Hartpury University
Research Governance Standard Operating Procedures

A. Introduction

1. The University has set out its expectations and standards for the conduct of research in its Code of Research Practice and through that Code seeks to implement the Concordat to Support Research Integrity. Breaches of these standards are dealt with through the Procedure for the Investigation of Allegations of Misconduct in Research.

2. To support the Code, the University has developed research governance and ethics policies and procedures that recognise the importance of addressing ethical matters while supporting the achievement of its collective research objectives.

3. Oversight of research governance is the responsibility of the Academic Dean, within the framework shown in Figure 1.

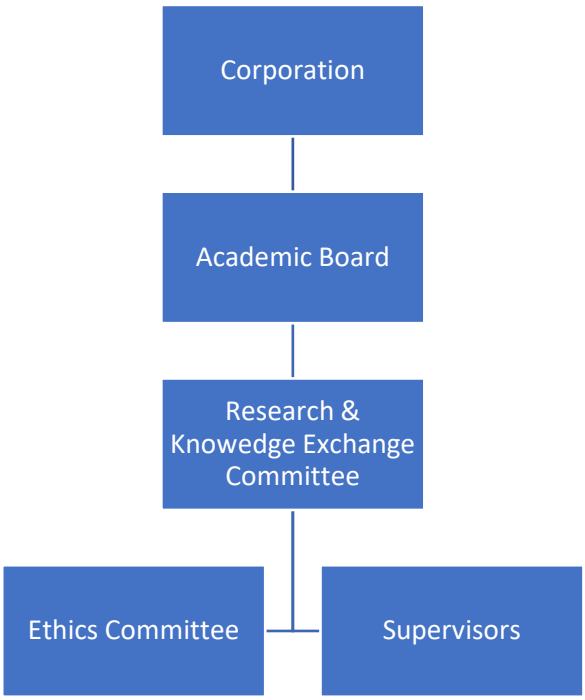

Figure 1: Hartpury Research Governance Framework

4. Each person involved in research has individual responsibilities, as set out in the Code of Research Practice. This is supplemented by the investigator responsibilities set out by the UK Policy Framework for Health and Social Care (see F.2).

5. These standard operating procedures set out the procedural requirements for research governance, including ethical review, health and safety, and monitoring and audit. All procedures should take into account the level of risk associated with any activity or project in order to ensure that the process is proportionate. These procedures are owned by the Research and Knowledge Exchange Committee, will be reviewed every three years, and may be updated from time to time between reviews. The Code of Research Practice and these Procedures take precedence over all other policies and procedures in regard to matters relating to research governance.

B. Ethical Review Process

6. Ethical review is required for all research projects. Particular consideration is taken where there are human or animal participants. It is the responsibility of the person proposing the research to obtain ethical approval before any activity takes place. Details of the current process are available in the Hartpury University Ethics Committee Process document for the current year (available here).

7. Activities that do not meet the Frascati definition of research (see the Code of Research Practice) but which involve the collection of human or animal data are required to undergo ethical review through the process described here. The use of animals as part of other normal Hartpury business (e.g. teaching or practice) is also subject to appropriate ethical review as part of its approval process. Any other activities that require ethical review (i.e. as required by a funder or other regulatory process) should also use this process.

8. The ethical review process is not a substitute for any other relevant legal, regulatory and professional or subject good practice requirements.

9. **Applications.** Applications for ethical review are undertaken using standard forms for staff and PGR student research, and undergraduate and postgraduate taught student research (available here). The forms indicate the documents that are required to be submitted alongside the form.

10. **Review.** The review of low risk undergraduate and postgraduate taught student research is undertaken by the student's supervisor. If a supervisor has any doubts, they should contact the Chair of the University Ethics Committee. Review of staff, PGR student and high risk undergraduate and postgraduate taught student research is undertaken by the Ethics Committee, which exists to safeguard the rights, safety, dignity and wellbeing of research participants – people and animals. The Committee will review research proposals and decide whether the research is ethical and therefore can be undertaken. If a proposal does not meet relevant requirements, they will suggest amendments if possible. The pool of reviewers available to the Committee includes all staff with a responsibility for research.

11. All applications must include a suitable risk assessment and supporting evidence. The Ethics Committee will wish to be assured that the activity is included within the University's insurance cover, with any additional premium being met by the project funding. The Committee may request further documents and proofs as required to understand the study and to gain assurance on its safety and the ethics that underpin it.

12. Research involving human participants must ensure the protection of the participants and their rights, including the right to withdraw. Informed consent is a central tenet of ethical research involving human participation and must be built into the design of the project unless the research question actively requires undisclosed observation. Particular care is required where the research involves children or vulnerable adults.

Incentives, additional payments and rewards paid to participants require approval by the Ethics Committee.

13. Research involving animals must ensure the protection of the animals and their owners or keepers. Informed consent applies to the owners or keepers of animals whether or not the owner or keeper is also a participant in the research.

14. If research is to be conducted in an institutional setting other than the University, e.g. NHS organisations, care homes, schools, prisons, etc, researchers must follow any ethics standards, procedures and regulatory guidelines of that institution. This will include obtaining approval from the local ethics committee, if required, and may necessitate obtaining a Disclosure and Barring Service (DBS) check.

