

## **Research Governance and Integrity Policy**

### **This Policy**

All staff, students and honorary staff members of the University of Bristol have a duty to the public, to themselves, to the University and funders to conduct research in the most conscientious and responsible manner possible. This 'Research Governance and Integrity Policy' sets clear standards for research and outlines the responsibilities of those involved. This includes academics, research staff, persons with honorary and substantive positions, undergraduate students, postgraduate students and anyone else conducting or supporting research under the University's auspices (hereinafter referred to as the 'Researchers'). The University expects all those engaged in research, and especially those with a specific responsibility as research leaders, to observe and promote these principles irrespective of their sources of funding or their area of research. The aim is to set standards that enhance research quality, integrity, compliance and that safeguard the public in line with the requirements for the [Concordat to support Research Integrity](#).

This Policy should be read in conjunction with the [University Policies on Public Interest Disclosure](#), [Research Misconduct](#) and [Ethics of Research](#) and with the relevant sections of a member of staff's Terms and Conditions of Employment.

### **1. Obligations**

Researchers shall comply with all applicable laws and statutes relevant to the conduct of research including, but not limited to, the Human Rights Act 1998, the General Data Protection Regulation and Data Protection Act 2018, the Human Tissue Act 2004, the Mental Capacity Act 2005, the Safeguarding Vulnerable Groups Act 2006, the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Animals (Scientific Procedures) Act 1986. For more information on regulations and access to links, please see [Annex 1](#).

Researchers are also required to conform to relevant guidance, directives and codes from the University, from organisations hosting and/or funding the research and from professional bodies in the field of the research see [Annex 2](#).

### **2. Principles of Research Conduct**

Researchers must adhere to the principles of research conduct outlined here:

**2.1 Honesty:** Researchers should be honest in respect of their own actions and intentions when undertaking research and in their responses and intentions towards the research of others. This applies to the whole range of research-related activities including experimental design, generating and analysing data, ensuring the accuracy of data, publishing results, storing research results, acknowledging the direct and indirect contribution of colleagues and collaborators and the refereeing and editing process. Anyone listed as an author on a paper must be familiar with the contents of the paper and able to identify his/her contribution to it. Principal authorship and other publication credit should accurately reflect the relative scientific or professional contribution of the individuals involved.

Researchers are expected to understand and apply the following:

- Plagiarism, deception or the fabrication or falsification of results will be treated as a serious disciplinary offence in accordance with the University's disciplinary regulations in the Staff procedures and Student Handbook
- Researchers must not engage in, nor conceal, misconduct and are expected to report cases of suspected misconduct in a responsible and professional manner, as described in the [Regulations on Research Misconduct](#) and [Whistleblowing](#) policies.

Researchers must determine the retention requirements for their research data and records on a project by project basis, taking account of:

- The legal and regulatory framework for particular types of research
- The terms and conditions imposed by external research sponsors and funders
- The commercial, political, cultural or ethical sensitivity of particular types of research, or any research for particular external sponsors

See <http://www.bris.ac.uk/secretary/records/> for records management advice and also guidance on record retention and archiving for studies involving human participants at <http://www.bristol.ac.uk/secretary/information-governance/>

**2.2 Integrity:** Integrity is about undertaking properly regulated research.

Researchers must comply with all legal and ethical requirements relevant to their field of study. They are expected to declare and resolve appropriately any real or potential conflicts of interest either of a financial or professional nature as outlined in the University's Conflict of Interest Regulations and the University's Anti-corruption and bribery policy:

<http://www.bristol.ac.uk/secretary/legal/conflict/>

<http://www.bristol.ac.uk/secretary/legal/bribery/>

The University is concerned with protecting the rights, dignity, health, safety and privacy of research subjects/participants, the welfare of animals and the integrity of the environment. It is also concerned with protecting the health, safety, rights and academic freedom of researchers and the reputation of the University as a centre for high-quality research. To this end, the University has its own [Ethics of Research Policy and Procedure](#) to govern the ethics of research across the University, and to comply with the legitimate requirements of outside research funders and collaborators. The procedure applies to everyone carrying out research under the auspices of the University. Approval from an appropriate research ethics committee is required for all research that involves human participants, their tissue, data or samples or has ethical implications (as defined in the [Ethics of Research Policy and Procedure](#)).

Informed consent from research participants is critical to the integrity of research unless there are sound legal or ethically approved reasons not to obtain consent. Obtaining consent should be seen as a process, not a one-off event. For more information and guidance see <http://www.bristol.ac.uk/secretary/data-protection/gdpr/gdpr-and-research/>.

Researchers working with the NHS should ensure that their research complies with NHS requirements including the [UK Policy Framework for Health and Social Care Research](#) to ensure that research including informed consent is conducted in accordance with appropriate guidelines.

