

Guidance Notes for all Research Involving Human Participants

PLEASE NOTE: If your study is eligible to apply for [HRA Approval](#) (it involves NHS staff or primary care sites only) some of the information in these guidance notes will not apply to you. Please contact us directly and we will guide you through the new process.

Introduction

The regulations governing the conduct of research involving human participants, their tissue and/or data are complex and it is essential that researchers have an awareness of the following:

- The Medicines for Human Use (Clinical Trials) Regulations 2004
<http://medicines.mhra.gov.uk/>
- The NHS Research Governance Framework for health and social care
<http://www.dh.gov.uk/>
- The Human Tissue Act 2004 - [Human Tissue Authority \(HTA\)](#)
- [The Mental Capacity Act](#)
<http://www.legislation.gov.uk/ukpga/2005/9/contents>
- [The Data Protection Act 1998](#)
<http://www.legislation.gov.uk/ukpga/1998/29/contents>
- [The Bribery Act 2010](#)
<http://www.legislation.gov.uk/ukpga/2010/23/contents>

For some research a Research Sponsor (Sponsor) is identified to take responsibility for the research in order to set standards that enhance research quality and safeguard the public.

If your research involves human participants, their tissue and/or data in any way, as a Chief Investigator or Student Supervisor you **MUST** do the following, **prior to commencing research**:

1. familiarise yourself with the requirements above, the key points are summarised in this guidance.
2. complete the Research Registration Checklist (available from <http://www.bristol.ac.uk/red/research-governance/>).
3. obtain a sponsorship authorisation and / or an approval letter from the University
4. obtain all the necessary permissions, including a 'letter confirming full sponsorship', before starting your research.

Contact the Research Governance Team

(<http://www.bristol.ac.uk/red/people/group/red/1602>) if you have any questions that are not addressed in this guidance.

Please note that under no circumstances may recruitment of research participants start until all of the permissions are in place. **In particular, please note that there are some exclusions to our insurance cover that mean we may need additional time to confirm insurance cover. Please refer to Note 5.**

The Research Registration Checklist is designed to help you understand the requirements at the application/project design stage; it will enable you to build them into your timescales, hopefully avoiding any unplanned delays or problems before you are ready to commence the research project.

Some of the approvals required to undertake the research may take some time to obtain and **MUST** be in place prior to commencing the research project or participant recruitment.

Guidance for completing the Research Registration Checklist

As indicated on the Checklist, you **MUST** answer these questions and seek engagement with the Research Governance Team in RED before you can commence the research. You

MUST be a University employee, have an Honorary Contract or be a registered postgraduate student (PhD, MD or equivalent):

Note 1 – Clinical Trial Regulations

Does the research project involve the investigation of the safety or efficacy of a medicine/foodstuff/placebo or a trial of a medical device in humans (including healthy volunteers and patients)?

Medicine/foodstuff/placebo: If 'yes', it is highly likely that the project falls within the Medicines for Human Use (Clinical Trials) Regulations 2004 and you will need to get a Clinical Trials Authorisation from the Medicines and Healthcare Products Regulatory Agency (MHRA) before starting the research project. A Sponsor is required and registration with the MHRA incurs a fee (which varies depending on the nature of the research), which will need to be funded by the project.

To help clarify the scope of the regulations, the MHRA website has an algorithm (<http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/IsclinicaltrialauthorisationCTArequired/index.htm>) which helps define what these regulations cover. If you are in any doubt about your research please look at the advice on the MHRA website. It is good practice to have a written record in your main trial file of any discussions or correspondence you may have had with the MHRA and the decisions made.

Important: Please note that it is a criminal offence for a trial to proceed without a Clinical Trials Authorisation, if one is needed.

Medical Device: Medical devices are defined as: “any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purposes of

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Alleviation of or compensation for an injury or handicap
- Investigation, replacement or modification of the anatomy or of a physical process
- Control of contraception

which does not have its principal intended action in or on the human body by pharmacological, immunological or metabolic means...”

