Research Governance Glossary v1.0

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Research Governance – Glossary of terms and abbreviations

Please note, this is intended as a summary of terminology, for quick reference. It does not constitute a policy or guideline for the conduct of research.

All items in **Bold** *are defined elsewhere in the glossary.*

ASU – Animal Services Unit	A Professional Services group overseeing facilities, services and support for University activities involving animals. Includes **AWERB**.
AWERB – Animal Welfare and Ethics Review Board	A review body who ensure compliance with the Animals (Scientific Procedures) Act and **UoB**'s commitment to the **3Rs** – through oversight of licenced activities and review of proposed research activity.
CAG – Confidentiality Advisory Group	An advisory body to the Secretary of State for Health and Social Care, who assess applications for **Section 251 Approval**.
Checklist Review	A more limited **UoB REC Review**. It is sufficient only for lower-risk studies, as determined by each committee. Most commonly for studies working only with anonymised data. Applications are submitted via **OREMS** and reviewed by the appropriate **UoB REC**'s Chairperson. A 10% sample of Checklist Reviews, reviewed by the Chairperson, are cross-checked by the full committee.
CI – Chief Investigator	In **HSC** Research: The **Investigator** with ultimate responsibility for the conduct of a **study**. In a multicentre **study** they are ultimately responsible for activity at all **Site**s – but delegate the oversight of individual **Site**s to **PI**s.
CIMD – Clinical Investigation of a Medical Device	A study which will generate data relating to the clinical safety or efficacy of a **Medical Device** where; - the device is not yet licenced; - or the device is being used in a manner not intended under its current licencing arrangement; - and/or data generate by the study will/may be used to apply for a change to the licence of the device, or to change the marketing of the device. Whether a study involving a device is a CIMD is often a complex question, **RGT** should be consulted early in the planning process. A CIMD must be approved by the **MHRA** before it can begin.
Clinical Trial Regulations – The Medicines for Human	Statutory Instrument 2004-1031 (as amended). UK legislation governing the conduct of **CTIMP**s.

Use (Clinical Trials) Regulations	Compliance is managed and monitored by the **MHRA**.
Concordat to Support Research Integrity	A mutually agreed set of principles for Researchers, Employers of Researchers and Funders of Research, intended to support and encourage the highest standards of **research integrity**. **UoB** are a signatory, as an Employer of Researchers.
Consent	See **Informed Consent**
CTIMP – Clinical Trial of an Investigational Medicinal Product	A study involving human participants, intended to assess the safety and / or efficacy or a **Medicinal Product**. This includes both novel, unlicenced medicinal products; where data generated may support the licencing of the product; and existing, licenced medicinal products – where data generated may support the extension of an existing licence (e.g. use for a different condition or patient population).
DREI – Division of Research, Enterprise and Innovation	Division of professional services incorporating (among others) **RGT**, **RCT** and **RD**.
F2	Case management system used by **RGT** and other professional services departments. Used as an e-mail client, for the storage of digital files and correspondence, and as a database and tracker for ongoing **HSC** research.
FREC – Faculty Research Ethics Committee	See **UoB REC**.
FWA – Federalwide Assurance	A prerequisite of **IRB** registration and obtained via the Department of Health and Human Services in the United States. Institutional FWAs are renewed every 5 years.
GCP – Good Clinical Practice	Principles governing the safe, ethical and effective conduct of health / social care research. There are a number of standards referred to as GCP, the two that are most commonly referred to are: 1: **ICH GCP** 2: The Principles of GCP as set out in the **Clinical Trial Regulations** Both of these standards are mandatory for **CTIMP**s, but also provide guiding principles for other types of **HSC Research.**
GCP Training	Training in the appropriate conduct of **HSC Research**. Typically centred on the Principles of **GCP**. Such training is mandatory for anyone working with participants or managing the data, records or conduct of a **CTIMP**, and recommended for anyone conducting those roles in other interventional **HSC Research**. Provided by healthcare organisations and commercial providers, online or in

