Research Governance and Integrity Policy

Summary

This policy sets out the University's expectations regarding the governance and integrity of research. It describes the obligations of those conducting research; the principles of Research Integrity and how the University seeks to uphold them; requirements relating to specific types of research; and the manner in which the Research Governance team provide oversight and monitoring.

Control information:	Control detail:
Owner	Pro Vice-Chancellor - Research and Innovation, Senior Team
Author	Head of Research Governance, Research, Enterprise and Innovation
Sponsor	Chair of the University Ethics of Research Committee
Consulted	University Ethics of Research Committee, University Research Committee
Approved by	Senate
Responsible area	Research, Enterprise and Innovation
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Reporting requirements	Concerns relating to health and socialcare research should be addressed to research-governance@bristol.ac.uk Concerns relating to other human participant research, or other research ethics concerns should be addressed to research-ethics@bristol.ac.uk Concerns or allegations relating to potential Research Misconduct should be addressed to research-misconduct@bristol.ac.uk
Applicable statutory, legal or best practice requirements	See Appendix 1: Regulations
Keywords	clinical, conduct, ethics, governance, integrity, research, trials
Related information	See Appendix 2: Other guidance and policies

Contents

1. Updates to this policy

1.1. This policy has been updated to reflect current practices in Research Governance and Integrity and to align to the new University of Bristol policy management framework.

1.2. It has been revised and re-ordered, to more clearly present the University's priorities and responsibilities relating to the conduct of relevant research.

1.3. The Principles of Research Integrity, in section 6, have been updated to align with the current *Concordat to Support Research Integrity*.

1.4. Our approach to Sponsoring health and social care research, which is in accordance with national standards, has been explicitly stated - for the avoidance of doubt.

1.5. Our limited involvement with research involving animals and research involving sensitive materials have been clarified.

2. Introduction

2.1. All staff, students and honorary staff members of the University of Bristol have a duty to the public, to themselves, to the University, and to funders to conduct research in the most conscientious and responsible manner possible.

2.2. 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 'Researchers').

2.3. 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 area of research, or their sources of funding. The aim is to set standards that enhance research quality, integrity, compliance and that safeguard the public.

2.4. This policy should be read in conjunction with other relevant guidelines and policies, including but not limited to, the Ethics of Research Policy: https://www.bristol.ac.uk/media-library/sites/red/documents/research-governance/ethics-of-research-policy.pdf, relevant sections of a member of staff's Terms and Conditions of Employment, and, for funded research, the Terms and Conditions of any funding agreement(s).

3. Scope

3.1. The University expects all researchers to consider fully the current and future ethical implications of their work. This policy applies to everyone carrying out research under the auspices of the University, whether their current place of work is within or outside University premises. 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 'Researchers'). It is the responsibility of the principal investigator of a project to ensure that all researchers involved in the project (including external & international collaborators) are aware of and comply with the policies of the University.

3.2. Research undertaken under the auspices of the University should meet, as a minimum, the governance and integrity standards required by the University, regardless of its place of conduct.

4. Definitions

4.1. See Research Governance Glossary.

5. Responsibilities

Researchers

5.1. 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 UK General Data Protection Regulations 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, the Medical Device Regulations 2002, and the Animals

(Scientific Procedures) Act 1986. For more information on regulations and access to links, please see Appendix 1.

5.2. 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 Appendix 2.

5.3. Researchers should take reasonable measures to ensure compliance with institutional, legal, ethical, moral and funder obligations in managing the project.

5.4. 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.

5.5. In the event of a conflict between the requirements of this policy and any other requirements or expectations upon the researchers or research project, advice should be sought from Research Governance research-governance@bristol.ac.uk).

5.6. Nothing in this policy should be read as undermining or conflicting with the Freedom of Speech Code of Practice or the right to academic freedom and freedom of speech. In the case of any conflict, the Freedom of Speech Code of Practice and the right to academic freedom and freedom of speech will take precedence. https://www.bristol.ac.uk/media-library/sites/secretary/documents/student-rules-and-regs/freedom-of-speech.pdf

6. Principles of Research Integrity

6.1. Researchers should be familiar with and adhere to the principles outlined in Universities UK's Concordat to Support Research Integrity:

6.2. "***Honesty*** *is crucial, from the presentation of research ideas and goals, through to authorship and financial contributions, and on to findings. Examples include honesty in: reporting research methods and procedures; gathering data and information; referencing work; representing and acknowledging the work of others; conveying interpretations; and making justifiable claims based on research findings.*"

6.3. 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.