Non CE Marked Devices - studies involving non-CE marked medical devices carried out in the UK may be regulated as clinical investigations under the Medical Devices Regulations 2002 and require approval by obtaining a letter of ‘no objection’ from the MHRA.

CE Marked Devices - if the product already has a current CE mark then set-up is reasonably straightforward. See <http://www.cesolutions.eu/ce-marking.html#1> for useful information about CE marking.

The MHRA Guidance on devices can be found at:

<http://www.mhra.gov.uk/Howweregulate/Devices/Clinicaltrials/>

All of these types of studies will take longer to set up than non-clinical trial/non-device studies. Please contact the Research Governance Team (research-governance@bristol.ac.uk) as soon as possible to discuss any such proposed studies and arrange an early set up meeting to ensure the Team can support you during the set-up and conduct of your study.

Note 2 – Research Governance Framework

Does the research project involve:

2a. patients, clients or carers of an NHS Trust or Social Care organisation or health related research involving prisoners?

2b. staff or premises of an NHS Trust or Social Care organisation?

If 'yes', the project falls within the scope of the Research Governance Framework for Health and Social Care (<https://www.gov.uk/government/publications/research-governance-framework-for-health-and-social-care-second-edition>). You will need to get written approval from the Research Management Office (or equivalent, e.g. R&D Office) of each NHS Trust or Social Care Organisation, on whose premises, patients, carers, clients or staff you are undertaking your research, before you start. Please contact the relevant organisation's Research Management Office to register your project and get written R&D Approval. Also see Notes 7 and 9.

Note 3 – Human Tissue Act

Does the research involve the procurement, import, use and/or storage of human tissue?

The Human Tissue Act 2004 (HT Act) makes it unlawful to remove, store or use human tissue from the living or deceased without consent for specified health-related purposes or public display and is punishable by a fine and/or 3 years' imprisonment. There are a number of activities in the HT Act that require a licence from the Human Tissue Authority before they can be lawfully undertaken.

The [Human Tissue Authority \(HTA\)](#) was set up to regulate the removal, storage, use and disposal of human bodies, organs and tissue for a number of Scheduled Purposes (such as research, transplantation, and education and training) set out in the HT Act. In order to carry out research and teaching, the University of Bristol uses and stores tissue that falls within the remit of the HTA: the University therefore has obligations under the HT Act. Studies involving human tissue require NHS Research Ethics Committee (NHS REC) approval or approval by a NHS REC registered Research Tissue Bank, unless confirmed otherwise by the Research Governance Team.

Further information is available from <http://www.bristol.ac.uk/red/research-governance/human-tissue/> and the [Human Tissue Authority website](#), including information on what needs licensing, and useful Codes of Practice on the use of tissue and appropriate consent.

Note 4 – Student Qualification

If the research project is part of a student qualification, please indicate the qualification that will be awarded at the end of the research project and the supervisor(s) that support you. This information enables the Research Governance Team to establish the appropriate levels of risk management and responsibility for the conduct of the research.

Note 5 – Insurance and Indemnity

5a. Irrespective of your answers to 1, 2 and 3 on the Research Registration Checklist, please note that you must allow extra time to arrange insurance for studies involving the following: drug/medical devices; children under 5; pregnant women; cohorts of more than 5000 participants; conception/contraception research; trials undertaken outside the UK; genetic engineering; clinically invasive procedures*; and research into Hepatitis, HIV/AIDS, CJD.

Please notify the University Insurance Office (Ginny Hope, Ginny.Hope@bristol.ac.uk, 0117 928 7791, Nicola Semple, Nicola.Semple@bristol.ac.uk, 0117 331 7030) if your research project involves any of the categories above as early as possible in the project set up. Also, please note there are no central or faculty funds to pay for the extra insurance if it is required; funding MUST come from the budget for your study.