	person. Those working in relevant areas should have updated **GCP Training** at least every three years.
HCRW – Health and Care Research Wales	An NHS organisation responsible for overseeing research interactions with the NHS in Wales.
HMPPS – His Majesty's Prison and Probation Service	A body required to review and approve any intended research in which participants will be identified because they are currently incarcerated or on probation in the UK. Applications are made via **IRAS**. (Not required if participants are identified in a different way, but happen to be in prison / on probation.)
HoRG – Head of Research Governance	***RGT** staff.* *Adam Taylor, adam.taylor@bristol.ac.uk* Manager of **RGT**. Member of **UERC**. Line manager to **REIM**, **RGO**s, **RHTM**s & **RGC**. Line managed by the *Director of Research Governance, Contracts and Compliance*, in **DREI**
HRA – Health Research Authority	An NHS organisation responsible for overseeing research interactions with the NHS in England, Scotland and Northern Ireland. The **HRA** act as an administrative body to other NHS bodies, including **NHS REC**s, and provide **HRA Approval**.
HRA/HCRW Approval	- Provided by the **HRA** and/or **HCRW**, as appropriate. - Required for any studies interacting with the NHS in a manner that will (or may) impact upon NHS time or resources. Including but potentially not limited to; Research taking place on NHS premises, use of NHS equipment (e.g. scanners), use of NHS services (e.g. labs), involvement of NHS staff (including for interview/questionnaire studies) where staff are identified through their role and/or they will be participating during their working hours. - Applications managed through **IRAS**.
HSC Research – Health / Social Care Research	Any study or studies requiring approval by the **HRA** and/or an **NHS REC**. Such research is governed by the **Policy Framework...** and requires a **Sponsor**.
HT Act – Human Tissue Act	Legislation introduced in 2004 governing the storage and use of material containing viable human cells, from human origin. **UoB** comply with the Act by ensuring that collections are stored under one of five Human Tissue licences (four research and one anatomy) and that individual studies involving the use of human tissue have appropriate **NHS REC** approvals.

HTA – Human Tissue Authority	A non-departmental public body of the Department of Health and Social Care who ensure national compliance with the **Human Tissue Act** by providing quality standards and guidelines and through a schedule of regular inspections.
HTWG – Human Tissue Working Group	A group including the Designated Individuals of all **UoB Human Tissue Licences**, the **RHTM**s, the Human TIssue Licence Holder and other interested parties. Responsible for the oversight of Human Tissue Licences, assurance of compliance with the HT Act and the sharing of best practice regarding the use and storage of **Relevant Material**.
Human Participant Research	A research project which involves any or all of: - Recruiting any persons to participate in the study in any manner; whether in-person or remotely, for active interventions, any form of testing or assessment, interviews, questionnaires, etc. - Use of or access to **Personal Data**. - Use or storage of **Relevant Material**.
Human Tissue Licence	1. A licence granted by the **HTA** for the use and storage of **Relevant Material** for a specified purpose. **UoB** hold 5 such licences: - Biomedical Sciences Building (Research) - Bristol Dental School and Hospital (Research) - Oakfield House (Research) - School of Anatomy (Anatomical examination) - South West Dementia Brain Bank (Research) Each licence is managed by a member of staff with appropriate knowledge, experience and access (as defined in the **HTA**) known as a Designated Individual. All licences are overseen by the **Human Tissue Licence Holder**. 2. The facilities, staff and holdings associated with a licence, as per 1. **Relevant Material** may be added to or removed from a Licence only with the express permission of the Designated Individual or their delegees.
Human Tissue Licence Holder	The individual with overall responsibility for the maintenance of **UoB**'s **Human Tissue Licences**.

	The Chief Operating Officer, Registrar & University Secretary; Lucinda Parr.
ICH GCP – International Council for Harmonisation, Good Clinical Practice	The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) seek to standardise the development and registration of medicines to allow international acceptance of research findings. Their work-products include ICH E6 Good Clinical Practice Guideline – a widely recognised standard for the practice of clinical research.
IMP – Investigational Medicinal Product	A **Medicinal Product** manufactured or procured for use in a **CTIMP**.
Independent Member	A member of a **UoB REC** or **UERC** who is not employed by **UoB**. At least one Independent Member must be present for a meeting to be quorate.
Infonetica	The framework system upon which **OREMS** is built.
Informed Consent	A key principle of ethical research. Participants must be provided with sufficient information to understand - the nature and purpose of the study - what will be asked of them, including; o treatments, interventions and investigations o attendance at appointments o completion of questionnaires or participation in discussions o access to and use of their data o the right to refuse or withdraw - who is conducting the research; o investigators o sponsor o funders - any compensation for their time, remuneration for expenses, etc. The nature and presentation of this information should be suited to the nature of the study (complexity, risk, time commitment, etc.) and must be approved as part of **REC Review**. Participants must be given appropriate time to consider and the opportunity to ask any questions or raise any concerns.