6.4. Researchers must not engage in, nor conceal, Research Misconduct and are expected to report suspected cases in a responsible and professional manner, as described in the Regulations on Research Misconduct: https://www.bristol.ac.uk/media-library/sites/red/documents/research-governance/regulations-on-research-misconduct.pdf or, if applicable, the Whistleblowing Policy: https://www.bristol.ac.uk/media-library/sites/secretary/documents/student-rules-and-regs/whistleblowing-policy.pdf.

6.5. "***Rigour*** *is demonstrated by behaviour that is in line with prevailing disciplinary norms and standards, including the use of appropriate methods. It may be evidenced through adherence to procedures, standards of practice and agreed protocols, as appropriate, and is expected when drawing interpretations and conclusions from research, including when communicating findings. The integrity of the research record should be protected through secure and rigorous approaches.*"

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

a. The legal and regulatory framework for particular types of research.

b. The terms and conditions imposed by external research sponsors and funders.

c. The commercial, political, cultural or ethical sensitivity of particular types of research, or any research for particular external sponsors.

6.7. **Research Records** relate to the conduct of a research project, they allow for accountability and reproducibility. They may include personally identifiable data of participants, or others – in which case researchers will need to determine whether this is intrinsic to the records or whether it needs to be considered separately (likely disposed of sooner). Records which do include personally identifiable data must be managed in a manner compliant with the General Data Protection

Regulations and Data Protection Act 2018. Guidance on Records management can be found here: http://www.bristol.ac.uk/secretary/records/.

6.8. **Research Data** relates to the outputs of research. It will only very rarely include personally identifiable data (e.g. if the research involves recorded interviews in which participants' facial-expressions are an important component) - typically it will only contain anonymised data. Research Data should ideally be shared as widely as possible, in order to increase transparency, reproducibility and to get the greatest possible use from the data. Participant Information and Consent Forms should clearly indicate researchers' intent for future data use, in order to gain consent for this. More information about the management of research data can be found on the Research Data Service pages.

6.9. "***Transparency*** *and open communication provide the foundation for the actions taken when conducting or communicating about research. Examples may include: declaring potential competing interests; reporting research data collection methods; acknowledging the use of tools such as emerging technologies; analysing and interpreting data; and publishing or otherwise sharing findings. This may include appropriate open research practices. It permits humility in the process, acknowledging errors committed in good faith and ensuring honest mistakes are seen as productive elements of research*."

6.10. Researchers 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-bribery policy.

6.11. "***Care and respect*** *are expected for everyone and everything involved in the research system, and for the protection of the integrity of the research record. They should be extended to everyone involved in the research process, all participants in research, and for the subjects, users and beneficiaries of research, including humans, animals, the environment and cultural objects. Those engaged with research must also show care and respect for the integrity of the research record.*"

6.12. Researchers will ensure that any risks that could impact on the health and safety of those involved in research, whether researchers, research 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. Internal and external guidance can be found here: https://www.bristol.ac.uk/research-enterprise-innovation/research-governance/preventing-harm/.

6.13. 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 research culture.

6.14. "***Accountability*** *is expected of everyone individually and collectively to create a research environment in which diverse individuals and organisations are empowered and enabled to own the research process and be accountable for their contributions to the research record. This includes being accountable to participants involved in research, and a responsibility to hold individuals and organisations to account when behaviour falls short of the standards set by the Concordat.*"

6.15. 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: https://www.bristol.ac.uk/inclusion/governance-policy-and-guidance/edi-policy-statement/

6.16. 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.

7. Suitability of funders / collaborators

7.1. 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:

a. illegal under UK law;

b. 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.

8. Research ethics

8.1. All research requires ethical consideration. In many cases this will mean a formal review. Information about the University's expectations and support regarding research ethics can be found in the Ethics of Research Policy: https://www.bristol.ac.uk/media-library/sites/red/documents/research-governance/ethics-of-research-policy.pdf

9. Research specific requirements

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

9.2. **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:

a. protocol

b. sponsor terms

c. terms and conditions of the approval of the relevant ethics committee(s)

d. terms and conditions of NHS permission / HRA and host organisation approval

e. terms and conditions of the approval of the Medicines and Healthcare products Regulatory Agency (MHRA)

f. terms and conditions of the funding body.

