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. In light of the fact that commercial sponsors retain responsibility for the laboratory testing involved in their research and will routinely audit and inspect subcontractors to ensure their own quality standards are maintained, this policy focuses on non-commercially funded or sponsored 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. Laboratories are not categorised based on the study types they participate in but are classified according to the likely impact on patient care and safety that their involvement in the research may have.

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 patient medical notes.

Standards required: Only appropriately accredited labs (e.g. CPA / UKAS) laboratories are permitted to perform this type of research. 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 accreditation in order to allow Category A Laboratories to be involved in research at this level. Laboratories of this standard may be subject to routine internal audit by the NHS.

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 NHS GG&C.

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

Checks to be undertaken: The University will require Category B laboratories to have been assessed using the NHS GG&C Vendor Assessment Form or similar checks from other Health Board or commercial equivalents when necessary.

Once a laboratory has been classed as Category B it will be registered on a central database held by the University. Status will be reviewed on a two yearly basis, unless the nature or number of the studies the laboratory conducts changes significantly. Laboratories of this standard may be subject to external audit by commercial companies, funding agencies, or charitable organisations and may for purpose, or request by the laboratory leader, be subject to audit by University or NHS Governance.

**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.

**The point of contact for all University of Glasgow Clinical Laboratory enquiries is:**

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