	The participant should then document that they have understood the information and wish to participate in the study. This could be physical or digital, so long as it can be retained for the duration of the study and traceable to an individual participant.
Integrity	See **Research Integrity**
Investigator	An individual who is appropriately trained, qualified and experienced (as determined for the particular study) to conduct some or all aspects of a research Protocol.
IRAS – Integrated Research Application System	Online form used to apply for **HRA**, **NHS REC**, **MHRA, CAG** and **HMPPS** approval. Initial filter questions determine which applications are required, data entered is then shared between the applications.
IRB – Institutional Review Board	A Research Ethics Committee registered with the Office for Human Research Protections (**OHRP**) within the United States Department of Health and Human Services. Human-participant studies require review by an IRB if they are funded by US national bodies (most commonly the National Institute for Health, NIH) or need to access US research datasets. The ALSPAC Law and Ethics Committee (ALEC) is a **UoB REC** *and* a registered IRB. ALEC IRB renewal is required every 3 years.
Licence Holder	The individual with ultimate responsibility for the management of the **HTA** licences, in accordance with the Act.
Medical Device	A device intended to treat, manage, mitigate, prevent or diagnose a clinical condition through physical (non pharmacological) means. Includes active implantable devices, in-vitro diagnostic devices and apps/software. Medical devices must be licenced as safe an appropriate for the used to which they are intended by the **MHRA** – in accordance with the **Medical Device Regulations**. See **CIMD** for information about to Medical Device research.
Medical Device Regulations	Statutory Instrument 2002-618 (as amended). UK legislation governing **Medical Device**s and **CIMD**s. Compliance is managed and monitored by the **MHRA**.
Medicinal Product	Any substance or combination of substances presented in a pharmaceutical form, with the intention of treating or

	preventing disease, making a medical diagnosis or for restoring, correcting or modifying physiological functions in human beings. Does not include foodstuffs or supplements.
MHRA – Medicines and Healthcare Products Regulatory Agency	The UK government body responsible for the licencing, marketing and provision of **Medicinal Products** and **Medical Devices** in the UK. Must approve **CTIMP**s and **CIMD**s before they can begin. Approvals sought through **IRAS**. Empowered to inspect **Site**s involved in the conduct of **CTIMP**s and/or **CIMD**s – to ensure compliance with relevant regulations – and to impose sanctions according to those regulations.
mNCA – Model Non-Commercial Agreement	A template agreement which can be employed between **UoB** and a **Site** – used for interventional **HSC** studies. Pre-approved by Research Contracts.
NHS REC – NHS Research Ethics Committee	Any one of the, roughly, 90 committees in the UK responsible for providing **NHS REC Review**. Committees are named for their geographic region but applications are assigned on the basis of availability, to any committee nationwide. Applications are made via the **IRAS** system. NHS RECs are administrated on behalf of the NHS by the **HRA**.
NHS REC Review	- Provided by an assigned **NHS REC** - Required for all studies involving; NHS patients (individuals identified and/or recruited via their clinical interaction with any NHS service), NHS service users (individuals identified and/or recruited via their non-clinical interaction with any NHS service), NHS Patient data, Relevant Material as defined in the **HTA** (UoB policy), and individuals identified and/or recruited via their interaction with social-care services – in most case (speak to Research Governance for confirmation). - Applications managed through **IRAS**.
OHRP – Office for Human Research Protections	A United States (U.S.) governmental organisation responsible for the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP is part of the Office of the Assistant Secretary for Health in the Office of the Secretary of Health in Human Services.

