

	scientific purposes (SANS10386 version 2 (2021)).
--	---

3.4.3. Comply with research contracts

Once the Innovation and Contracts Management Office approves a research contract, it must ensure that the researchers who are subject to the contract:

- have access to the contract; and
- are aware of all obligations and risks that the University accepted during the contract negotiation.

Researchers must ensure that they:

- understand the obligations that the contract places on them and request further legal advice from the Innovation and Contracts Management Office where necessary;
- develop strategies to mitigate any risks that the University accepted during the negotiation of the contract;
- align their research proposal to the obligations and risks created by the contract;
- periodically review the contract to ensure that they comply with it; and
- inform the Innovation and Contracts Management Office if there are changes to the research proposal that would require the contract to be amended or if the researchers, University or another party is in breach of the contract.

3.5. Respect intellectual property and intellectual property rights

The University and researchers must protect the IP that research creates and respect any IP rights that others may have.

Researchers must:

- identify what IP their research will generate;
- declare any IP that their research creates to the University; and
- keep IP confidential and respect the rights of other IP holders.

3.5.1. Identify intellectual property and determine who owns it

IP is defined in the Definitions section of this Regulation. All researchers must understand what IP is and help the University to protect it. Researchers must determine whether their research will create any new IP as early as possible in the research process. New IP could include new processes, software, methods of doing something, products, apparatus, compositions of matter and living organisms or an improvement of or new uses for existing things.

The following principles govern ownership of IP created by research activities at the University:

- If the researcher is a student, an employee, a contractor or a visiting researcher or lecturer, the University owns the IP generated by the researcher even if the research was commissioned or funded by an external organisation.
- If the researcher is a University employee and is jointly appointed by the University and an external organisation, the agreement with the University and the external organisation must stipulate who owns the IP.
- The University holds the copyright of a thesis, dissertation or scholarly article authored by students.
- The University will not unreasonably withhold permission for publications from a thesis or dissertation by University students who are authors or co-authors of a thesis, dissertation or scholarly article.
- The University assigns the copyright in scholarly and literary publications (e.g., academic articles and textbooks) created by employees to the authors.
- The University can agree in writing that IP generated by a student, employee or contractor belongs to someone else (e.g., an external organisation funding the research, a student, an employee or a visiting researcher or lecturer).

Researchers must ensure that:

- they understand who owns the IP that they create; and
- the Innovation and Contracts Management Office approves agreements regarding IP concluded between the University and any external organisation or researchers.

For more information, consult the University's Intellectual Property Policy, Intellectual Property Compliance Regulation or ask the Innovation and Contracts Management Office for advice.

3.5.2. Declare intellectual property to the University

This section applies to potentially valuable IP, other than a thesis, dissertation or scholarly article or other copyrighted material.

Researchers must:

- disclose any new IP that their research will create to the Department of Research and Innovation and the relevant head of department by completing the Invention Disclosure Form annexed to the University's Intellectual Property Policy;
- co-operate with the Department of Research and Innovation to formally register any IP created as a result of their research activities at the University; and
- preserve complete and accurate research records (for example a laboratory notebook) and apply a proper system of laboratory management to claim uniqueness and establish the date of an IP invention in the event of a challenge.

Researchers are not allowed to independently register IP that is created through their research activities at the University without the University's written approval.

3.5.3. Keep intellectual property confidential

Researchers must take steps to maintain the confidentiality of protectable IP until the University has obtained protection.

For further information on handling confidential information, consult the University's Information Security Management Policy.

3.6. Secure research data, research findings and intellectual property

Researchers must adequately secure Research Data, research findings and IP against:

- breaches of confidentiality;
- failures of integrity; and
- interruptions to the availability of information.

See the University's Information Security Management Policy for more information about information security obligations.

The University must protect Research Data and comply with data protection obligations by:

- developing and implementing policies, procedures and guidelines that comply with the POPIA Code of Conduct for Research;
- reviewing and providing advice to researchers on Research Data management plans and how to comply with this Regulation and the University's Information Security Management Policy, Protection of Personal Information (Privacy) Policy and Records Management Policy; and
- ensuring that researchers have access to infrastructure and technology that protect Research Data or, where another organisation or service provider provides the infrastructure, ensuring that the University concludes contracts with them that provide satisfactory safeguards.