**2.3 Co-operation:** Whilst recognising the need for Researchers to protect their own research interests and those of any funding body, the University encourages Researchers to be as open as possible in discussing their work and exchanging ideas with other professionals and the public and to engage with open access requirements, see <http://www.bristol.ac.uk/library/research-support/>. Once results have been published, the University expects Researchers to make available relevant data and materials to other Researchers, where reasonably requested, always provided that this is consistent with data protection legislation. Results can only be released in line with any ethics approval and consent which cover the data and

materials, and any related intellectual property rights and confidentiality obligations see <http://www.bristol.ac.uk/staff/researchers/open-access/>.

2.3.1 Data Protection: Personal data are data relating to a living individual who can be identified by that information (or from that and other information in the possession of the data user) including any expression of opinion about the individual and any indication of the intentions of the data user/controller in respect of that individual. Any work involving processing, storing or recording personal data must meet the requirements of the General Data Protection Regulations and Data Protection Act 2018. It is the Researcher's responsibility to ensure that personal data is collected in accordance with this Regulation. See <http://www.bris.ac.uk/secretary/dataprotection/>.

2.3.2 Intellectual Property: It is the usual practice for the University to own any intellectual property (IP) arising from research unless otherwise agreed with a funding body, subject to a sharing agreement with staff and students over any income from exploitation. IP is described as the outputs of creative endeavour in literary, artistic, industrial and scientific fields which can be protected under legislation i.e. the research results. Researchers should consider the potential of the IP arising from their research and take reasonable measures to protect any such IP. Researchers should be fully aware of the University's IP policy at <http://www.bristol.ac.uk/red/research-commercial/ipr.html> or within the Staff Handbook. The University recognises that publication of results may need to be delayed for a reasonable period pending protection of any intellectual property arising from the research.

2.3.3 Indemnity: The University has an obligation to undertake a liability risk assessment on projects involving the following categories: drug studies, children under 5; pregnant women; cohorts of more than 1500 participants; fertility studies; work overseas; genetic engineering; clinically invasive procedures; vulnerable adults and/or vulnerable young persons; research into HIV/AIDS; CJD and/or Hepatitis C. The Researcher should work with the Research Governance Team in advance of undertaking projects in these areas. See <http://www.bristol.ac.uk/secretary/insurance/clinical-research-insurance/> for further information.

**2.4 Accountability:** Researchers should recognise that in and through their work they are ultimately accountable to the general public and should act accordingly. They should ensure that any research undertaken complies with any agreements, terms and conditions relating to the project, allows for proper governance and transparency and is undertaken with financial probity. Researchers must follow the requirements and guidance of any professional bodies in their field of research.

In the event of a conflict between funding conditions and this policy, advice should be sought from the Division of Research & Enterprise Development (<http://www.bristol.ac.uk/red/>).

**2.5 Training and Skills:** Within a research group, the lead Researcher is expected to be responsible for, and encouraging to all members of the research team in developing their skills, and to lead and foster an open exchange of research ideas with the aim of engendering a positive culture of research integrity. Researchers must ensure that appropriate direction of research and supervision is provided at all stages of the research process, including preparation of funding applications in accordance with the University's financial regulations, data recording, data analysis and publication policies. All Researchers should take reasonable measures to ensure compliance with Sponsor, funder, institutional, legal, ethical and moral obligations in managing the project. Researchers should ensure that they have the necessary

skills, training and resources to carry out research to the required standards, and should ensure any gaps are filled by appropriate training (see staff development <http://www.bris.ac.uk/staffdevelopment/>).

The University is committed to creating and sustaining a positive and supportive working environment for our staff and students. As a provider of employment and education, we value the diversity of our staff and students and remain committed to creating an inclusive culture as outlined in policies regarding Equality and Diversity

<http://www.bristol.ac.uk/inclusion/governance-policy-and-guidance/edi-policy-statement/>

**2.6 Health and Safety:** Researchers will ensure that any risks that could impact on the health and safety of those involved in research, whether researchers, research subjects, patients, participants or others are assessed and effectively managed to reduce the risk of injury or harm or ill health to themselves, the wider community or environment, in accordance with the University's Health and Safety policy and associated Health and Safety guidance for research undertaken in the community <http://www.bristol.ac.uk/safety/media/gn/research-comm-gn.pdf>

### **3. Suitability of funders/collaborators**

The University's policy is that it does not knowingly collaborate with, or accept any monies from, sources of funding where the aims of the bodies concerned are:

- illegal under UK law;
- contrary to the research, education or wider aims or objectives of the University or if, by so doing, the wider interests of the University, in particular its ability to raise funds or obtain grants, are likely to be materially harmed, this includes, but is not limited to, tobacco industry funding.

The University has developed a due diligence process for research activity and anyone with concerns regarding the nature of a potential funding body or collaborator should contact the [Head of Research Governance](#). [Annex 4](#) provides a summary of University guidance and policies in this area.