Clinical / NHS research

9.3. Researchers undertaking 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 Appendices 1 and 2).

9.4. Research involving NHS organisations or otherwise conducted in accordance with the UK Policy Framework for Health and Social Care Research, must have an agreed Sponsor, as defined in the Framework:

> "*The sponsor is the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. All health and social care research has a sponsor. The sponsor is normally expected to be the employer of the chief investigator in the case of non-commercial research or the funder in the case of commercial research (The employer or funder is not automatically the sponsor; they explicitly accept the responsibilities of being the sponsor). The sponsor has overall responsibility for the research*"

In accordance with this, the University of Bristol will generally act as Sponsor for research where the Chief Investigator is substantively employed by the University, or is a student of the University – in which case their academic supervisor should act as Chief Investigator. This is **not** automatic; anyone seeking Sponsorship by the University should make a request to Research Governance (this is included as an option when submitting a Research Registration Checklist), this will be assessed by the Research Governance team, to determine whether the University of Bristol can act as Sponsor.

9.5. Where the University is acting as Sponsor, the Research Governance team will take on most of the oversight responsibilities of sponsorship and act as a first point of contact, as 'Sponsor Representatives' – this responsibility is delegated by the PVC for Health and Life Sciences. Other departments though will retain their usual responsibilities for applicable aspects of the Sponsor role, such as financing, procurement, contractual arrangements and insurance.

9.6. Research into investigational medicinal products and medical devices in human participants is strictly regulated. Researchers are responsible for ensuring they

have all the necessary approvals to undertake this research. Appendix 3 gives detailed requirements in relation to Researcher responsibilities and obligations in this area.

Human tissue research

9.7. Research (or educational work) involving human tissue, as defined by the Human Tissue Act 2004, must be conducted in accordance with the University Human Tissue Act Code of Practice, which can be found here: https://www.bristol.ac.uk/research-enterprise-innovation/research-governance/human-tissue/resources/.

Research involving animals

9.8. Research involving animals is governed by the Animal Services Unit, more information can be found here: https://www.bristol.ac.uk/animal-research/.

Sensitive materials / research

9.9. Where researchers have a legitimate research need to access materials (online or otherwise) which are sensitive, controversial, or may raise questions of legality, there are processes within the University to support and protect such research and researchers. If you have any questions regarding this, contact Research Governance (research-governance@bristol.ac.uk) who will advise or refer you, as required.

10. The Quality Assurance Framework

10.1. The University shall provide guidance and shall work to create and maintain a culture of research that encourages and supports researchers to meet all expectations of Research Integrity standards and appropriate research conduct. The University shall provide training where required to enable Researchers to meet their obligations.

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

a. 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.

b. The review of planned training by research teams and departments, and the direct provision of training relating to research governance, ethics and integrity.

c. Support for the University's internal audit processes.

d. Support for external (e.g. funder) audits and inspections of projects.

10.3. For studies requiring review by the HRA and/or an NHS REC, sponsored by the University, Research Governance will arrange for the monitoring of ten percent of studies each year. This will include; all studies subject to MHRA oversight (in accordance with their agreed risk assessment plans), studies selected by Research Governance for cause, and others selected at random.

11. Insurance

1.1. Information about insurance for research projects can be found here: https://www.bristol.ac.uk/red/research-governance/research-advice/research_insurance/.

Appendix 1: Regulations

1. Regulations

1.1. The following regulations, including any extant or subsequent amendments, may be applicable to research involving human participants. This is not intended as an exhaustive list.

a. The Medicines for Human Use (Clinical Trial) regulations 2004

Applicable to Clinical Trials of Investigational Medicinal Products (as defined by the Act - broadly speaking, drug trials).

b. Medical Device Regulations 2002

Applicable to research involving Medical Devices (as defined by the regulations).

c. All guidance and commentary pertaining to the above, provided by the MHRA, HRA or comparable government bodies.

d. The Human Tissue Act 2004

Applicable to research involving 'Relevant Material' (as defined by the Act).

e. The Data Protection Act 2018

Applicable to any research that involves the collection, use or storage of identifiable personal data (as defined by the Act).

f. The Mental Capacity Act 2005

Applicable to research involving participants who are, or may be, suffering from diminished mental capacity.

g. Human Rights Act 1998

Potentially applicable to any research.

h. Safeguarding Vulnerable Groups Act 2006

Potentially applicable to research involving children or vulnerable adults.

