|  |  |
| --- | --- |
| https://www.yournewu.co.uk/wp-content/uploads/2013/04/USW-logo-Raspberry-Screen_2.jpg | **Research and Innovation Services**Research Governance Checklist  |
| **Project Information – Please consider before initiating a research project** |
| This Research Governance Checklist intends to help Researchers identify and navigate the many research governance considerations of initiating and running a research study. This is intended as a starting point and is not intended to cover in depth the requirements or policies of the University. If you are unsure about any section of this checklist, please consult the supplementary guidance documents or the relevant pages on the University intranet. Alternatively, please contact Research and Innovations Service (RISe) to discuss any queries RISe@southwales.ac.uk |
| Please ensure you are familiar with: [The Concordat for Research Integrity](https://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2012/the-concordat-to-support-research-integrity.pdf), and Health and Social Care studies must be familiar with 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/)  |
| **Collaboration** |
| **Are you expecting external organisations (including universities or businesses) or volunteers to contribute time, materials, information or data to this project?** |
| If YES. Before the project starts, please ensure there is a Project Agreement (contract) in place to manage the involvement of each external organisation in the project. RISe can facilitate this where needed. RISe@southwales.ac.uk  |
| Please ensure you have read and understand these aspects of the Project Agreement (contract). The Principal Investigator must understand all obligations and limitations before agreeing to them. | Data Protection Act |
| Intellectual Property |
| Publication and dissemination |
| Confidentiality |
| Insurance / Indemnity |
| Financial terms |
| **Preliminary Approval to Pursue a Project** |
| Are you certain that the University will underwrite and support your project? Overseas and research that poses possible reputational risk research will require approval **before** bid submission via the Research Risk Matrix process. HERE |
| **External Funding** |
| **Will this project be externally funded?**  |
|  |
| If YES. Please ensure the project has obtained internal EFAS approval **before** an external funding application is submitted.  |
| If YES. Once funded, please ensure **all** funder requirements and stipulations are understood and accounted for. |
| **Will this project require peer review before submission to an external organisation, such as for external funding, external ethical approval, NHS sponsorship, or adoption on an NHS research portfolio.**  |
| If YES, please request and ensure the project proposal has been peer reviewed via RISe@southwales.ac.uk |
| **Insurance and Indemnity** |  |
| **Will the project require the University to provide insurance or indemnity cover for this work?**  |
| If YES, are you certain that the University will provide cover? |
| If YES, and any of these caveats apply, you must contact the Research Governance Officer because insurance / indemnity cover is not automatically provided for these activities. Jonathan.sinfield@southwales.ac.uk  | Investigating or participating in methods of contraception |
| Assisting with or altering the process of conception |
| The use of drugs or administering of chemicals to humans or animals |
| The use of surgery? (other than biopsy) |
| Genetic engineering |
| Participants under 5 years of age? (other than activities above) |
| Participants known to be pregnant? (other than activities above) |
| Pharmaceutical product/appliance designed or manufactured by host institution |
| Work outside of United Kingdom |
| If NO, please ensure evidence of insurance / indemnity cover is obtained from the lead project partner and covers all activity intended to take place on USW premises. If it is not covered, you will need to seek explicit insurance / indemnity cover for those activities. |
| Evidence of USW insurance / indemnity cover is available from the Research Governance Officer (RISe). Jonathan.sinfield@southwales.ac.uk  |
| **Data Management and Samples** |
| **Will the project funder or external partners stipulate any specific data management conditions?**  |
| If YES, the Principal Investigator must ensure that they and the research team understand what these are, and how they will be met. |
| If NO, the Principal Investigator must ensure that they and the research team understand the USW requirements and policy and how they will be met during the project.  |
| **Will this project need a data management plan (DMP)? Either stipulated by your funder or a USW template?** |
| If externally funded, please ensure the correct DMP template is used. If not externally funded, please ensure the USW template is used.  |
| **Will the project need to comply with the General Data Protection Regulations (2018)?**  |
| If YES, please ensure the project team are aware of their obligations around collecting, storing, and disposing of personal data under the GDPR. Protocols for managing GDPR data must be put in place from the outset. Please contact the Data Compliance Officer.  |
| **Will this project use any samples obtained from another organisation?** |
| If YES, please ensure a Material Transfer Agreement (MTA) been put in place between USW and the supplier. Please request via RISe@southwales.ac.uk(Relevant materials may include cultures, cell lines, plasmids, nucleotides, proteins, bacteria, transgenic animals, pharmaceuticals, other chemicals, alloys and other materials with scientific or commercial value) |
| **Risk Assessment** |
| **Will your project require a risk assessment?**  |
| If YES, please ensure an approved risk assessment is in place before any research activities commence.  |
| **Research Ethics Approval**  |
| **Will this project require Research Ethics approval from USW?**  |
| If YES, please ensure this project obtains USW Research Ethics Approval at before any data collection starts..  |
| **Working with Vulnerable Groups** |
| **Will the project involve working with vulnerable groups? Including children, vulnerable adults, Offenders, HMP Services, or Probation Service, and Adults who lack mental capacity.**  |
| If YES, does this research require researchers to have DBS checks in place? Please ensure DBS checks are in place before contact with any vulnerable groups occurs. |
| **Will the project include issues that are related to extreme groups, security issues, ministry of defence work, terrorism, or radicalisation?** |
| If YES, please ensure this project been registered with the USW PREVENT process. |
| **Health Related Research** |
| **Will the USW be the *Sponsor[[1]](#endnote-1)* for this project under the UK Policy Framework for Health and Social Care Research (2018)?**  |
| If YES, please ensure your project complies with the USW requirements for providing sponsorship. You will need to follow the process to apply for sponsorship. |
| **Will this project require NHS ethical approval via IRAS?** |
| If YES, please ensure your Faculty Research Ethics Chair is aware and has had the opportunity to review your NHS Ethics application before it is submitted.  |
| **Will this project require R&D Management approval (permission)?** |
| **All** projects intended for the NHS require NHS permission before they can commence.  |
| **Will any USW staff require Honorary Contracts, Research Passports or similar to access the external resources of a collaborating organisation, such as the NHS, Prison Service, Police Service, or Ministry of Defence?** |
| **Will the project involve Human Tissue or human tissue samples?** |
| If YES, is the Human Tissue a *‘relevant material’* according to the Human Tissue Act (HTA)? |
| If YES. USW **does not** have a HTA license - please ensure that your project does not breach the Human Tissue Act.  |
| **Training and the research team** |
| **Will any of the research team require training before carrying out their intended project roles? Please also consider any skills or competencies that require refresher training, or renewal.** |
| If YES. Please ensure all training needs are completed before the data collection starts. It is the responsibility of the Principal Investigator to ensure that **all** members of the research team are suitably trained and qualified for their project roles. The Principal Investigator should record all training relevant to the project and may be asked to evidence the qualifications and competencies that are in place. |
| **Publishing and Authorship** |
| **Please ensure the research team are familiar with the USW policy on Publishing and authorship. HERE** |
| **Impact** |
| **Are there clear plans for developing, managing and recording the impact that will be produced by this project?**  |
| If NO. Please ensure the Principal Investigator has read and is familiar with the University pages on Research Impact and Innovation..  |

1. ***Sponsor*** is the organisation taking responsibility for the management, safety and design of the project. [↑](#endnote-ref-1)