### **4. Research Specific Requirements**

In addition to the research principles, research in the following areas must also adhere to research specific requirements:

#### ***4.1 Clinical, NHS and Human Tissue Research***

Where appropriate to the nature of the research, researchers undertaking clinical, NHS and human tissue research shall conduct the project in strict accordance with the:

- protocol
- sponsor terms
- terms and conditions of the approval of the relevant ethics committee(s)
- terms and conditions of NHS permission / HRA and host organisation approval
- terms and conditions of the approval of the Medicines and Healthcare products Regulatory Agency (MHRA)
- terms and conditions of the funding body

##### **4.1.1 Clinical and NHS research**

Researchers undertaking clinical research and research involving the NHS must adhere to all applicable regulations and guidelines concerning the set-up, review, management and reporting of such research (listed in [Annexes 1](#) and

[2\)](#), as amended from time to time. In addition, research into investigational medicinal products and medical devices in human participants is strictly regulated and Researchers are responsible for ensuring they have all the necessary approvals to undertake this research. [Annex 3](#) gives detailed requirements in relation to Researcher responsibilities and obligations in this area. All Researchers who are involved in the conduct of clinical trials must undertake training in the following: good clinical practice (where this is a legal requirement), research design, regulatory and ethics approval, confidentiality, data management, record keeping and data protection.

#### 4.1.2 Human Tissue Research

The University has developed a Code of Practice (see <https://www.bristol.ac.uk/red/research-governance/human-tissue/>) to ensure that the regulatory framework in respect of research involving human tissue is successfully implemented into the University's practices, guidance and policies. Researchers are expected to comply with this Code.

The Code provides a resource for anyone working for the University with human organs, tissue and cells (together "Relevant Material") in an educational or research setting.

#### **4.2 Research involving animals**

Research involving animals should be conducted in accordance with the law and have the approval of the appropriate bodies, see 'The Animals (Scientific Procedures) Act 1986

[http://www.opsi.gov.uk/acts/acts1986/pdf/ukpga\\_19860014\\_en.pdf](http://www.opsi.gov.uk/acts/acts1986/pdf/ukpga_19860014_en.pdf). Where required, Home Office and any other licences must be in place for the University, the Researchers and the project.

Researchers should consider, at an early stage in the design of any research involving animals, the opportunities for reduction, replacement and refinement of animal involvement (the three Rs). Researchers should refer to the University policy on working with animals

<http://www.bristol.ac.uk/university/governance/policies/animal-policy.html>

#### **4.3 Requirements in relation to the Prevent Duty**

The University is subject to the Prevent Duty which places specific responsibilities on a variety of activities to ensure that people are prevented from being drawn into terrorism. A Prevent Compliance Group was set-up with the aim of undertaking a risk assessment and developing an action plan for [the Office for Students](#) who are monitoring compliance of the HE sector on behalf of the Government. The existing research ethics and integrity approval process will ensure that staff and students undertaking research into sensitive areas are effectively supported and protected when undertaking this work to ensure academic freedom. Support is available from the Research Governance Team in RED working closely with the IT Security team.

#### **5. The Quality Assurance Framework**

The University shall provide guidance and shall work to create and maintain a culture of research that encourages and supports researchers in good research conduct. The University shall provide training where possible to enable Researchers to meet their obligations.

For studies involving human participants, the University shall provide the following tools and training to enable compliance with this Policy:

- a template risk assessment in the form of a research registration checklist to guide Researchers through the regulations and to enable them to register their project and ensure that the correct approvals are obtained

- training and education in the regulations governing these areas of research through staff development, individual researcher training, e-learning, external training providers and the Faculty of Health Sciences Research Governance training programme' training programme.
- monitoring of research projects in accordance with University monitoring/audit procedures. All University studies that are registered on the Research Governance system will be eligible for monitoring by an independent service provider [a Service Level Agreement is in place with University Hospitals Bristol NHS Foundation Trust (UH Bristol) to provide this].
- support of and engagement with internal and external audits and inspections of projects in this area of research
- an annual report from the Research Governance Team to the University Ethics of Research Committee

## **Annex 1 – Regulations**

The following regulations may be applicable to research involving human participants (collectively referred to as 'Regulations')