* All procedures that are clinically invasive, **excluding**:

- the insertion of needles for the purpose of taking blood samples only;
- the measurement of physiological processes using non-invasive methods;
- the collection of body secretions and excretions by non-invasive methods for analysis;
- questionnaire and interview-only studies;

- the use of already-held or routinely collected tissue samples which would otherwise be disposed of.

5b. If you have answered 'yes' to questions 1, 2a or 3, this indicates that you will need to apply for NHS ethics review and/or NHS R&D approval using the [Integrated Research Application System \(IRAS\)](#) (see note 7 below). Questions A76 and A77 of the IRAS application form are about indemnity and insurance and there are some specimen answers available at: <http://www.bristol.ac.uk/secretary/insurance/insuranceforresearch.html>. You will also need to attach a letter from our Insurance Officer (<http://www.bristol.ac.uk/secretary/insurance/>) who will wish to see your protocol, draft ethics form and information sheet in order to assess the project for insurance implications.

If you have answered 'yes' to 2b, this indicates that you will need to apply for Faculty Research Ethics Committee review via the University online ethics tool <http://www.bristol.ac.uk/red/ethics-online-tool>.

If you are going overseas on University business, you should apply for insurance clearance through the University Insurance Office <http://www.bristol.ac.uk/secretary/insurance/travel/guide.html>.

Note 6 – Funder

Please identify the funder for the research project, approximate level of funding and who has undertaken the peer review. This will help the Research Governance Team to establish whether there is appropriate peer review and sufficient resources for the scale of the proposed research.

Peer review is required for:

- studies where the funder does not have an independent peer review process in place
- individual projects that form part of a programme grant (where the funder does not undertake specific project peer review)
- studies that are not externally funded, apart from student projects where peer review is the responsibility of the supervisor.

Note 7 – Ethical Review

7a: NHS Research Ethics Committee/Social Care Research Ethics Committee review

To ascertain if your research project needs an ethical review from the NHS, please indicate if your project involves any of the following:

Extract from GafREC 2011:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213753/dh_133993.pdf

- a. potential research participants identified from, or because of, their past or present use of the services listed above (including services provided under contract with the private or voluntary sectors), including participants recruited through these services as healthy controls;
- b. potential research participants identified because of their status as relatives or carers of past or present users of these services;
- c. collection of tissue (i.e. any material consisting of or including human cells) or information from users of these services;
- d. use of previously collected tissue or information from which individual past or present users of these services could be identified, either directly from that tissue or information, or from its combination with other tissue or information in, or likely to come into, the possession of someone to whom the tissue or information is made available;
- e. xenotransplantation (i.e. putting living cells, tissue or organs from animals into people), which, as a matter of Government policy, is recommended to take place in a controlled research context, carried out with a research protocol approved by a REC within the UK Health Departments' Research Ethics Service;

- f. health-related research involving prisoners, for which the National Offender Management Service, Scottish Prison Service and Northern Ireland Prison Service require review by a REC as well as compliance with their own approval procedures;
- g. social care research projects funded by the Department of Health, which must always be reviewed by a REC within the Research Ethics Service for England
- h. people who lack (or lose) the capacity to give informed consent to take part (or to keep taking part) in the research;
- i. processing of confidential patient information without consent where this would otherwise breach confidentiality;
- j. material consisting of or including human cells, which has been taken from the living or the deceased;
- k. patients who are cared for in private and voluntary sector nursing homes (in England, Wales and Northern Ireland) and/or residents of residential care homes (in Northern Ireland only);
- l. exposure to ionising radiation;
- m. medical devices that are not CE-marked (i.e. not compliant with European Directives) or CE-marked medical devices that have been modified or are being used for a new purpose;
- n. investigational medicinal products;
- o. practising midwives conducting a clinical trial;
- p. protected information from the Human Fertilisation and Embryology Authority register.

If you have answered 'yes' to any of the above, your research **MUST** seek ethics review from a NHS REC or SCREC.