15. **Studies requiring medical or veterinary supervision.** Studies that involve physical intervention (e.g. the administration of dietary supplements, prescription or controlled drugs, herbal supplements with significant side-effects or large amounts of alcohol) or therapies for injured humans or animals may require medical or veterinary supervision. All such studies will be subject to full review by the University Ethics Committee and may have additional conditions applied as part of the approval. Studies of this type are likely to incur additional insurance costs, to be covered by the project.

16. **Legal issues.** The role of the University Ethics Review process is to ensure that proposed research projects meet ethical standards, and not to vet them for legality. However, if a reviewer conducting a low-risk review, or the Ethics Committee as a whole, has reason to believe that a proposed research project, although ethically acceptable in other respects, may involve either a risk of a breach of the law, or may uncover breaches of law by participants in the study then the reviewer or the Chair respectively should seek legal advice on the issues through Chief Operating Officer in the first instance.

17. **Collaborative research.** Where research is undertaken in collaboration with another organisation, the University would normally expect the lead organisation to be responsible for ethical review, subject to assurance that the organisation operates to similar standards. Proof of the outcome of the ethical review must be provided to the Ethics Committee.

18. **Amendments.** Any substantive changes to a project (e.g. study design, consent forms, procedures, co-investigators, funding, questionnaires, etc.) must be notified to the approver of the original application (i.e. supervisor or the University Ethics Committee) for their review and approval. Changes should not be implemented until re-approval has been granted. Amendments to studies should be changes within the scope of the original study, not new studies that are simply related to the original study.

19. **Studies not starting and studies that are terminated.** Studies that do not commence having been given approval or that are suspended or terminated early should be formally recorded as such. The reason for suspension or not starting should be recorded, however trivial. The study cannot start or recommence without a new approval, which will take into account the reasons for the non-commencement or suspension.

20. If a suspension happens as a consequence of a harm or a suspected harm (a Serious Adverse Event (SAE) or Suspected Unexpected Serious Adverse Reaction (SUSAR)), there should be a review by a small independent panel, with involvement of the Principal Investigator and team or student and supervisor, to understand if the protocol was followed or not, whether the SUSAR was caused by the study or by some other cause, and what lessons might be learnt for this study or for others of a similar nature. The findings should be documented in a short report. Such a review is not looking to find

blame, but if it were to find possible research misconduct, that would trigger an allegation to be investigated.

21. **Reporting of adverse or unexpected events.** Principal Investigators and supervisors must report any adverse (undesirable and unintended) and unexpected events arising out of the research to the Chair of the University Ethics Committee within five days. In the case of a serious adverse event, the research must be halted immediately and the Principal Investigator or supervisor must inform the Chair of the University Ethics Committee within 24 hours.

22. The primary goal of recording adverse and unexpected events during research is to provide a learning exercise for both researchers and the Ethics Committee, and departments are asked to encourage reporting of problems during research.

23. **Monitoring and audit.** The University Ethics Committee will report annually to the Research and Knowledge Exchange Committee on the portfolio of applications, including reporting on any suspensions, terminations and adverse or unexpected events. The Ethics Committee may request that a random sample of researchers who have received ethical approval undertake a self-audit to report on any deviations or unexpected events. The Ethics Committee may also select a small random sample of projects to audit itself, to understand how ethical aspects of research are being considered throughout the life cycle of studies. The results of self-audits and Committee audits will be included in the Committee's annual report.

C. Health and Safety in Research

24. The University's Health and Safety Policy applies to our research in order to ensure that activities take place without detriment to staff, student, visitors and animals. Good practice in health and safety is part of strong research integrity and high quality.

25. All significant risks should be assessed using the risk assessment form (available here). Advice is available from the Health, Safety & Logistics Manager.

D. Overseas Research, Travel and Insurance

26. Researchers undertaking studies overseas should seek to understand the ethical and research governance requirements of the countries that they will be visiting. This may include licences and permissions to use certain equipment, visit specific areas or obtain ethical review from local ethics committees if researching government departments (or similar) that need 'gate-keeper' permissions. Due diligence should be undertaken to make sure that all local legal and regulatory requirements are met and that ethical issues are understood and acknowledged.

27. If a research project involves overseas travel, applicants must complete an International Travel Application form (available here) taking account of the International Travel Policy (available here). Researchers are required to check and understand Foreign, Commonwealth & Development Office (FCDO) travel advice before completion of the form, and identify any safety or security risks in their risk assessment.

28. Plans to travel to countries with significant risks (as identified by the FCDO's travel advice) will require clear justification, planning and risk mitigation.

29. Researchers who are visiting countries that the FCDO identify as having significant risks may benefit from taking advice from other researchers or organisations with recent practical experience of the travel to the area. The requirement for completing and

submitting an International Travel Application form and associated risk assessment does not exclude nationals who are students or staff at Hartpury who are returning to their home country to undertake research.

30. The University Ethics Committee may withhold ethical approval if it is not satisfied that matters relating to researcher safety have been sufficiently considered.