1. The Medicines for Human Use (Clinical Trial) regulations (2004) incorporating the following legislation [as amended from time to time] (hereinafter referred to as the Legislation):
  - The Medicines for Human Use (Clinical Trials) Regulations 2004  
<https://www.legislation.gov.uk/uksi/2004/1031/contents/made>
  - Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use  
<http://www.eortc.be/services/doc/clinical-eu-directive-04-april-01.pdf>
  - Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:091:0013:0019:EN:PDF>
  - Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use  
[http://ec.europa.eu/health/documents/eudralex/vol-4/index\\_en.htm](http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm)
  - UK Medicines Act 1968 and the updates contained in applicable Statutory Instruments, in particular, Statutory Instrument 2004/1031, Statutory Instrument 2006/1928 and Statutory Instrument 2006/2984  
<http://www.legislation.gov.uk/ukpga/1968/67>
  - ENTR/F2/BL D(2003) Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial. European Commission, (revision 3 of March 2010 )  
[https://ec.europa.eu/health/sites/health/files/files/clinicaltrials/docs/pc\\_rev3\\_2009-11/collins\\_rory\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/clinicaltrials/docs/pc_rev3_2009-11/collins_rory_en.pdf)
  - Detailed guidance on the collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use (June 2011) )  
[https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2011\\_c172\\_01/2011\\_c172\\_01\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2011_c172_01/2011_c172_01_en.pdf)CPMP/ICH/135/95: "Note for Guidance on Good Clinical Practice" [http://ec.europa.eu/health/files/eudralex/vol-10/3cc1aen\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol-10/3cc1aen_en.pdf)
  - Annex 13 to the EU Guide to Good Manufacturing Practice, 'Manufacture of Investigational Medicinal Products', February 2010  
[http://ec.europa.eu/health/files/eudralex/vol-4/2009\\_06\\_annex13.pdf](http://ec.europa.eu/health/files/eudralex/vol-4/2009_06_annex13.pdf)
  - CPMP/ICH/377/95: (E2A) "Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting"  
[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/09/WC500002749.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002749.pdf)
  - EudraLex Volume 10 – Clinical Trials  
<http://ec.europa.eu/health/documents/eudralex/vol-10/>
2. Device regulations including European Directives 90/385/EEC, 93/42/EEC, and 98/79/EEC (as amended from time to time)  
<https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety>
3. The Human Tissue Act 2004 <https://www.legislation.gov.uk/ukpga/2004/30/contents>
4. The Data Protection Act 2018 and the General Data Protection Regulation  
<http://www.legislation.gov.uk/ukpga/2018/12/contents/enacted>The Mental Capacity Act 2005 <https://www.legislation.gov.uk/ukpga/2005/9/contents>
5. Human Rights Act 1998  
[http://www.opsi.gov.uk/acts/acts1998/ukpga\\_19980042\\_en\\_1](http://www.opsi.gov.uk/acts/acts1998/ukpga_19980042_en_1)
6. Safeguarding Vulnerable Groups Act 2006  
<https://www.legislation.gov.uk/ukpga/2006/47/contents>

## **Annex 2 - Relevant Guidance and Policies**

### 1. University:

University Ethics of Research Policy and Procedure

<http://www.bristol.ac.uk/red/research-governance/ethics/>

- University Research Governance including Research Registration Checklist  
<http://www.bristol.ac.uk/red/research-governance/>
- University Insurance Office  
<http://www.bristol.ac.uk/secretary/insurance/>
- University Purchasing Policy  
<http://www.bristol.ac.uk/directory/procurement/>
- University policy on working with animals  
<http://www.bristol.ac.uk/university/governance/policies/animal-policy.html>
- Open access  
<http://www.bristol.ac.uk/staff/researchers/open-access/>
- Health and Safety guidance on research undertaken in the community  
<http://www.bristol.ac.uk/safety/media/gn/research-comm-gn.pdf>

See policies applicable to staff and students on the Secretary's Office website at:

<http://www.bristol.ac.uk/secretary/> and/or the University Governance website at:

<http://www.bristol.ac.uk/university/governance/policies/>

Including:

- Conduct Procedure for Members of Staff (Ordinance 28);
- Rules and Regulations for Students;
- Data protection guidance;
- Insurance;
- Public Interest Disclosure;
- Research Misconduct;
- Research Practice

### 2. Other guidance/policies:

(Note: this is not a comprehensive list and will vary depending on the nature of the research, its funders, relevant professional bodies, collaborators etc.)

- World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects  
<https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>
- Universities UK Concordat to support Research Integrity  
<https://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2019/the-concordat-to-support-research-integrity.pdf>
- The Integrated Research Application System for applying for permissions and approvals for health and social care/community research in the UK:  
<https://www.myresearchproject.org.uk/>
- The Social Care Research Ethics Committee  
UK Framework for Health and Social Care Research (PDF)  
<http://ethicsguidebook.ac.uk/Social-Care-Research-Ethics-Committee-191>
- UK Policy Framework for Health and Social Care Research  
<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>
- The UK Research Integrity Office: Code of Practice for Research  
<http://www.ukrio.org/what-we-do/code-of-practice-for-research/>
- Economic and Social Research Council: Research Ethics Framework  
<http://www.esrc.ac.uk/files/funding/guidance-for-applicants/esrc-framework-for-research-ethics-2015/>
- Medical Research Council: Ethics and research guidance  
(<https://mrc.ukri.org/research/policies-and-guidance-for-researchers/good-research-practice/>)
- The Royal Academy of Engineering: Statement of ethical principles  
<http://www.raeng.org.uk>



### **Annex 3: Responsibilities when undertaking Clinical Trials of Investigational Medicinal Products and Devices**

All Clinical Trials of an Investigational Medicinal Product (CTIMP) or Devices trials will need a Sponsor (see below for definitions) to take responsibility for the trial. The University can be the Sponsor for a CTIMP or a Devices trial where the Chief Investigator (CI) is a University employee, subject to an acceptable risk assessment and the appropriate approvals being in place before formal sponsorship is agreed.

