LEADERSHIP AND EMBEDDING A CULTURE OF RESEARCH INTEGRITY

4.1 Overall University management responsibility

The University is committed to providing the right framework for research integrity to flourish. In part, this means providing clear guidance about policies, procedures and responsibilities and the training and support necessary for researchers to play their role. It is also important to monitor the implementation of such policies and procedures.

4.2 The research governance structure at UWE Bristol

- 4.2.1 Ultimate responsibility for research governance rests with the Vice Chancellor (VC) and Board of Governors. The key Committee with oversight of research governance, reporting ultimately to the Governors via Academic Board, is the University Research and Knowledge Exchange Committee, and the senior level oversight rests with the Pro Vice-Chancellor Research and Enterprise, reporting through to the VC. PVC and Heads of College, College Deans of Research and Enterprise and Heads of Schools (HoS) all play a key role in the governance structure. It is important to understand, however, that research governance is everyone's business – all staff and students involved with research at the University have a responsibility to play their appropriate part in ensuring our research is conducted to the highest standards of research integrity. Responsibilities are described in more detail below.
- 4.2.2 Within the University, it is the responsibility of the Senior Management Team, PVC Heads of College, College Deans (both Research & Enterprise and Learning & Teaching) and Heads of Professional Services to ensure that research is conducted in accordance with good research practice. Where research is being conducted by Professional Service staff, responsibility rests with the Head of Service. The Pro Vice-Chancellor Research and Enterprise has overall executive responsibility for overseeing the review and implementation of the UWE Bristol Policy on Good Research Conduct and this Code of Conduct. The Pro Vice-Chancellor Research and Enterprise Yis Research Governance Manager, who is the first point of contact for research integrity and conduct matters.

4.3 Research project management

4.3.1 Different funders and authorities use different terms for a research Project Manager (e.g. Principal Investigator, Chief Investigator). UWE Bristol uses the term Project Manager to indicate a formal University management role in relation to a project. This does not necessarily refer to the person responsible for the day-to-day activities of managing the project, but to the person with overall University management responsibility for the project. Where UWE Bristol is the lead institution, this will usually be the first named applicant on the funding application. Where another institution leads, a UWE Bristol Project Manager should be appointed from amongst the UWE Bristol co-applicants to take management responsibility for the UWE Bristol part of the project.

- 4.3.2 All research projects must have a designated UWE Bristol Project Manager, including internally funded projects and research undertaken as part of personal research and scholarship. For postgraduate research student projects this will be their Director of Studies. For students conducting research as part of taught courses this will be the Student Research Supervisor (see also section 5.3.3 on Supervision). For visiting researchers, a permanent UWE Member of Staff will need to take overall responsibility for the research.
- 4.3.3 The Project Manager is the person designated as taking overall responsibility within the team of researchers for the design, conduct and reporting of the study and has responsibility for ensuring compliance with all aspects of the UWE Bristol Code of Good Research Conduct. This includes ensuring that:
 - the research is carried out in accordance with this Code (and related guidelines, regulations, procedures and Health and Safety Standards);
 - all research project staff, including public research partners, are aware of the provisions of the Code and any research practice guidelines produced by relevant professional and other bodies. Where the provisions of this Code are in conflict with those of any partner organisation, such as a collaborator or funder, agreed arrangements must be included in the contractual agreements between the parties concerned¹;
 - the dignity, rights, welfare and safety of researchers and any research participants are safeguarded;
 - the project complies with all legal, regulatory, contractual and ethical approval requirements;
 - the University's research project approval process is adhered to for externally funded research;
 - the research is carried out as defined in the original proposal to the funder (where applicable), and that any proposed changes to the protocol are approved by the appropriate funder and the relevant research ethics committee where appropriate;
 - staff and doctoral research is entered onto the UWE Research Governance Record, or equivalent), is kept updated where the research changes, and the UWE Research Data Management Plan is uploaded;

¹ Advice and support will be available to the Project Manager from the Research Governance team and the Contracts team

- clinical trials, and where appropriate other health related research, are registered on an appropriate external register, in accordance with the regulation of clinical trials, and recorded on the UWE Research Governance record (or equivalent)²;
- human tissue research is registered on the UWE Bristol Human Tissue Research Register, appropriate approvals for the project are in place, and it complies with the national regulations for use of Human Tissue in Research, further details of which are at: <u>https://www.hta.gov.uk/guidance-professionals/regulatedsectors/research</u> (Please note: teaching activities involving human tissue must <u>be logged on the UWE Human Tissue Teaching Register</u>);
- animal/animal by-product research is registered on the UWE Bristol Animal and Animal By-Products Register, has been approved by the UWE Bristol Animal Welfare and Ethics Sub-Committee (AWESC) and complies with the national and international legal and regulatory requirements for research involving animals/animal by-products (**Please note**: these requirements also relate to teaching activities involving animals/animal by-products);
- where necessary, the <u>UK Policy Framework for Health and Social Care</u> obligations, including reporting of serious adverse events, and the <u>HRA</u> <u>information governance requirements</u> are complied with (see also section on use of patient data in the UWE Handbook of research ethics);
- appropriate procedures are in place to protect project data (and its integrity and confidentiality) during collection, processing, analysis and storage, and that it is appropriately archived or destroyed upon completion of the research, complying with UWE research data management requirements;
- reports on research progress and outcomes are produced on schedule, to an acceptable standard and in accordance with funder or ethics requirements, and assessment requirements are set out for students;
- findings are consistent with principles of open access, are open to critical review through accepted research and professional channels, and disseminated promptly as appropriate to participants (for student research this requirement applies only where judged appropriate by the Student Research Supervisor);
- appropriate agreements governing the research are set in place, with involvement of the UWE Contracts Team;
- the terms of any confidentiality and intellectual property rights agreements are complied with, any intellectual property arising is managed and reported appropriately and any conditions regarding publication arrangements are in place;

² Whilst the requirement to register clinical trials is mandatory, in line with the WMA Declaration of Helsinki October 2013 (https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-

principles-for-medical-research-involving-human-subjects/^{), and H}ealth Research Authority ^{Guidance, It is also recommended for reasons of transparency that all other research into human health should also be registered in a publicly accessible database.}

- research project staff, including public research partners, are appropriately skilled, trained and supported in their work on the project, and students acquire research skills to the necessary level in the course of their research training.
- the Project file for the research is set up and maintained.

4.4 Research Governance Project Record Keeping

- 4.4.1 All staff and doctoral research must be entered on to the UWE Research Governance Record (RGR), or equivalent, by the UWE Project Manager (or the DoS for student research). The record must be created at an early stage in the life of the research and kept updated throughout. At the end of the research this must be archived. If the UWE Project Manager leaves the University, or their role, they must ask the HoS to allocate a new UWE Project Manager. It is the HoS's responsibility to ensure that this has taken place.
- 4.4.2 The UWE Project Manager should maintain a Research Governance Project file for the research. This should comprise the key documents which demonstrate that governance requirements have been complied with, including, for example:
 - copy of up-to-date RGR and previous versions
 - all research ethics applications and approvals and amendments
 - up-to-date UWE Research Data Management Plan and previous versions
 - agreements, such a Collaboration, Data Sharing Processing Agreements, Material Transfer Agreements
 - licenses and permits
 - records of required and relevant training for the research team
 - student progression documents
 - risk assessments

What is required will vary depending on the research, but these are indicative of what would be required to be able to demonstrate that the necessary research governance requirements are in place. The file may be electronic (securely held in line with UWE requirements) or paper – the crucial thing is that these core documents should be readily available for the researcher to use and for audit if required.