Loughborough University **The Centre for Biological Engineering**	**Management & Control of Materials**			
Document Ref: RM-POL-006	Version Nº:	1.0	Issue Date:	January 2016

Policy

The Centre for Biological Engineering (CBE) shall establish and maintain a system to control and manage the flow of materials into and out of the organization, including materials acquisition, inventory control and storage, materials movement, and waste management. Under this system, the CBE shall establish written procedures, and where necessary quality records, to govern the acquisition, identification, storage, use, transport and disposal applied to the following materials, or a combination thereof, for research use:

- Biological material of human origin (cellular and acellular), which may include purchased or supplied human tissues, cells, cell lines, body fluids or excreta for research use.
- Biological material of animal origin (cellular and acellular), which may include, purchased or supplied tissues, cells, cell lines, body fluids or excreta for research use.
- Biologically-derived material or, material which, either by accident or design, contains biological agents, including bacteria, viruses, micro-organisms, genetically modified organisms / micro-organisms (GMOs, GMMs), or any other biological agents which might pose a risk to health and safety or the environment.
- Material that is or may contain a hazardous chemical substance(s).

Acquisition of Materials for Research Use

The CBE has established and shall maintain procedures to manage and control the sourcing and procurement of all purchased and supplied hazardous or potentially hazardous material for research use. These procedures shall ensure that the purchase, acquisition and transfer of all materials for research use, from external academic institutions, industry partners or commercial organisations is governed by the following principles:

- Each individual CBE researcher has the responsibility to ensure that material for research use is acquired and transferred from organisations that meet applicable safety and/or quality requirements for the material and its transfer;
- All sourced material shall be adequately defined according to its intended use before it can be purchased, acquired or otherwise transferred to the CBE;
- Before the material can be acquired, purchased or otherwise transferred to the CBE, a written risk assessment, approved by the relevant authority (designated individuals responsible for safety and quality compliance within the CBE and the University, as defined in QS-POL-003), shall ensure, as a minimum:
    - that material is correctly identified and classified,
    - that appropriate compliance procedures and training are in place,

- that appropriate control measures for transport, storage, use and disposal of incoming material are in place,
- that relevant notifications have been made to the Competent Authority, as applicable *(eg under the COSHH Regulation 2002; under the Genetically Modified Organisms (Contained Use) Regulations 2000, as amended 2005)*
- that relevant licensing requirements or conditions of ethical approval have been met *(eg under DEFRA; under Schedule 5 of the Anti-terrorism, Crime and Security Act 2001; under the Human Tissue Act (2004), under NHS REC governance or under UK governance framework for stem cell research)*

Receipt of Incoming Materials

The CBE has established and shall maintain procedures to ensure that:

- Incoming biological material is physically quarantined or segregated until conformance to specified safety and/or quality requirements or acceptance criteria is checked and verified by the relevant authority and the material released for storage or use.
- Non-conforming biological material or material with incomplete test results is prevented from unintended use and its disposition evaluated and documented to determine and record the appropriate process for its use, transfer or disposal to minimize the hazards to personnel, the environment and other material being processed or stored.

Storage of Materials

The CBE has established and shall maintain documented procedures to ensure that:

- Appropriate methods are applied to the preservation, and recovery (freeze/thaw) of all biological materials to prevent damage, loss or contamination;
- All materials are stored under the appropriate conditions in designated and appropriately labelled areas within the CBE to permit controlled access and segregation, and ensure that the integrity and security of the material is not compromised;
- Storage conditions for all critical materials are monitored and data recorded or reviewed periodically to ensure the required environmental conditions are maintained during storage. Where appropriate this shall include alarm systems to alert personnel before critical conditions are breached;
- Facility and storage areas are maintained and contingency arrangements are in place to manage facility utility breakdowns and/or failure of the storage areas for critical material.

- Material stored under applicable licences is identified and that a secure records system is in place to ensure the traceability of material during storage and movement of material from receipt to end use, disposal or transfer.