In order to be able to undertake the Sponsor role the University delegates (whilst avoiding any conflict with trial agreements) certain responsibilities and obligations to the CI to enable them to manage the day-to-day research project. The University, as Sponsor, and the CI must abide by the Regulations and comply with their obligations as detailed below:

#### **DEFINITIONS**

Adverse Event	Any untoward medical occurrence in a clinical study participant
Device	A device is medical technology that is used in diagnosis, prevention, treatment and alleviation of disease. A device does not achieve its primary effect by pharmacological, immunological or metabolic means. For the purposes of this document Devices that are unmodified CE marked or are intended to be used for in-vitro examination of substances derived from the human body are excluded from this definition
IMP	Investigational Medicinal Product. A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial including a medicinal product which has a marketing authorisation but is, for the purposes of the trial being used or assembled (formulated or packaged) in a way different from the approved form or being used for an unapproved indication or when used to gain further information about an approved use.
NHS REC Project/Study Protocol	NHS Research Ethics Committee The CTIMP described in the protocol The document, and any amendments, that describe the objectives, design, methodology, statistical considerations and organisation of a CTIMP, as approved by the relevant authorities, including the Sponsor, NHS REC, MHRA, NHS host trusts
SAE	Serious Adverse Event as defined in the Legislation
Sponsor	The organisation that takes responsibility for the initiation, management and financing (or arranging financing) for the Project
SUSAR	Suspected Unexpected Serious Adverse Reaction as defined in the Legislation
Trial Master File	The file containing all essential documents to enable the proper conduct of the CTIMP and monitoring of the trial in accordance with the Legislation

#### **OBLIGATIONS OF THE SPONSOR**

To be satisfied that:

- The Project respects the dignity, rights, safety and well-being of participants and the relationship with care professionals
- An appropriate process of independent expert review has demonstrated that the Project proposal is worthwhile, of high scientific quality and represents good value for money
- An appropriate research ethics committee has reviewed the Project and has given a favourable opinion in writing
- Appropriate arrangements are in place for the registration of the trial
- The CI and other key researchers, including those at collaborating sites, have the necessary expertise and experience and have access to the resources and support needed to conduct the proposed Project successfully
- The proposed arrangements and resources will allow the collection and proper retention of high quality, accurate data and the proposed systems and resources are those required to allow appropriate data analysis and data protection.

- Arrangements proposed for the Project are consistent with all applicable Regulations, statutes and guidelines
- Organisations and individuals involved in the Project agree the division of responsibilities between them

To ensure that:

- Satisfactory arrangements are in place for the management and monitoring of the Project, and that these are documented
- Satisfactory arrangements are in place for the conclusion of the Project including appropriate plans for reporting the Project, disseminating the findings, archiving, data retention and destruction
- The Trial Master File has copies of the following: the informed consent form; the CI's CV; the application to the relevant NHS REC, HRA, MHRA and the approval letters when received; the Protocol and any approved amendments thereto.

To ensure that there is agreement in writing on appropriate arrangements for:

- Recording, reporting and reviewing adverse events and any significant developments as the Project proceeds, particularly those which put the safety of individuals or the integrity of the University at risk. The University has paid University Hospitals Bristol NHS Foundation Trust (UH Bristol) to provide this service  
<http://www.uhbristol.nhs.uk/research-innovation/information-for-researchers/>
- Approval of any modifications to the Project design
- A robust system to alert the University and other stakeholder organisations including the NHS REC, HRA and MHRA if significant developments occur as the Project progresses, whether in relation to the safety of individuals or the scientific direction
- Ensuring that all members of the research team have appropriate contracts in place to fulfil their obligations in the CTIMP and enable the CI and the University as Sponsor to fulfil their obligations

The University has put in place a service level agreement with UH Bristol to enable UH Bristol to undertake certain Sponsor responsibilities on its behalf for all University sponsored studies regardless of where they are hosted. These activities include: monitoring of studies; supporting, assessing and reporting Adverse Events, SUSARs and SAEs to the relevant authorities; pharmacy support for IMP management; reporting serious breaches and urgent safety measures.

#### **OBLIGATIONS OF THE CHIEF INVESTIGATOR**

As a University employee of a University sponsored CTIMP or Devices trial, the CI of the Project must ensure that the following are adhered to:

1. The dignity, rights, safety and well-being of research participants will be given priority at all times.
2. The Protocol shall be strictly adhered to. However, adherence to the Protocol shall not override the CI's clinical judgement to use alternative measures if they believe these are needed to protect research participants for whom they are clinically responsible. Any such instances must be reported as an Adverse Event, SAE or SUSAR as detailed in paragraph 9.
3. The CI has the necessary experience, suitable qualifications, training and expertise to undertake the tasks associated with the Project. The CI is also responsible for ensuring that any research staff undertaking the Project have the necessary experience, suitable qualifications, training and expertise to undertake the tasks associated with the Project. Any such training shall include good clinical practice training for the CI and any research staff in the team which have clinical research responsibilities. Copies of relevant training certificates shall be included in the Trial Master File.
4. The CI will ensure that students and research staff have adequate supervision, support and training to undertake their roles in the Project.

