

University of Glasgow Clinical Laboratory Definitions and Categorisations

Background

University of Glasgow staff and students must be aware of the laboratory standards required to ensure compliance with current UK legislation governing clinical research. These include ensuring clinical data is stored securely and that all relevant ethical and regulatory conditions are met and adhered to.

Scope

This policy document sets out the extent to which University of Glasgow laboratories can be involved in clinical research, including studies involving clinical material and human tissue. The policy relates to all clinical laboratory research conducted by University staff or students. As such, this policy is relevant to both commercially sponsored and academically led research.

Laboratory Categories

Outlined below are types of clinical research laboratories located within the University. Each is given a category and the type of research permitted to be performed in each category is defined.

Category A Laboratories: may perform research that can impact on clinical care. For example, where the tests performed are part of the clinical protocol and may be used to regulate dose of drug or type of intervention, or be used to inform inclusion/exclusion in a study. This also includes results from any research that will be retained in participant medical notes or communicated to a medical professional.

Standards required: Only laboratories with demonstrable quality management systems in place that are compliant with the principles of Good Clinical Practice are permitted to conduct research that will impact clinical care. In general, these laboratories will be University laboratories located within an NHS facility and involved in clinical diagnostics.

Checks to be undertaken: The University will require evidence of up to date relevant accreditation or documentation confirming GCP compliance. Evidence may include an up to date accreditation certification or documentary evidence of GCP compliance from an appropriate external audit of the laboratory facilities and infrastructure.

Category B Laboratories: may perform research where the results of the research will not impact individual patient care but will be reported or published as part of a clinical study as defined in the original study protocol. For example, where the analysis does not impact on the treatment of the recruit but is important for informing the study outcome and is described in the clinical trial protocol.



This includes research where failure to adhere to high quality standards will jeopardise the integrity of the study, has ethical implications for the study, or has reputational implications for the University or its clinical partners in the NHS.

Standards required: These laboratories will have auditable operating procedures and quality systems in place.

Checks to be undertaken: The University will require Category B laboratories to conduct routine internal audits of the quality systems in place.

Category C Laboratories: may perform research where it has no impact on clinical care or clinical interpretation of the study data for basic or laboratory based translational studies and is not included as a specific test in a clinical protocol. These may be post-hoc analyses or proof of concept translational studies.

Standards required: Any appropriately equipped laboratory may perform this type of research. These laboratories should, however, be able to demonstrate basic levels of good laboratory practice and quality control.

Checks to be undertaken: Laboratories of this standard will not be routinely audited but may be on request from the laboratory leader.

Any laboratory involved in the collection, storage or analysis of clinical material derived from a Clinical Trial of an Investigational Medicinal Product (CTIMP) must gain approval from the University Governance Office before analysis or storage of material can begin. Documentary evidence of accreditation or GCP compliance will be required for all laboratories involved in CTIMP related activity.

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