	Responsible for registering **IRB**s.
OID – Organisation Information Document	A template agreement which can be employed between **UoB** and a **Site** – used for non-interventional / limited intervention **HSC** studies. Pre-approved by Research Contracts.
OREMS – Online Research Ethics Management System	**UoB** system, accessible by all staff and students, used to apply for UoB REC Review.
Personal Data	Data relating to any individual which does or could allow for the identification of that individual. Defined in applicable data protection regulations.
PI – Principal Investigator	**HSC** Research: In multicentre studies, an **Investigator** with responsibility for the conduct of a **study** at a specific site. They report to the **CI.** (Note. A **CI** may also be PI at their own site, or may delegate this to another **investigator**.) Other Research: The investigator(s) with ultimate responsibility for the conduct of a **study**. Usually the principal applicant(s) on a grant.
PIC – Participant Identification Centre	A healthcare providing organisation who will, on the instruction of a study team, search their records for potentially eligible participants and either refer them to the research team or provide their contact details. Not a **Site**.
PIC Agreement	A template agreement which can be employed between **UoB** and a **PIC**. Pre-approved by Research Contracts.
Policy Framework	See **UK Policy Framework to Support Health and Social Care Research**
Protocol	A document detailing the hypothesis, method and intended conduct of a study. Required for ethical review.
PVC-R – Pro-Vice-Chancellor for Research	A senior **UoB** academic with responsibility for the oversight of research conduct – chair of **URC**.
REA – Research Ethics Administrator	***RGT** staff.* *Aisling Marray - Aisling.Marray@bristol.ac.uk* *Marc Moyce - marc.moyce@bristol.ac.uk* Responsible for the administration of **OREMS**, administrative support to **FREC**s and correspondence relating to **UoB REC**s. Line managed by **REIM**.
RCT – Research Contracts Team	Professional Services department, in **DREI**. Responsible for negotiating contracts and other agreements for research undertaken by the University's academic staff.

RD – Research Development	Professional Services department, in **DREI**. Responsible for providing expert support to academic members of staff who are seeking external funding for their research and acting as a contact point for funding agencies and partners.
REC – Research Ethics Committee	See **NHS REC** and **UoB REC**.
REC Review	Review by an appropriate **Research Ethics Committee** of the proposed processes, participants and documentation for a research project. For all **Human Participant Research** this must be completed prior to any study activity.
Relevant Material	Material derived from a human being, who is living or who died less than 100 years ago, which contains – or potentially contains – one or more viable human cell(s). Such material is defined by and subject to the **HT Act.**
Registered	Term used by Research Governance to refer to studies which are; (a) **HSC** studies Sponsored by another organisation for which UoB will act as a **Site**, or (b) studies which do not require a **Sponsor,** according to our definition, but a partner requires that we agree to act in that capacity, or (c) studies which do not require a **Sponsor,** according to our definition, but they involve a particular risk, which requires additional tracking.
REIM – Research Ethics and Integrity Manager	***RGT** staff.* *Liam McKervey, liam.mckervey@bristol.ac.uk* Responsible to the administrative oversight of **UoB REC**s, management of **OREMS**, and our **Research Integrity** activities. **Member of UERC**. Line manager to **RIO** & **RGA**s. Line managed by **HoRG**.
Research Culture	Broadly defined principles imposed by funders relating to University policies and structures that may impact on research. Including, but not limited to: - reproducibility - responsible innovation - collaboration, interdisciplinarity and multidisciplinarity - transparency and openness - public involvement - equality and diversity - career paths, and training environments, which reward a variety of engagement with research, not just publication

Research Culture Committee	Committee tasked with overseeing **UoB's** engagement with the **research culture** agenda. Chaired by the Associate Pro Vice-Chancellor for Research Culture.
Research Integrity	Processes that support the 5 Principles, set out in the **Concordat to Support Research Integrity**; 1. upholding the highest standards of rigour and integrity in all aspects of research 2. ensuring that research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards 3. supporting a research environment that is underpinned by a culture of integrity and based on good governance, best practice, and support for the development of researchers 4. using transparent, timely, robust and fair processes to deal with allegations of research misconduct should they arise 5. working together to strengthen the integrity of research and to review progress regularly and openly Primarily overseen by the **REIM** and **RIO** roles in **RGT**, this includes in practice; - authorship guidance and disputes - preventing harm in research - reporting integrity breaches to funders - reputational risk relating to research funders - research misconduct
Research Project	A defined series of activities, gathering and analysing data, in order to test a hypothesis. Synonymous with **Study**. *Not* synonymous with a research grant, fellowship or other unit of funding – which may involve multiple Research Projects.
RGC – Research Governance Coordinator	***RGT** staff.* *Christine Bennett, chris.bennett@bristol.ac.uk* Responsible for administrative tasks relating to **HSC** research, **F2** and the research-governance@bristol.ac.uk shared inbox.