5. Recruitment of research participants shall not commence without the following being in place in writing:

- Medicines and Healthcare products Regulatory Agency (MHRA) approval i.e. the Clinical Trials Authorisation for a CTIMP or a 'letter of no objection' for a Device trial
- HRA Approval and NHS Research & Development confirmation of Capacity and Capability where required.
- NHS REC approval
- Indemnity arrangements
- Full sponsorship approval

In the event that any of the above approvals are withdrawn, the Project will be automatically suspended by the CI until all approvals are once again in place and the Sponsor has agreed that the Project can re-start. The CI must notify the Sponsor of this activity.

6. Where research participants are NHS patients, each member of the research team, including the CI, who has direct involvement with any research participants and/or person identifiable data, shall have a full or honorary NHS contract (or an NHS research passport if appropriate).

7. Any substantial and non-substantial amendments<sup>1</sup> to the Project will be agreed by the University as Sponsor, the HRA, relevant NHS Research & Development Departments, NHS REC and the MHRA as applicable to the type of amendment, the amended Project will not proceed without all applicable approvals. Once agreed, the CI will notify any such amendments to all other parties participating in the Project.

8. The Project will be conducted in accordance with the Legislation.

9. The University has delegated certain Sponsor responsibilities to UH Bristol and the CI must, in the first instance, use the following UH Bristol services and procedures (and reflect this in the Protocol):

- i. Provision of support and advice to University researchers in all aspects of pharmacovigilance including Adverse Events, SAEs, SUSARs, serious breaches and urgent safety measures management and reporting
- ii. IMP Management
- iii. Reporting of any SAEs and SUSARs on behalf of University to NHS REC and the MHRA in accordance with the Legislation
- iv. Reporting any serious breaches and urgent safety measures on University sponsored Projects

If any SAEs or SUSARs occur during the Project the CI shall be responsible for reporting these to UH Bristol, NHS REC and, where applicable, the MHRA in accordance with the Legislation. The CI will also notify the Sponsor for information.

10. The CI is also responsible for ensuring that:

- Arrangements are in place for the management of financial and other resources provided for the Project, including the management of any arising intellectual property.
- Accurate records will be maintained in a timely manner and made available for audit and monitoring as required. The Protocol shall include details on data retention and archiving at the end of the Project. Destruction of any Project data at the end of the Project or at the end of the agreed retention period shall only occur with the written approval of the Sponsor. The Project records will be retained in accordance with the Legislation.
- The findings from the Project will be open to critical review and appropriately disseminated. Data from the Project will be verified prior to publication.
- Any suspected research misconduct and/or fraud is reported promptly to the appropriate employing organisation or to the Sponsor through their own misconduct procedures.
- The University Insurance Officer is notified immediately of any event that may give rise to an insurance claim.
- The Project will only be conducted by the CI and/or members of the research team unless the Sponsor has agreed a contracts pathway with the CI detailing all third party

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<sup>1</sup> Substantial amendments are described in the NHS REC Standard Operating Procedures at <https://www.hra.nhs.uk/approvals-amendments/>

contractors and suppliers of any equipment, services or consumables required by the Project. The CI will adhere to the contracts pathway, notify and agree with the Sponsor any deviations from the contracts pathway and will ensure that appropriate contractual arrangements are in place and proper procurement practice is undertaken in line with the University purchasing policy<sup>2</sup>.

- If the project has any external funders and/or commercial collaborators the CI will not proceed without ensuring that the University (Research and Enterprise Development) is satisfied with the legal and contractual arrangements.
- The Sponsor is notified as soon as possible if for any reason the CI is no longer able to act as CI.

11. The CI shall ensure that:

- an annual progress report is made to NHS REC in accordance with NHS REC approval, and copied to the Sponsor and UH Bristol
- a development safety update report is made to the MHRA and REC in a timely manner in accordance with the conditions of the Clinical Trials Authorisation and the Legislation, and copied to the Sponsor and UH Bristol
- at all stages of the CTIMP, all relevant paperwork concerning approvals, amendments, annual reports, suspensions, SAEs and SUSARs are copied to the Sponsor

The University reserves the right to withdraw sponsorship and take whatever action is necessary to ensure the safety of research participants and its ability to act as Sponsor if it believes the CI is not fulfilling their obligations. In addition, non compliance with the obligations by the CI may lead to action under the University's Disciplinary Procedures and may invalidate the terms of any University insurance for the trial.

#### **OBLIGATIONS OF THE RESEARCHER**

All members of the research team involved in a CTIMP that are University employees or have an honorary contract with the University must also adhere to the obligations applicable to them in respect of the Regulations and must assist in enabling the CI and the Sponsor to meet the Regulations.

#### **Table of responsibilities for a CTIMP/Devices Trial**

Note: Where both the Sponsor and NHS Organisation are named in respect of a particular responsibility, liability for such responsibility is not joint. Their respective responsibility shall be as laid down in applicable legislation, guidance and the governance arrangements for the Study or as is otherwise applicable to their respective roles in the Study.