Appendix 2: Other Guidance and Policies

1. University guidance and policies

- Research Governance Glossary
- University Ethics of Research Policy
- University Research Governance processes
- University Purchasing Policy
- Open access
- Health and Safety guidance on research undertaken in the community
- University Human Tissue Act Code of Practice

1.2. See policies applicable to staff and students on the Secretary's Office website and/or the University Governance website.

1.3. Including:

- Conduct Procedure for Members of Staff (Ordinance 28)
- Rules and Regulations for Students
- Data protection guidance
- Insurance
- Whistleblowing Policy
- Regulations on Research Misconduct
- Research Practice

2. Other guidance/policies

2.1. **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
- Universities UK Concordat to support Research Integrity
- The Integrated Research Application System for applying for permissions and approvals for health and social care/community research in the UK
- HRA Guidance for Social Care Research
- UK Policy Framework for Health and Social Care Research
- The UK Research Integrity Office: Code of Practice for Research
- Economic and Social Research Council: Research Ethics Framework
- Medical Research Council: Ethics and research guidance
- Human Tissue Authority Codes of Practice

Appendix 3: Responsibilities

1. Responsibilities when undertaking Clinical Trials of Investigational Medicinal Products and Clinical Investigations of a Medical Device

1.1. All Clinical Trials of an Investigational Medicinal Product (CTIMPs) or Clinical Investigations of a Medical Device (CIMDs) will need a Sponsor (see below) to take responsibility for the trial.

1.2. The University can be the Sponsor for a CTIMP or a Devices trial where the Chief Investigator (CI) is a substantive University employee, subject to an acceptable risk assessment and the appropriate approvals being in place before formal sponsorship is agreed.

1.3. In order to be able to undertake the Sponsor role, the University delegates certain responsibilities and obligations to the CI to enable them to manage the day-to-day research project. The Research Governance team will take on most of the oversight responsibilities of the Sponsor and act as a first point of contact, as 'Sponsor Representatives'. Other departments though will retain their usual responsibilities for applicable aspects of the Sponsor role, such as financing, procurement, contractual arrangements and insurance matters.

1.4. The University, as Sponsor, and the CI must abide by the Regulations and comply with their obligations as detailed below:

2. Obligations of the Sponsor

2.1. To be satisfied that:

a. The Project respects the dignity, rights, safety and well-being of participants and the relationship with care professionals.

b. 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.

c. Appropriate approvals and permissions are in place for the Project including but not limited to research ethics committee and Health Research Authority

review, and confirmation of capacity and capability from participating organisations.

d. Appropriate arrangements are in place for the registration of the trial.

e. Appropriate arrangements are in place for insurance cover of the trial.

f. 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.

g. 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.

h. Arrangements proposed for the project are consistent with all applicable Regulations, statutes and guidelines.

i. Organisations and individuals involved in the Project agree the division of responsibilities between them.

j. Appropriate arrangements are in place for supply of the IMP or device and consistent with all applicable Regulations, statutes and guidelines.

2.2. To ensure that:

a. Satisfactory arrangements are in place for the management and monitoring of the Project, and that these are documented.

b. Satisfactory arrangements are in place for risk management of the project, and that these are documented.

c. 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.

d. A Trial Master File has been established and, where applicable, Investigator Site Files. The Trial Master File contains records evidencing the intentions and conduct of the study, and is stored and maintained in such as manner as

to facilitate accurate, consistent and accountable administration - in accordance with all applicable regulations and guidelines.

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

a. 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.

b. Approval of any modifications to the Project design.

c. 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.

d. Ensuring that all members of the research team have appropriate contracts in place to fulfil their obligations in the project and enable the CI and the University as Sponsor to fulfil their obligations.

University Hospitals Bristol and Weston NHS Foundation Trust (UHBW)

2.4. UHBW are contracted by UoB to undertake certain Sponsor duties on its behalf for all University sponsored studies, regardless of where they are hosted.

2.5. These duties include: monitoring of studies; supporting, assessing and reporting Adverse Events, SUSARs and SAEs to the relevant authorities; pharmacy support for IMP management.

2.6. These duties remain the responsibility of the University, as Sponsor.

3. Obligations of the Chief Investigator

3.1. The CI of a UoB sponsored CTIMP or CIMD must ensure that the following are adhered to:

a. The dignity, rights, safety and well-being of research participants will be given priority at all times.

b. 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 appropriately reported.

c. It must be demonstrated that 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 their delegated tasks. Any such training shall include good clinical practice training. Copies of relevant training certificates shall be included in the Trial Master File.

d. The CI will ensure that students and research staff have adequate supervision, support and training to undertake their roles in the Project.

e. 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
   - NHS Research & Development confirmation of Capacity and Capability where required.
   - NHS REC favourable opinion and HRA Approval.
   - Indemnity arrangements.
   - Full sponsorship approval and green light issued by the Sponsor Representative.