Researchers must:

- develop research proposals that include an accurate and achievable Research Data management plan and are based on the guideline and checklist for Research Proposals on the PeopleSoft Ethics Application and Approval System;
- follow the approved research proposal or obtain approval again (if approval was required in terms of 3.3.5) if their Research Data management deviates from the plan outlined in their research proposal;
- ensure that research participants' rights are respected; and
- co-operate when the University reviews or requests a report on their compliance with the research proposal.

3.7. Share, publish or reuse research data and research findings responsibly

The University balances the public interest in research activities and open access with IP and privacy rights when it decides to share, publish or reuse research findings and Research Data. Researchers must:

- disseminate their research findings (whether positive or negative) in a timely, accessible, responsible and competent manner within the bounds of what is possible and appropriate from an ethical, regulatory and contractual perspective; and
- ensure that their research proposal includes an accurate description of any planned sharing, publication or reuse of Research Data.

3.7.1. Share and publish research findings and research data

Sharing or publishing includes:

- sharing with other researchers who are not participating in the research;
- sharing with external organisations who are collaborating with the University;
- sharing with research participants;
- publishing Research Data in a public repository, a journal article, a news report, a press release or a press interview, or a monograph or book;
- submitting an abstract to an external conference;
- submitting a poster to an external conference;
- discussing details of research, Research Data and research findings in an external workshop, blog, email or nonaccredited journal;
- making presentations at an external conference or event;
- demonstrating an invention created through research activities;
- applying an invention created through research activities in industry; and
- submitting a dissertation for examination.

Researchers are encouraged to publish relevant Research Data to support and underpin their published research findings. This means that:

- once researchers have decided to publish their research findings, if possible and appropriate they should deposit their Research Data and accompanying metadata in an institutional Research Data management system, an accredited open-data repository, or an accredited or trusted discipline-specific repository;
- researchers should ensure that all published Research Data is supported by accurate citation guidelines and a Digital Object Identifier (DOI) to ensure that the Research Data is unambiguously identifiable and that appropriate attribution and credit are given; and
- researchers must inform the Department of Library Services about which other data repositories they have published their Research Data and accompanying metadata to.

Researchers must publish their Research Data under the least restrictive licence possible, for example, a Creative Commons licence.

However, researchers should follow these principles to determine whether it is appropriate to share or publish Research Data:

<p>Is the University aware of the sharing?</p>	<p>Researchers must declare any future sharing or publications of Research Data and research findings in their research proposal or inform the University when they become aware of intended sharing or publication.</p>
<p>Is a research participant or other individual or organisation asking for access to their own Personal Information?</p>	<p>Individuals or organisations have a right to their Personal Information; however, there are exceptions (e.g., where sharing the information would compromise someone else's privacy or IP rights or disclosing the information would be detrimental to the research participant).</p> <p>If the researcher does not want to provide access to the information, the research participant must be referred to informationofficer@up.ac.za.</p>
<p>Does the Research Data that the researcher wants to share contain identified or identifiable Personal Information of research participants or other individuals or organisations?</p>	<p>Researchers must always anonymise any Personal Information before sharing Research Data or research findings. For more information about when personal information is considered identified or identifiable, see the POPIA Code of Conduct for Research.</p> <p>In instances where this is not possible, the researcher must evaluate the sharing of Personal Information and determine:</p> <ul style="list-style-type: none"> • whether consent from the research participant is required; • whether adequate safeguards are in place to protect personal information; • which contracts (e.g., data-sharing agreements) must be concluded before the personal information is shared; and • whether it is necessary to seek further advice from the Research Data Management Committee.