	Line managed by **HoRG**.
RGO – Research Governance Officer	***RGT** staff.* *Anna Brooke, anna.brooke@bristol.ac.uk* *Kat Dolan, kat.dolan@bristol.ac.uk* Responsible for facilitating and reviewing the required ethical and regulatory applications for **HSC Studies**, tracking the progress . Line managed by **HoRG**.
RGT – Research Governance Team	Professional Services department, in **DREI**. Responsible for; - Advising staff and students on how to set up and conduct research projects that involve human participants, their tissue and/or data - Providing oversight and administrative support to **UoB RECs**. - Facilitating and reviewing applications required for the conduct of HSC research - Acting as **Sponsor** for studies governed by the **Policy Framework**, where the **CI** is a **UoB** staff member or student. - Producing guidance and managing processes which contribute to **UoB**'s adherence to the **Concordat to Support Research Integrity**.
RHTM – Research and Human Tissue Manager	***RGT** staff.* *Rachel Davies, rachel.davies@bristol.ac.uk* *Alia Ataya, alia.ataya@bristol.ac.uk* Responsible for the oversight of **Studies** involving **Relevant Material** being collected, stored and analysed on the basis of an **NHS REC Review**, rather than held on a **Human Tissue Licence.** Administrators to the **HTWG**. Responsible for the oversight of **UoB Sponsored Clinical Trials** (Rachel Davies) and **UoB Sponsored CIMDs** (Alia Ataya). Line Manager to **RQO** (Rachel Davies) Line Managed by **HoRG**
RIO – Research Integrity Officer	***RGT** staff.* *Nathan Street, nathan.street@bristol.ac.uk* Responsible for practical activities in support of **Research Integrity**. Line managed by **REIM**.
RQO – Research Quality Officer	***RGT** staff.* *Matt Hewson, matt.hewson@bristol.ac.uk*

	Responsible for the recording and upkeep of **RGT** processes, particularly Standard Operating Procedures. Line managed by **RHTM**.
SCREC – NHS Social Care REC	One of the three **NHS REC**s 'flagged' for the review of research in **social care settings**. A study would be assigned to a SCREC based on information provided in its **IRAS** application.
Section 251 Approval	Section 251 of the NHS Act describes specific circumstances in which identifiable healthcare data can be accessed for research purposes – and the process for applying for approval. It requires that an application be made to the **CAG** via **IRAS**.
Site	An organisation at which research activity will be conducted and / or whose staff will conduct research activity. Not a **PIC**.
Social Care Research	Research on the subject of social care.
Social Care Setting	Locations or organisations providing social care services. Including residential care homes – whether NHS, private or other. **HSC Research** in a social care setting will require input from RGT and may involve more or different processes and complexities than other types of **HSC Research**.
Sponsor / Sponsored / Sponsorship	All research projects falling within the scope of the UK **Policy Framework** for Health and Social Care Research, (typically those requiring approval from an NHS REC and/or the HRA) must have a designated Sponsor organisation – with responsibilities defined in the Framework. Where UoB is the Sponsor for a study, Research Governance will speak as Sponsor to all matters relating to ethics and governance.
SREC – School Research Ethics Committee	See **UoB REC**.
Study	A defined series of activities, gathering and analysing data, in order to test a hypothesis. Synonymous with **Research project**.

	Not synonymous with a research grant, fellowship or other unit of funding – which may involve multiple Studies.
UERC – University Ethics of Research Committee	Committee responsible for managing **UoB REC**s and providing guidance and oversight to contribute to research being conducted to the highest standards of ethics and integrity.
UK Policy Framework to Support Health and Social Care Research	Quality standard which must be adhered to by all parties involved in the conduct and management of **HSC Research**.
UoB – University of Bristol	Our august institution.
UoB REC – UoB Research Ethics Committee	A University of Bristol School or Faculty Research Ethics Committee (**SREC/FREC**). Committees are composed of members appointed by their School / Faculty; a chair, typically from a different School / Faculty; and one or more **Independent Member**(s). Committees meet on a regular schedule and provide **UoB REC Review**.
UoB REC Review	Required for any research project which involves directly recruiting human participants or the use of human participant data. Provided by a **UoB REC** and applied for via **OREMS**. A **Checklist Review** is appropriate for lower-risk studies, as determined by each committee – most commonly for studies working only with anonymised data.
URC – University Research Committee	Faculty and Professional Services committee with a remit of overseeing research activity at **UoB**.
Worktribe	System used by **UoB** to track costings, applications and expenditure of research funding.
3Rs	Principles intended to support more humane research involving animals. 1. Replacement – Avoiding or replacing the use of animals in areas where they otherwise would have been used. 2. Reduction – Minimising the number of animals used consistent with scientific aims. 3. Refinement – Minimising the pain, suffering, distress or lasting harm that research animals might experience.