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

f. Where research participants are NHS patients, each member of the research team, including the CI, who engages with them in a clinical context, shall

have a full or honorary NHS contract (or an NHS research passport, if appropriate).

g. Any amendments to the Project will be defined and managed in accordance with the HRA amendment process: https://www.hra.nhs.uk/approvals-amendments/amending-approval/. Amendments must be reviewed and agreed by the University, as Sponsor, the HRA, relevant NHS Research & Development Departments, the NHS REC and the MHRA as applicable to the type of amendment. The amended Project will not proceed without all applicable approvals and the issue of updated sponsorship by the Sponsor Representative. Once agreed, the CI will notify any such amendments to all other parties participating in the Project.

h. The project will be conducted in accordance with all applicable legislation.

i. The University has contracted certain Sponsor duties to UHBW and the CI must, in the first instance, use the following UHBW services and procedures (and reflect this in the Protocol):

- 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.
- IMP Management.
- Reporting of any SAEs and SUSARs on behalf of University to NHS REC and the MHRA in accordance with the Legislation.

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

3.2. The CI is also responsible for ensuring that:

a. Arrangements are in place for the management of financial and other resources provided for the Project, including the management of any arising intellectual property.

b. Accurate records will be maintained in a timely manner and made available for audit, inspection 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.

c. The findings from the Project will be open to critical review and appropriately disseminated. Data from the Project will be verified prior to publication.

d. Any suspected research misconduct and/or fraud is reported promptly to the appropriate employing organisation or to the Sponsor through their own misconduct procedures.

e. The University Insurance Officer is notified immediately of any event that may give rise to an insurance claim.

f. 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 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[1].

g. If the project has any external funders and/or commercial collaborators the CI will not proceed without ensuring that the University (Division of Research, Enterprise and Innovation) is satisfied with the legal and contractual arrangements.

h. The Sponsor is notified as soon as possible if for any reason the CI is no longer able to act as CI.

3.3. The CI shall ensure that:

[1] Purchasing policy and procedures at http://www.bris.ac.uk/Depts/Bursar/Purchasing/

a. A development safety update report is provided to the Sponsor for review and, once agreed, submitted to the MHRA and REC in a timely manner, in accordance with the conditions of MHRA approval and the Legislation.

b. At all stages of the project, all relevant paperwork concerning approvals, amendments, annual reports, suspensions, SAEs and SUSARs should be available to the Sponsor.

c. 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.

4. Obligations of the Researcher

4.1. All members of the research team involved in a project 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.

Tables of responsibilities for a CTIMP/Devices Trial

4.2. **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.

4.3. **Note:** The tables below set out responsibilities in relation to a CTIMP/CIMD trial. The Sponsor is the University of Bristol and where an activity sits with a certain team this has been indicated; all other activities are overseen by the Research Governance team.

Table 1: Study preparation (all studies)

Responsibility to	Responsible Party	If Responsibility is delegated, name the body / individual that it is delegated to
a) Ensure that insurance or indemnity arrangements are in place to cover liabilities.	Sponsor (Insurance Officer)	Not applicable
b) Secure and administer funding for the Study.	Sponsor (Finance Office)	Not applicable
c) Secure and contract for the supply of resources including medicinal products / devices / Contract Research Organisation services.	Sponsor (Purchasing)	Not applicable
d) Ensure that the appropriate contracts and agreements are in place for the Study.	Sponsor (Research Governance & Research Contracts)	Not applicable

Table 2: Applications and registration (all studies)

Responsibility to	Responsible Party	If Responsibility is delegated, name the body / individual that it is delegated to
a) Ensure that the Protocol has undergone independent scientific and statistical review and is compliant with the relevant regulations/ guidelines.	Sponsor	Not applicable

b) Prepare all required documentation, including the Participant Information Sheet and Consent Form, to the Sponsor for review, prior to REC submission.	Sponsor (Review)	CI (Create)
c) Prepare and submit ethics application.	Sponsor (Review)	CI (Create)
d) Register the Study with an appropriate protocol registration scheme.	Sponsor	CI
e) Obtain NHS permission.	Sponsor	CI

Table 3: Protocol amendments (all studies)