	<p>The Unit for Academic Information Technology may also be approached to perform a risk assessment of any external organisation to ensure that any Research Data concerning identifiable human research participants will be secure.</p> <p>For more information about when personal information is considered identified or identifiable, see the POPIA Code of Conduct for Research.</p>
Does the Research Data that the researcher wants to share include human biological materials or animal materials?	<p>Researchers must consult with the Innovation and Contracts Management Office and ensure that a material transfer agreement, data-sharing agreement or other applicable agreements are concluded before the Research Data or research findings are shared.</p>
Is the Research Data subject to a confidentiality agreement?	<p>Researchers must always determine whether the Research Data are subject to a confidentiality agreement. If this is the case, the researcher must ensure compliance with the confidentiality undertaking.</p>
Does the Research Data contain valuable IP?	<p>If the Research Data contain valuable IP, it may infringe upon any IP rights or jeopardise any IP filings. Therefore, researchers must obtain permission from the Innovation and Contracts Management Office before sharing the Research Data to ensure that the University has the right to share the personal information and that all IP rights are protected.</p>

3.7.2. Reuse research data

Generally, researchers may only use Research Data for their original intended purpose. However, the University acknowledges that there are compelling practical, ethical and scientific reasons for reusing Research Data.

The principles set out below apply when:

- personal information of prospective research participants is collected from sources other than the research participant (e.g., a University database or public record) for recruitment purposes;
- Research Data is collected by other researchers at the University; and
- Research Data was collected by an external organisation or researcher for previous research.

Researchers must follow these principles to determine whether it is appropriate to reuse Research Data:

<p>Has the University approved the reuse of Research Data?</p>	<p>The reuse of Research Data must be set out in the research proposal or the research proposal must be amended and re-approved as soon as the researcher decides to reuse Research Data.</p> <p>The Innovation and Contracts Management Office must also approve the reuse of Research Data.</p>
<p>Has the researcher completed the further processing assessment if the data is identifiable?</p>	<p>This assessment is required if the Research Data of human participants will be reused in an identifiable format. The assessment has been incorporated into the PeopleSoft Ethics Application and Approval System.</p>
<p>Have the research participants consented to the reuse of the Research Data?</p>	<p>Consent is not always legally required, but the University encourages researchers to obtain consent from research participants before reusing data. Researchers must set out how consent will be obtained in the research proposal.</p>

3.8. Report research data management incidents

Researchers must report research data management incidents as soon as they become aware of them. The University must assess incidents and ensure that the resulting risks are mitigated and that steps are put in place to prevent repeat incidents.

3.8.1. What a research data management incident is

For the purposes of this Regulation, an incident includes:

- contraventions of any legislation, regulations, codes, contracts or other binding rules that relate to Research Data management; or
- information security incidents such as breaches of confidentiality, failures of integrity or interruptions in the availability of Research Data.

Here are examples of incidents that must be reported:

- Lost or stolen Research Data (e.g., when hackers steal or ransom Research Data when unencrypted devices are lost or stolen, or when hard copy records are lost).
- Not backing up Research Data or not regularly checking that Research Data can be retrieved from backups.
- When someone external to the University gains unauthorised access to systems, hardware or software that contains Research Data.
- Accidentally or deliberately sending Research Data to a University employee or an external individual who is not authorised to receive it (e.g., accidentally sending a spreadsheet with Research Data to the wrong email address).
- Disposing of Research Data insecurely (e.g., dumping hard copies in waste bins without shredding or not removing information from a device before dumping or reselling it).
- Information security incidents that occur at external organisations that had access to Research Data (e.g., collaborators or service providers).
- An external organisation shares or publishes Research Data without the University's written permission.
- Not deidentifying personal information when it is possible to deidentify it (i.e. not making Research Data anonymous before publishing or sharing it).
- Obtaining personal information from unlawful sources (e.g., obtaining personal information from a credit bureau for marketing purposes without permission).
- Not obtaining informed consent when it is required.
- Not notifying research participants on how and why their personal information will be processed.
- Not ensuring that personal information is complete, accurate, not misleading and updated when necessary (e.g., failing to update personal information everywhere it is stored when a research participant updates the information).
- Commencing research without the University's approval in terms of 3.3.5.

3.8.2. How to report a research data management incident

If a researcher suspects that an incident has occurred, it must be reported to the Research Data Management Committee at igapp@up.ac.za as soon as possible.

3.8.3. How the University will manage incidents

Research data management incidents will be managed by the Research Data Management Committee, in consultation with:

- the relevant deputy dean and research ethics committee;
- the Deputy Information Officer Committee if the incident involves personal information; and
- the Information Technology Major Incident Co-ordination Response Team if it is a significant cybersecurity incident or if the incident threatens the University's information technology infrastructure.