	<b>Responsibility to:</b>	<b>Responsible Party:</b>	<b>If Responsibility is delegated, name the body / individual that it is delegated to:</b>
<b>1. Study preparation (All studies)</b>	a) Ensure that insurance or indemnity arrangements are in place to cover liabilities.	Sponsor (Insurance Officer)	
	b) Secure and administer funding for the Study.	Sponsor or NHS Organisation (Finance Office)	
	c) Secure and contract for the supply of resources including medicinal products / devices / Contract Research Organisation services.	Sponsor (Purchasing)	
	d) Ensure that the appropriate contracts and agreements are in place for the Study.	Sponsor or NHS Organisation	

<sup>2</sup> Purchasing policy and procedures at <http://www.bris.ac.uk/Depts/Bursar/Purchasing/>

	<b>Responsibility to:</b>	<b>Responsible Party:</b>	<b>If Responsibility is delegated, name the body / individual that it is delegated to:</b>
	e) Notify the substantive employers of investigators in writing, in advance of the Study commencing, of their participation in the Study.	Sponsor or NHS Organisation	
<b>2. Applications and Registration (All studies)</b>	a) Ensure that the Protocol has undergone independent scientific and statistical review and is compliant with the relevant regulations/ guidelines. b) Prepare Participant information sheet and consent form, including where appropriate consent to providing Participant tissue, sample, medical data or other material to the Sponsor and other relevant documents prior to ethics submission. c) Prepare and submit ethics application. d) Register the Study with an appropriate protocol registration scheme. e) Obtain NHS permission.	Sponsor  Sponsor  Sponsor Sponsor  Sponsor	  CI  CI CI  CI
<b>3. Protocol Amendments (All studies)</b>	a) Prepare and submit proposed substantial amendments of the Protocol to the regulatory authority(ies), relevant ethics committee and NHS Site. b) Ensure all investigators are aware of dates of approval and implementation of all such amendments.	Sponsor  Sponsor	CI  CI
<b>4. Study Conduct (All studies)</b>	a) Ensure that legislation in relation to research is followed within the Site b) Ensure that the Study Site team members are appropriately qualified and experienced to undertake the conduct of the Study. c) Ensure that Study Site team have current substantive or honorary employment contracts in place, where required. d) Ensure that no Participant is recruited until a favourable ethical opinion has been provided e) Ensure that no Participant is recruited to the Study until satisfied that all relevant regulatory permissions and approvals have been obtained. f) Put and keep in place arrangements to allow all investigators to conduct the Study in accordance with the Protocol and clause 2 of this Agreement g) Ensure that the Study is managed, monitored and reported as agreed in the Protocol. h) Ensure that the rights of individual Participants are protected and that they receive appropriate medical care whilst participating in the Study. i) Maintain and archive Study documentation at the Site.	Sponsor  Sponsor  NHS Organisation  Sponsor  Sponsor  Sponsor  Sponsor  Sponsor and NHS Organisation  Sponsor and NHS Organisation	Site Investigator  Site Investigator   CI  CI  CI  CI  CI or Site Investigator  CI or Site Investigator

	<b>Responsibility to:</b>	<b>Responsible Party:</b>	<b>If Responsibility is delegated, name the body / individual that it is delegated to:</b>
	<p>j) Ensure that all data and documentation are available for the purposes of monitoring, inspection or audit and that the appropriate consent has been provided by the Participant.</p> <p>k) Inform appropriate health or social care professionals if their patient is a Participant in the Study in accordance with the Research Governance Framework.</p> <p>l) Ensure adequate facilities, resources and support are available to conduct the Study at the Site.</p> <p>m) Report suspected research misconduct.</p> <p>n) Notify the regulatory authority(ies) of the end of the Study and submit a report within 1 year of the end of study declaration.</p> <p>o) Notify the regulatory authority(ies) and relevant ethics committee if the Study is terminated early.</p>	<p>Sponsor and NHS Organisation</p> <p>Sponsor</p> <p>Sponsor and NHS Organisation</p> <p>Sponsor and NHS Organisation</p> <p>Sponsor</p> <p>Sponsor</p>	<p>CI or Site Investigator</p> <p>CI</p> <p>Study team in accordance with employer misconduct policies</p> <p>CI</p> <p>CI</p>
<b>5. Adverse events (All studies)</b>	<p>a) Maintain detailed records of all adverse events as specified in the Protocol.</p> <p>b) Report adverse events as agreed in the Protocol and to legal requirements and in accordance with NHS Organisation policy.</p> <p>c) Ensure that procedures are in place for emergency unblinding of the randomisation code.</p> <p>d) Promptly inform regulatory authorities, ethics committees and investigators (and manufacturers in the case of Device trials) of any urgent safety measures taken to protect Participants in the Study.</p> <p>e) Ensure that annual safety reports and end of Study reports are generated and submitted to the regulatory authority and relevant ethics committee within the required timeframes.</p> <p>f) Ensure that all investigators are, at all times, in possession of the current relevant safety information for the Study.</p>	<p>Sponsor</p> <p>Sponsor</p> <p>Sponsor</p> <p>Sponsor</p> <p>Sponsor</p> <p>Sponsor</p>	<p>CI and UH Bristol</p> <p>CI and UH Bristol</p> <p>CI and UH Bristol Pharmacy (or IMP supplier via contract)</p> <p>CI and UH Bristol</p> <p>CI</p> <p>CI</p>
<b>6. Data Management (All studies)</b>	<p>a) Design of case report forms and database.</p> <p>b) Ensure appropriate analysis of data.</p>	<p>Sponsor</p> <p>Sponsor</p>	<p>CI</p> <p>CI</p>
<b>7. Publication (All studies)</b>	<p>a) Initiate and coordinate review and submission of abstracts, posters and publications.</p>	<p>Sponsor</p>	<p>CI</p>
<b>8. Archiving (All studies)</b>	<p>a) Ensure that all Study records are archived appropriately on conclusion of the Study</p>	<p>Sponsor and NHS Organisation</p>	