If you are in any doubt, please contact the Research Governance Team by emailing a summary of the proposed research to research-governance@bristol.ac.uk.

The NHS ethics application form is available on the IRAS system at: <https://www.myresearchproject.org.uk/>. Questions A4 and A64 requires a Sponsor to be identified, and if you would like this to be the University of Bristol you should complete the Research Registration Checklist accordingly. You should identify Dr Birgit Whitman as the Sponsor contact on the ethics application form at these questions. The Research Governance Team will provide you with an electronic authorisation of your form via the IRAS system. Both the NHS REC and R&D forms can be authorised by any member of the Research Governance Team.

If ethical review by a NHS Research Ethics Committee is needed, you will need to answer the questions about insurance and indemnity (questions A76 and A77) and provide a letter of insurance. If your research involves any of the categories outlined in Note 5a above, Ginny Hope, the Insurance Officer (genny.hope@bristol.ac.uk, 928 7791) **MUST** see the ethics application form and confirm in writing that insurance is in place before you can commence the research.

Please note: If your study involves only staff or premises of an NHS Trust or Social Care organisation, this now requires University (or equivalent) ethics approval. However, please note that if your study involves elements that would require NHS REC review **and** NHS staff/premises you do not need to split your study into separate studies for different levels of ethical review. The entire study should be reviewed by a NHS REC.

Management/R&D approval from the relevant NHS Trust R&D departments will still be required for studies involving solely staff and/or premises of a NHS Trust or Social Care organisation. The R&D application form is available at: <https://www.myresearchproject.org.uk/>. Question A64 requires a Sponsor to be identified, and if you would like this to be the University of Bristol you should complete the Research Registration Checklist accordingly.

7b: University Ethics Review

If the proposed research has **ethical implications** but does not need ethical review from a NHS REC, it might still need University of Bristol ethics approval, or an ethics review by other organisations in the case of collaborative studies. Ethics review

through your Faculty / School / Departmental Research Ethics Committee follows Faculty procedures. Applications are made using the Online Ethics Tool <http://www.bristol.ac.uk/red/ethics-online-tool>, unless otherwise stated; please contact your Faculty Research Ethics Officer for clarification. Information on the University's Faculty Research Ethics Officers, Faculty processes and the Ethics of Research Policy and Procedure is available at: <http://www.bristol.ac.uk/red/research-governance/ethics/>.

Ethical implications will be particularly important to consider where, for example, research involves human subjects, particularly vulnerable people, it uses human data or human material, there are serious health and safety implications, animal experiments are involved, there is a risk of damage to the environment, the impact of the research may be emotionally damaging, the research is politically or socially sensitive, or the source of funding for the research has the potential to compromise the University's position as a publicly funded charitable body.

Please note: Research should only have one ethics review, and normally the decision on which is the most appropriate ethics committee should take into account firstly the statutory requirements, and then the location of Chief Investigator and the formal ethics review structures in place in each organisation.

Note 8 – Sponsorship

8a: If the answer to any of the questions 1, 2a, 2b or 3 is 'yes', would you like the University to be the Sponsor for the project?

Please note that the University of Bristol would consider undertaking the role of Sponsor if the Chief Investigator or the Student Supervisor responsible for the research is a University of Bristol employee or holds an Honorary Contract. **It is important to note that if the University declines to be the Sponsor for your project and you haven't identified an acceptable alternative Sponsor, under no circumstances can you do the research under the auspices of the University or use University staff, equipment, facilities or laboratories in the project.**

8b: Is another organisation acting as Sponsor?

If another organisation has agreed to take on the role of the Sponsor, you must tell us who will be the Sponsor. Please send us the study protocol, ethics approval letter and written confirmation of sponsorship. On receipt we will issue a study registration e-mail. There might be instances where it is not necessary to register your study with us, e.g., UoB staff involved only in advisory boards, steering committees, peer review or consultancy; please contact us through research-governance@bristol.ac.uk to clarify.