The Research Data Management Committee must:

- take immediate action to contain the incident and mitigate any risks created by the incident;
- assign the relevant deputy dean as incident owner;
- engage with and notify external and internal stakeholders of an incident that affects them;
- identify, collect and preserve information that can serve as evidence;
- analyse incidents;
- recommend disciplinary action if the incident was caused or exacerbated by research misconduct;
- adjust procedures to mitigate the risk of future incidents and to improve the responses to future incidents; and
- ensure appropriate follow-up reports.

3.9. Act against research misconduct

The University must act against research misconduct to protect the integrity of its research.

3.9.1. What research misconduct is

Research misconduct occurs when a researcher fails to:

- obtain approval for the research (if it is required in terms of 3.3.5) before starting it;
- follow applicable regulatory requirements;
- follow the approved research proposal;
- behave ethically and exercise acceptable practices within the research community;
- acknowledge contributions;
- respect someone else's IP rights;
- manage research funds responsibly; or
- submit and publish their research findings when required.

3.9.2. How the University will act against research misconduct

The relevant ethics committee(s) will consider complaints of research misconduct.

Complaints must be referred to the chairperson of the relevant research ethics committee(s). Each ethics committee must develop its own procedure and guidelines for handling complaints of research misconduct. The procedure must ensure that researchers are given adequate notice and receive a fair hearing and that the decisions of the research ethics committee are unbiased.

The research ethics committee must report the outcome of its investigation with suggested corrective actions to the relevant faculty committees and the Chairperson of the Senate Committee for Research Ethics and Integrity. The corrective actions may include that the researcher is instructed to cease the research.

The faculty must take appropriate corrective action, which includes the authority to:

- instruct the researcher to cease all research immediately;
- in the case of students, refer the matter to the Disciplinary Committee (Students) for further disciplinary action; and
- in the case of employees, refer the matter to the Vice-Chancellor and Principal for further disciplinary action.

The Animal Ethics Committee may report incidents to the Registrar's Office for further investigation.

4. Consequences of non-compliance

4.1. For the University

Non-compliance with this Regulation could damage the University's reputation as a world-class research institution and undermine the credibility of the research performed at the University. Reputational damage and a lack of credibility harm the University's relationship with researchers, funders and other collaborators and prevent the University from attracting research opportunities.

Non-compliance can also lead to substantial fines, criminal prosecution, loss of accreditation, financial losses (e.g., a loss of funding) and lost opportunities (e.g., to commercialise IP) for the University.

4.2. For researchers

Non-compliance with this Regulation could harm researchers' credibility and result in disciplinary action.

4.3. For research participants or communities, and the environment

Unethical or unlawful research may cause research participants or communities, or the environment harm and distress.

4.4. For animals

Unethical or unlawful research may cause animals or owners or curators of animals harm and distress.

5. Definitions

Animal Research	<p>Animal Research involves the use of any animal or animal-derived samples, tissue, or biological matrix for research purposes by any person undertaking the research at the University of Pretoria, irrespective of the project being approved by another external animal ethics committee (Also known as Institutional Animal Care and Use Committee - IAUCAC).</p> <p>The said research would include use of any of the University animal or laboratory facilities, external facilities and studies undertaken in the field or under natural conditions.</p> <p>Animal research also includes the use of animal or animal-derived samples for teaching/training purposes including short course/continuing education.</p> <p>Research could include studies such as biomedical research, safety testing, testing of medicines, behavioural studies, nutritional studies, zoological studies, veterinary clinical trials, case studies, primary cell culture and reproduction studies.</p> <p>Please note that for studies involving animal owners or sampling people who are in close contact with animals, further approvals will be required outside of the animal ethical approval.</p>
-----------------	--

