Policy:

UoB Principles of GCP for Clinical Research

# Purpose

This policy describes the set of University of Birmingham (UoB) principles of Good Clinical Practice (GCP) for the designing, conducting, recording and reporting of research that involves human participants. Compliance with the 23 principles of GCP (listed below) provides assurance that the rights, safety and well-being of research participants are protected and respected, and ensures the integrity of the research data.

# Scope

This policy applies to all clinical research sponsored by the UoB. This policy also applies to clinical research projects approved by a UoB research ethics committee (REC) that are instructed to follow these principles of GCP. Where clinical research is (co-) sponsored by another institution, this policy should be followed as far as possible, and in line with the contractual agreement between the UoB and the other institution.

# Implementation plan

This policy will be implemented in line with this document’s effective date.

# Stakeholders

* UoB staff members and others working with the UoB clinical research quality management system (QMS).

# UoB Principles of GCP for Clinical Research

## Principle 1: Safety

The safety and well-being of the individual prevail over the interests of science and society.

## Principle 2: Competence

All the people involved in managing and conducting a research project are qualified by education, training and experience, or otherwise competent under the supervision of a suitably qualified person, to perform their tasks.

## Principle 3: Scientific and Ethical Conduct

Research projects are scientifically sound and guided by ethical principles in all their aspects.

## Principle 4: Integrity, Quality and Transparency

Research is designed, reviewed, managed and undertaken in a way that ensures integrity, quality and transparency.

## Principle 5: Interventional Product Information

The available non-clinical and clinical information on an interventional product shall be adequate to support the proposed research project.

## Principle 6: Protocol

The design and procedures of the research are clearly described and justified in a research protocol, where applicable conforming to a standard template and/or specified contents.

## Principle 7: Legality

The researchers and sponsor familiarise themselves with relevant legislation and guidance in respect of managing and conducting the research.

## Principle 8: Respect for Privacy

All information collected for, or as part of, the research project is recorded, handled and stored appropriately and in such a way and for such time that it can be accurately reported, interpreted and verified, while the confidentiality of individual research participants remains appropriately protected. Data and tissue collections are managed in a transparent way that demonstrates commitment to their appropriate use for research and appropriate protection of privacy.

## Principle 9: Benefits and Risks

Before the research project is started, any anticipated benefit for the individual participant and other present and future recipients of the health or social care in question is weighed against the foreseeable risks and inconveniences once they have been mitigated.

## Principle 10: Medical Care

The medical care given to, and medical decisions made on behalf of, participants should always be the responsibility of an authorised health professional (i.e. doctor, dentist, nurse or pharmacist).

## Principle 11: Approval

A research project is started only if a REC and any other relevant approval body have favourably reviewed the research proposal or protocol and related information, where their review is expected or required.

## Principle 12: Participant Rights

The rights of the participants’ physical and mental integrity are safeguarded.

## Principle 13: Insurance and Indemnity

Adequate provision is made for insurance or indemnity to cover liabilities that may arise in relation to the design, management and conduct of the research project.

## Principle 14: Choice

Research participants are afforded respect and autonomy, taking account of their capacity to understand. Where there is a difference between the research and the standard practice that they might otherwise experience, research participants are given information to understand the distinction and make a choice, unless a research ethics committee agrees otherwise. Where participants’ explicit consent is sought, it is voluntary and informed. Where consent is refused or withdrawn, this is done without reprisal.

## Principle 15: Interventional Products Management

Interventional products should be manufactured, handled, and stored in accordance with applicable regulations, where appropriate. They should be used in accordance with the approved protocol.

## Principle 16: Patient, Service User and Public Involvement

Patients, service users and the public are involved in the design, management, conduct and dissemination of research, unless otherwise justified.

## Principle 17: Information about the Research

For all clinical research projects approved by the Health Research Authority (HRA): in order to avoid waste, information about research projects (other than those for educational purposes) is made publicly available before they start (unless a deferral is agreed by or on behalf of the research ethics committee).

## Principle 18: Compliance

Sanctions for non-compliance with these principles may include appropriate and proportionate administrative, contractual or legal measures by funders, employers, relevant professional and statutory regulators, and other bodies.

## Principle 19: Justified Intervention

The intended deviation from normal treatment, care or other services is adequately supported by the available information (including evidence from previous research), where appropriate

## Principle 20: Ongoing Provision of Treatment

The research protocol and the participant information sheet will explain the special arrangements, if any, after the research intervention period has ended (e.g. continuing or changing the treatment, care or other services that were introduced for the purposes of the research), where appropriate.

## Principle 21: Integrity of the Care Record

All information about treatment, care or other services provided as part of the research project and their outcomes is recorded, handled and stored appropriately and in such a way and for such time that it can be understood, where relevant, by others involved in the participants’ care and accurately reported, interpreted and verified, while the confidentiality of participants’ records remains protected, where appropriate.

## Principle 22: Duty of Care

The duty of care owed by health and social care providers continues to apply when their patients and service users take part in research. A relevant health or social care professional retains responsibility for the treatment, care or other services given to patients and service users as research participants and for decisions about their treatment, care or other services. If an unmanageable conflict arises between research and patient interests, the duty to the participant as a patient prevails, where appropriate.

## Principle 23: Accessible Findings

Other than research for educational purposes and early phase trials, the findings, whether positive or negative, are made accessible, with adequate consent and privacy safeguards, in a timely manner after they have finished, in compliance with any applicable regulatory standards, i.e. legal requirements or regulators’ expectations. In addition, where appropriate, information about the research’s findings is available, in a suitable format and timely manner, to those who took part in it, unless otherwise justified.

# Related documents

* UoB-CQM-POL-001 Clinical Research Quality Manual

Note the UoB QMS documents can be found on the [Clinical Research Compliance Team (CRCT) website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx). Internal work instructions can be obtained from the CRCT (crct@contacts.bham.ac.uk) and/or from the Research Governance Team (RGT: researchgovernance@contacts.bham.ac.uk).

# References and frameworks

* UoB Code of Practice for Research: <http://www.birmingham.ac.uk/Documents/university/legal/research.pdf>

# Abbreviations and definitions

| Term | Description |
| --- | --- |
| Authorised health professional | An authorised health professional is defined as a doctor, dentist, nurse or pharmacist.  |
| Clinical research  | Any health-related research on humans. |
| Clinical study  | Any health-related research study on humans. This includes a study:* administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
* involving qualitative methods only
* limited to working with human tissue samples (or other human biological samples) and data (specific project only)
* limited to working with data (specific project only).
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| Clinical trial | For clinical trials using an investigational medicinal productAny investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy.For all other clinical trialsProspective biomedical research on human subjects that is conducted to allow safety (or more specifically, information about adverse drug reactions and adverse effects of other treatments) and efficacy data to be collected for health interventions. Examples include devices, surgery and radiotherapy trials. |
| CRCT | Clinical Research Compliance Team |
| Good Clinical Practice (GCP) | A standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of the trial subjects are protected. |
| QMS | Quality management system |
| REC | Research ethics committee |
| RGT | Research Governance Team |
| UoB | University of Birmingham |

See also the [Glossary of Terms](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/Glossary-of-Terms.aspx).