Responsibility to:		Responsible Party:	If Responsibility is delegated, name the body / individual that it is delegated to:
<b>9. Clinical Trials involving Medicinal Products or Devices</b>	a) Ensure that the Study is conducted in accordance with the principles of Good Clinical Practice (GCP).	Sponsor	CI
	b) Request Clinical Trials Authorisation for CTIMP or 'letter of no objection' for Device trial from the regulatory authority (MHRA in the UK) including an application for an EudraCT number.	Sponsor in collaboration with CI	
	c) Ensure that Investigational Medicinal Product (IMP) or Device is not used for any purposes other than the conduct of the Study and is used in strict accordance with the Protocol.	Sponsor and NHS Organisation	
	d) Ensure that all Serious Adverse Events (SAE), other than those specified in the Protocol as not requiring immediate reporting, are promptly assessed as regards the requirement for expedited reporting to the regulatory authority and relevant ethics committee.	Sponsor	UH Bristol
	e) Ensure that SAEs are reviewed by an appropriate committee for the monitoring of trial safety.	Sponsor	UH Bristol
	f) Ensure that all Suspected Unexpected Serious Adverse Reactions (SUSAR) are identified and fully reported to the regulatory authority and relevant ethics committee within the required timelines.	Sponsor	UH Bristol
	g) Ensure that investigators are aware of any SUSARs occurring in relation to the Investigational Medicinal Product (IMP).	Sponsor	UH Bristol
	h) Ensure IMP is provided and labelled in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004.	Sponsor	CI and UH Bristol Pharmacy (or IMP supplier via contract)
	i) Ensure that IMP is stored in appropriate and secure conditions and that detailed records are maintained regarding its movement from delivery to return/destruction.	Sponsor and NHS Organisation	CI

(source: UK Clinical Research Collaboration - model agreement for non-commercial research)

#### **Annex 4: Summary statement on University of Bristol policies and guidance regarding controversial sources of funding.**

##### **Current guidance and policies:**

Below is a brief summary of the current University of Bristol policies and guidance in the area of controversial funding:

##### **A. Ethics of Research Policy and Procedure [version 6, approved 22/5/2015]:**

###### *Paragraph 2. Types of research*

Virtually all research will have ethical implications, however there are some areas of research where the ethical implications will be particularly important. The following is not an exhaustive list, however some examples of such areas of research are: where it involves human participants (particularly children and vulnerable adults); where it uses human data or human material; where there are serious health and safety implications; where animal experiments are involved; where there is a risk of damage to the environment; where the impact of the research may be emotionally damaging; where the research is politically or socially sensitive; where there might be a reputational risk to the University and where the source of funding for the research has the potential to compromise the University's position as a publicly funded charitable body.

##### **B. Guideline on Good Research Practice [adopted by Senate - October 2003]:**

###### *Section 4: Integrity*

Includes 'Researchers are expected to declare and manage appropriately any real or potential conflicts of interest either of a financial or professional nature'

###### *Section 11. Tobacco Industry Funding Guidance*

The University's policy is that it does not knowingly accept any monies from sources funded by the tobacco industry. Anyone with concerns regarding the nature of a potential funding body should contact the Director of Research & Enterprise Development.

##### **C. Investment and Banking Policies [approved by Council - March 2006]:**

Includes the following statements:

The Finance Director, assisted by investment advisers approved by Finance Committee, will:

- i. Not invest the University's endowment assets in the stocks, shares, bonds or units of companies, trusts, governments or other institutions, if the aims of the bodies concerned are contrary to the research, education and wider aims or objectives of the University or their activities are illegal under UK law;
- ii. Not invest in the stocks, shares, bonds or units of companies, trusts, governments or other institutions, if, by so doing, the wider interests of the University, in particular its ability to raise funds or obtain grants, are likely to be materially harmed.

The Finance Director, after consultation with Finance Committee, will:

- i. Not enter banking arrangements with institutions, if the aims of the institutions concerned are contrary to the research, education or wider aims or objectives of the University or if, by so doing, the wider interests of the University, in particular its ability to raise funds or obtain grants, are likely to be materially harmed.

The minutes from this Council meeting approved the paper subject to it being amended to reflect the decision taken prior to the Council meeting by the Vice-Chancellor and Chair of Council that holding shares in tobacco companies might damage the funding streams from health-based charities.