Health research	<p>Health research is:</p> <ul style="list-style-type: none"> • research conducted by students or staff of the Faculty of Health Sciences; • all internal or external research involving patients, healthcare workers or other staff, or biological material from Steve Biko Academic Hospital, Kalafong Hospital, Tshwane District Hospital, Weskoppies Hospital, the National Health Laboratory Service or the Oral and Dental Hospital; • research in which students of the Faculty of Health Sciences are the research participants; or • research conducted at other faculties that meets the rest of this definition. <p>Health research includes all quantitative and qualitative research related to the health of humans, the provision of health services, the development or application of pharmaceuticals, medicines and related substances, and the development of health technology. It includes:</p> <ul style="list-style-type: none"> • clinical trials, audits and Surveys; • health-related laboratory research; • in vitro, in vivo and ex vivo Health research; • research conducted on data that was collected previously for another research project, clinical purposes or health educational purposes; • research on education in the Faculty of Health Sciences; • research involving patients, healthcare workers or other hospital staff as research participants; • research on chemicals or instruments; • research using audits and Surveys; • case reports and case series for publication and conference presentations; and • service delivery statistics for degree or publication purposes.
-----------------	---

Intellectual property	<p>IP means all outputs of creative endeavour in any field that can be protected by statute or not, within any jurisdiction, including all:</p> <ul style="list-style-type: none"> • forms of copyright and copyrightable works (e.g., a thesis, dissertation or article); • design rights, whether registered or unregistered; • patents or patentable material; • trademarks; • know-how and trade secrets; • rights in databases, information and Research Data; • biological organisms and material, and reagents; • discoveries, mathematical formulae, specifications, diagrams and drawings; • algorithms; • expertise, techniques, research results and inventions; • integrated circuit chips, computer software and programs; • laboratory notebooks; • business and research methods; • actual and potential teaching and distance-learning material; • the University's name, badge and other trademarks associated with the operations of the University; and • any other items as the University may from time to time specify in writing. <p>IP means any creation of the mind that can be protected by law from use by any other person, whether in terms of South African law or foreign IP law. It includes statutory inventions, patent applications and registrations as defined in the Patents Act 57 of 1978, copyrighted works as defined in the Copyright Act 98 of 1978, plant breeders rights as defined in the Plant Breeders Rights Act of 1999, designs, design applications and registrations as defined in the Designs Act 195 of 1993, trademarks, trade mark applications and registrations as defined in the Trade Marks Act 194 of 1993, confidential or proprietary information, know-how and trade secrets.</p>
-----------------------	--

<p>Personal information</p>	<p>Personal information means any information relating to an identifiable individual (living or deceased) or an existing organisation (a company, public body, university, etc.). This includes the personal information of research participants, members of the public or other individuals or organisations.</p> <p>Examples include:</p> <ul style="list-style-type: none"> • identifiers such as a name, identity number, student number, staff number, account number, customer number, company registration number, tax number, photos, videos, or any other unique information that can be used to identify a person; • demographic information such as race, gender, sex, pregnancy, marital status, national or ethnic or social origin, colour, sexual orientation, age, religion, conscience, belief, culture, language and birth; • information relating to physical or mental health, well-being or disability; • background information such as education, financial, employment, medical, criminal or credit history; • contact details such as physical and postal address, email address, telephone number, online identifier (e.g., a person’s Twitter handle) or location information; • biometric information: this refers to techniques of identification that are based on physical, physiological, or behavioural characterisation such as blood-typing, fingerprinting, DNA analysis, retinal scanning, and voice recognition; • someone’s opinions, views, and preferences; • private or confidential correspondence and any further correspondence that would reveal the contents of the original correspondence; • views or opinions about a person, such as interview notes and trade references; and • the criminal behaviour of a data subject to the extent that such information relates to the alleged commission by a data subject of any offence; or any proceedings in respect of any offence allegedly committed by a data subject or the disposal of such proceedings.
<p>Research data</p>	<p>Research Data is any information that has been collected, observed, generated or created to validate original research findings. Although usually digital, Research Data also includes non-digital formats such as laboratory notebooks and diaries.</p>

Survey	<p>A Survey is a means of collecting data using structured or semi-structured instruments that may be written, oral (including face-to-face, telephone or focus groups) or online modes of questioning and data collection, including collection of institutional information.</p> <p>All internal and external parties who would like to Survey UP staff, students, alumni and other university stakeholders are subject to the University's Survey Policy.</p>
Supervisor	A person appointed to guide an undergraduate, postgraduate or postdoctoral student through their academic research.