E. External Quality or Operating Standards

31. Some of the University's research is or will be subject to external quality or operating standards, such as GxP (Good Practice) or ISO standards. Good Practice requirements may include clinical, laboratory, manufacturing and veterinary clinical settings, amongst others. Relevant ISO Standards include 9001 (Quality Management) and 27001 (Information Security Management). External standards may particularly apply in collaborative work or where a University researcher is undertaking some aspect of their research at another organisation's premises. In such circumstances, researchers should work to those regulatory or local standards.

F. Annexes

F.1 ToRs and Role Descriptions

- Ethics Committee ToRs (available here).
- Ethics Committee Chair's Role Description (available here).

F.2 Responsibilities of investigators and the Chief Investigator of sponsored studies (from the UK Policy Framework for Health and Social Care)

(Note that the terminology Chief Investigator as used in the Framework and related regulation is synonymous with the terminology of Principal Investigator used in academic research.)

The following material is an extract from the UK Policy Framework for Health and Social Care (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)

9.2. The chief investigator is the overall lead researcher for a research project. In addition to their responsibilities if they are members of a research team, chief investigators are responsible for the overall conduct of a research project, including:

a. satisfying themselves that the research proposal or protocol takes into account any relevant systematic reviews, other research evidence and research in progress, that it makes effective use of patient, service user and public involvement where appropriate and that it is scientifically sound, safe, ethical, legal and feasible and remains so for the duration of the research, taking account of developments while the research is ongoing;

b. satisfying themselves that the research proposal or protocol has been submitted for appropriate independent expert ('peer') review and revised in light of that review;

c. satisfying themselves that, if expected or required, the proposal has been submitted for review by and obtained approval from a research ethics committee and any other relevant approval bodies;

d. satisfying themselves that everyone involved in the conduct of the research is qualified by education, training and experience, or otherwise competent, to discharge their roles in the project;

e. satisfying themselves that the information given to potential participants is in a suitable format and is clear and relevant to their participation in the research and, where consent is required, to their decision-making about taking part in the research;

f. adhering to the agreed arrangements for making information about the research publicly available before it starts (unless a deferral is agreed by or on behalf of the research ethics committee);

g. adhering to the agreed arrangements for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after the research has finished;

h. starting the research only once the sponsor has confirmed that everything is ready for it to begin;

i. adhering to the agreed procedures and arrangements for reporting (e.g. progress reports, safety reports) and for monitoring the research, including its conduct, the participants' safety and well-being and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments; and

j. adhering to the agreed arrangements for making information about the findings of the research available, including, where appropriate, to participants.

9.3. Students should not normally take the role of chief investigator at any level of study, as this function should be undertaken by supervisors or course leaders.

a. Relevant supervisors (or course leaders, where different) should be encouraged to develop and lead research projects that individual students at Masters level and below can contribute to at different stages. Undergraduate students should only conduct research projects in isolation that involve direct contact with patients, service users or the public in a health or social care setting if on-site supervision arrangements mitigate any risks.

b. A research culture should be fostered amongst relevant undergraduate students by encouraging an awareness of health and social care research, research ethics and public involvement, and enabling them to develop skills in research methods. Students from courses that are not primarily related to health and social care, such as business studies or IT, who wish to undertake research involving patients or service users, their data or tissue, or the public in a health or social care setting should have a co-supervisor with relevant experience that will help them understand the care context and the associated research process.

c. The contribution of students to the development, conduct and reporting of the research should be appropriately acknowledged like that of other contributors, e.g. in accordance with journal editors' authorship criteria.

9.4. Research should be conducted in accordance with a research proposal or protocol – a document that describes clearly what will be done in the research. This is important so that the researchers can all understand consistently what they are supposed to do and so that the research can be properly analysed and, if necessary, reproduced. Public involvement plays an important role in research design and

planning. Well-planned and well-written research proposals, protocols and procedures are key to carrying out research successfully. They help avoid subsequent amendments, which are time-consuming and costly for the funder, the researchers and the approval bodies. However, high-quality research proposals, protocols and procedures are only effective if they are followed. Not adhering to the research proposal or protocol has the potential for adverse impact and reputational risk to all parties involved. For research participants, this compromises any informed consent given; for the researcher, it creates a scientific risk that the research data (or their credibility) may be compromised; and for sponsors, there is often a financial and resource implication, particularly where a suspension to recruitment or extensive investigation are involved.

9.5. Research proposals, protocols and procedures should be clear, comprehensive and easily accessible to the research team. Good document management and version control are essential so that, for instance, the same single version of the research proposal or protocol is being followed in the same way by everyone involved. Otherwise, the data collected could not be reliably compared, undermining the findings of the research. There is often an expectation or requirement for documents to be revised and updated during the lifespan of studies and these expectations and requirements may come from various organisations. It is important to ensure that changes to the research proposal or protocol are submitted for review, if expected or required, by a research ethics committee and any other relevant approval bodies and, if approved, that they are introduced uniformly across all relevant research sites.

Approval and Review Cycle

Date Last Approved	March 2022
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Approving Committee	Academic Board
Status	Draft
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