Note 9 – Access to NHS participants and their information

In addition, please note that you and all other staff working on the project who have access to any NHS patients, NHS patient identifiable information, children, vulnerable adults must have the appropriate access clearances e.g. NHS research passport, letter of access, DBS/CRB checks.

Further information is available at:

- Research passports
http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx or contact the relevant NHS Trust(s) Research Management Office.
- DBS/CRB checks <https://www.gov.uk/government/organisations/disclosure-and-barring-service> and <http://www.bristol.ac.uk/hr/resourcing/additionalguidance/crb/>

Note 10 – Declaration signatures

The Research Registration Checklist should be completed and e-mailed to the Research Governance Team from the University e-mail account of the Chief Investigator. Where the University is not the Sponsor but a University employee is a collaborator for a study that involves human participants, their data and/or tissue, that employee should complete and e-mail the checklist as above.

In the case of a student project at the level of PhD, MD or equivalent, the student can act as the Chief Investigator. When the student submits the checklist their supervisor's details should be completed on the checklist and the supervisor should be copied into the e-mail. For all other student qualifications (e.g. MSc, undergraduate degrees), the Chief Investigator is the Student Supervisor.

If you have any queries relating to this contact the Research Governance Team.

Further reading / references

1. University of Bristol policies and guidance

Information and help is available from the Research & Enterprise Development website at <http://www.bristol.ac.uk/red/research-governance/>

Research Governance Team: <http://www.bristol.ac.uk/red/people/group/red/1602>; research-governance@bristol.ac.uk.

Research Governance and Integrity Policy <http://www.bristol.ac.uk/red/research-governance/practice-training/rqi.pdf>

Ethics of Research Policy and Procedure <http://www.bristol.ac.uk/red/research-governance/practice-training/researchethicspolicy.pdf>

Code of Practice for working with human tissue <http://www.bristol.ac.uk/red/research-governance/human-tissue/resources/>

Policy on Public Interest Disclosure
<http://www.bristol.ac.uk/secretary/studentrulesregs/public.html>

Regulations on Research Misconduct
<http://www.bristol.ac.uk/secretary/studentrulesregs/researchmisc.html>

Data Protection: <http://www.bris.ac.uk/secretary/dataprotection/>

Disclosure and Barring Service [/CRB:](http://www.bristol.ac.uk/hr/resourcing/additionalguidance/crb/)
<http://www.bristol.ac.uk/hr/resourcing/additionalguidance/crb/>

Anti-Corruption and Bribery Policy
<http://www.bris.ac.uk/secretary/legal/briberyact/policy>

Conflict of Interest Regulations
<http://www.bristol.ac.uk/secretary/legal/conflict.html>

Institutional policy on open access to research publications
<http://www.bristol.ac.uk/library/support/research/policy.pdf>

The University of Bristol Research Data Service offers advice, support and training in all areas of research data management and is responsible for the university's Research Data Repository
<http://data.bris.ac.uk/>

2. NHS Trusts

University Hospitals Bristol NHS Foundation Trust - Research & Development:
<http://www.uhbristol.nhs.uk/research-innovation/>

North Bristol NHS Trust Research & Development:
<http://www.nbt.nhs.uk/research>

3. National policies and guidance

EU Clinical Trials Directive/Medicines and Healthcare products Regulatory Agency (including algorithm):
<http://www.mhra.gov.uk/Howweregulate/Medicines/index.htm>

NHS Ethics and R&D Applications:
<https://www.myresearchproject.org.uk>

Governance arrangements for Research Ethics Committees (GafREC 2011):
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213753/dh_133993.pdf

Clinical trials toolkit (with a useful risk assessment tool):
[http://www.ct-toolkit.ac.uk /](http://www.ct-toolkit.ac.uk/)

MRC human tissue e-learning module
<http://www.rsclern.mrc.ac.uk/>

NHS Research Passport:
http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx

Disclosure and Barring Service
<https://www.gov.uk/government/organisations/disclosure-and-barring-service>