6. Roles and responsibilities

The Information Officer (Vice-Chancellor and Principal)	<p>The Vice-Chancellor and Principal is the University's Information Officer. The Information Officer has a coordinating function that focuses on the policy-based protection of all information, including Research Data, research findings and IP.</p> <p>The Information Officer's responsibilities are set out in the University's Information Governance Policy.</p>
The Senate Committee for Research Ethics and Integrity	<p>The Senate Committee for Research Ethics and Integrity must:</p> <ul style="list-style-type: none"> • approve a comprehensive policy on research ethics and integrity at the University; and • evaluate and improve the existing policy measures of the University following the statutory requirements on the University and best practices for research ethics and integrity.
The Department of Research and Innovation	The Director: Department of Research and Innovation is responsible for the operational implementation, quality assurance, evaluation and review of this Regulation.
Deputy information officers (Registrar, Director: Information Technology, Vice-Principal: Research,	<p>The deputy information officers are members of the Deputy Information Officers Committee. The Registrar is the Chair. The Manager: Information Governance will act as the Secretariat.</p> <p>The deputy information officers must monitor and report on the implementation of the University's Information Governance Policy, Information Security Policy, Protection of Personal Information (Privacy) Policy and Records Management Policy to the Information Officer and the Information Technology, Risk and Audit Committee</p>

<p>Innovation and Postgraduate Education, Vice-Principal: Academic, all directors and all heads of professional services)</p>	<p>of Council. Their responsibilities are set out in the Information Governance Policy.</p> <p>The Vice-Principal: Research, Innovation and Postgraduate Education and the Vice-Principal: Academic must monitor and report on the implementation of this Regulation to the Information Officer and the Senate Committee for Research Ethics and Integrity.</p>
<p>Deans and deputy deans</p>	<p>Deans, with the help of their deputy deans, must implement, monitor and advocate for compliance with this Regulation in their faculties.</p>
<p>Research ethics committees</p>	<p>The various research ethics committees must consider, advise on, approve or reject research proposals that do not comply with this Regulation and its supporting procedures.</p>
<p>Research Data Management Committee</p>	<p>The Research Data Management (RDM) Committee consists of:</p> <ul style="list-style-type: none"> • the RDM Team in the Department of Library Services; • the Director: Research and Innovation; • the Manager: Information Governance; • the Unit for Academic Information Technology; and • deputy deans (research postgraduate degrees) (standing invitation). <p>The RDM Committee must:</p> <ul style="list-style-type: none"> • review the University's research approval processes to ensure that compliance with the University's policies, legislation, codes or other binding rules are considered as part of the research approval processes; • provide advice to researchers on Research Data management; and • manage Research Data management incidents.
<p>Survey Coordinating Committee</p>	<p>The Survey Coordinating Committee approves and manages Surveys at the University and monitors the Survey processes to ensure that they comply with the Survey Policy.</p>
<p>Innovation and Contracts Management Office</p>	<p>The Innovation and Contracts Management Office must:</p> <ul style="list-style-type: none"> • review and approve all research-related contracts to ensure that the interests of the University and researchers are protected; and • provide advice to researchers on how to comply with their contractual obligations to funders and other collaborators.

Principal investigators	<p>Principal investigators must:</p> <ul style="list-style-type: none"> • submit a research proposal; • apply for approval from the relevant bodies before commencing research; • ensure that researchers follow the approved research proposal when conducting their research or apply for approval for an amended proposal in the case of material changes; • ensure that the appropriate contracts are concluded and that researchers comply with their obligations; • manage funding and resources; • report incidents and complaints of academic misconduct; • ensure that the rights of research participants are protected; and • participate in audits by the University, funders or regulators.
Researchers	<p>All researchers must:</p> <ul style="list-style-type: none"> • comply with this Regulation; and • ensure that they follow the approved research proposal when conducting their research or apply for approval for an amended proposal in the case of material changes.

7. Associated documents

Information Governance Policy

Information Security Management Policy

Intellectual Property Policy

Protection of Personal Information Policy

Records Management Policy

Survey Policy

8. Document metadata

Document number:	<i>S 5103/23</i>
Document version:	<i>S 5103/23 is the first approved version</i>
Document approval authority:	<i>Senate</i>
Document approval date:	<i>Approved at an Extraordinary meeting of Senate on 28 February 2023</i>
Document owner:	<i>Director: Department of Research and Innovation</i>
Visibility: Display on staff intranet	✓

S 5103/23

Display on student intranet Display on public web	
--	--