Responsibility to	**Responsible Party**	**If Responsibility is delegated, name the body / individual that it is delegated to**
a) Prepare and submit proposed amendments of the project to the regulatory authority(ies), relevant ethics committee and NHS Site.	Sponsor (Review)	CI (Create)
b) Ensure all investigators are aware of dates of approval and implementation of all such amendments.	Sponsor	CI

Table 4: Study conduct (all studies)

Responsibility to	Responsible Party	If Responsibility is delegated, name the body / individual that it is delegated to
a) Ensure that legislation in relation to research is followed within the Site	Sponsor	Site Investigator
b) Ensure that the Study Site team members are appropriately qualified and experienced to undertake the conduct of the Study.	Sponsor	Site Investigator
c) Ensure that Study Site team have current substantive or honorary employment contracts in place, where required.	Site(s)	Not applicable
d) Ensure that no Participant is recruited until a favourable ethical opinion and relevant regulatory permissions and approvals have been obtained	Sponsor	CI
e) Ensure that no Participant is recruited to the Study until Sponsor Representative has issued green light.	Sponsor	CI
f) Put and keep in place arrangements to allow all investigators to conduct the Study in accordance with the Protocol.	Sponsor	CI

g) Ensure that the Study is managed, monitored and reported as agreed in the Protocol.	Sponsor	CI
h) Ensure that the rights of individual Participants are protected and that they receive appropriate medical care whilst participating in the Study.	Sponsor and Site(s)	CI or Site Investigator
i) Maintain and archive Study documentation at the Site.	Sponsor and Site(s)	CI or Site Investigator
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.	Sponsor and Site(s)	CI or Site Investigator
k) Inform appropriate health or social care professionals if their patient is a Participant in the Study in accordance with the Research Governance Framework.	Sponsor	CI
l) Ensure adequate facilities, resources and support are available to conduct the Study at the Site.	Sponsor and Site(s)	Not applicable
m) Report suspected research misconduct.	Sponsor and Site(s)	Study team in accordance with employer misconduct policies
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.	Sponsor (Review)	CI (Create)

o) Notify the regulatory authority(ies) and relevant ethics committee if the Study is terminated early.	Sponsor (Review)	CI (Create)

Table 5: Adverse events (all studies)

Responsibility to	**Responsible Party**	**If Responsibility is delegated, name the body / individual that it is delegated to**
a) Maintain detailed records of all adverse events as specified in the Protocol.	Sponsor (via UHBW)	CI
b) Report adverse events as agreed in the Protocol and to legal requirements and in accordance with NHS Organisation policy.	Sponsor (via UHBW)	CI
c) Ensure that procedures are in place for emergency unblinding of the randomisation code.	Sponsor	As per contract.
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.	Sponsor (via UHBW)	CI
e) Ensure that annual safety reports and end of Study reports are generated and submitted to the regulatory	Sponsor	CI

authority and relevant ethics committee within the required timeframes.		
f) Ensure that all investigators are, at all times, in possession of the current relevant safety information for the Study.	Sponsor	CI

Table 6: Data management (all studies)

Responsibility to	**Responsible Party**	**If Responsibility is delegated, name the body / individual that it is delegated to**
a) Design of case report forms and database.	Sponsor	CI
b) Ensure appropriate analysis of data.	Sponsor	CI

Table 7: Publication (all studies)

Responsibility to	**Responsible Party**	**If Responsibility is delegated, name the body / individual that it is delegated to**
a) Initiate and coordinate review and submission of abstracts, posters and publications.	Sponsor	CI

Table 8: Archiving (all studies)

Responsibility to	Responsible Party	If Responsibility is delegated, name the body / individual that it is delegated to
a) Ensure that all Study records are archived appropriately on conclusion of the Study	Sponsor and Sites(s)	Not applicable

Table 9: Clinical trials involving medicinal products or devices

Responsibility to	Responsible Party	If Responsibility is delegated, name the body / individual that it is delegated to
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	Not applicable
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	CI & Local investigators

d) Ensure that all Serious Adverse Events (SAE), other that 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 (via UHBW)	Not applicable
e) Ensure that SAEs are reviewed by an appropriate committee for the monitoring of trial safety.	Sponsor	CI
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 (via UHBW)	Not applicable
g) Ensure that investigators are aware of any SUSARs occurring in relation to the Investigational Medicinal Product (IMP).	Sponsor	CI
h) Ensure IMP is provided and labelled in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004.	Sponsor	As per contract with supplier / manufacturer
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 Site(s)	CI

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