Transport of Materials

The CBE has established and shall maintain procedures to ensure that:

- The release and transfer of any stored material from the CBE to another organisation is carried out and documented in accordance with applicable transport legislation and licensing or conditions of ethical approval or consent;
- All persons undertaking any role in the transport chain are properly trained;
- All appropriate licenses are obtained for movement of certain types of biological material into and out of the UK, including but not limited to; importing and exporting human pathogens; importing and exporting animal pathogens; importing and exporting GMOs; importing and exporting biological material sourced from humans; importing and exporting biological material sourced from animals; material covered by the anti-terrorism legislation;
- All materials classified as dangerous goods for the purposes of transport by road (ADR), rail (RID) and air (ICAO-IATA), under both national and international legislation, are packaged, labelled, documented and transported in such a way that maintains safety, minimizes the likelihood of theft, damage or loss and protects the quality and integrity of the material for its intended use after transport and delivery to its destination;
- Adverse events, reactions, and/or incidents occurring during transport of any material are investigated and documented;

Waste Disposal

The CBE has established and shall maintain a system that will govern the safe disposal of all hazardous chemical or biological waste generated by CBE staff, as defined by the COSHH Regulations, the GMO Regulations and the "Healthcare Waste Technical Memorandum (HTM07-01): Safe Management of Healthcare Waste", produced by the Department of Health.

Under this system, the CBE has established and shall maintain documented procedures to ensure that:

- All such waste is stored, treated and disposed of in a manner that complies with requirements of UK hazardous waste legislation and applicable licences or conditions of ethical approval or consent;

- The identification, segregation and security of storage of such waste is adequate for the prevention of exposure of staff, the public and the environment to hazardous or potentially hazardous substances in the waste;
- Precautions are taken to avoid confusion and mix ups within and outside the boundaries of the CBE premises;
- Adequate instruction, equipment, training and supervision is provided to enable all workers to observe their duty of care in the disposal of such waste;

Risk Assessments

The CBE has established and shall maintain a documented risk assessment process to:

- Ensure that the organisation's facility, practices and processes are compliant with the relevant statutory requirements and accepted guidance;
- Determine and record the risk of damage to material integrity where applicable, and to human health and/or harm to the natural environment arising from exposure to identified physical, chemical and/or biological hazards during proposed work activities within the CBE;
- Determine and record the level of containment and the control measures required to undertake proposed work involving the acquisition, storage, use and disposal of hazardous or potentially hazardous material;
- Determine and record the classification of sourced material to ensure that all relevant registrations/notifications required for the work are made, that all relevant licenses or ethical approvals are in place and that all applicable procedures, documentation and records have been established;
- Ensure that the person who carries out the risk assessment is competent to do so, and that all persons undertaking a work activity are aware of the content of the risk assessment and the risks associated with the work;
- Ensure that the risk assessment procedure is approved by the relevant authority (designated individuals responsible for safety and quality compliance within the CBE and the University, as defined in QS-POL-003) before the material can be acquired, purchased or otherwise transferred to the CBE and before any proposed work can commence;
- Ensure that risk assessments are recorded using the appropriate forms and are reviewed on a frequency determined by the risk to ensure that each is still relevant for the work activity concerned or where there is reason to suspect that the original assessment is no longer valid or where there has been a significant change in the activity to which the assessment relates;

Loughborough University The Centre for Biological Engineering	Management & Control of Materials			
Document Ref: RM-POL-006	Version No:	1.0	Issue Date:	January 2016

- Ensure that all risk assessments with supporting documentation are held in the central quality area within the CBE and accessible to all CBE staff.

Version History

Version Reviewed	Date Revised/ Reviewed	DCN No	Revision Summary	New Version Number
1.0	4th December 2017 by C.Kavanagh	N/A No Changes made	No Amendments Minor editorials only including addition of revision dates.	1.0 No new version required.
1.0	2nd December 2019 by C.Kavanagh	N/A No Changes made	No Amendments Minor editorials only including addition of revision dates.	1.0 No new version required.
1.0	6th December 2021 by C.Kavanagh	N/A No Changes made	No Amendments Minor editorials only including addition of revision dates.	1.0 No new version required.
1.0	4th December 2023 by C.Kavanagh	N/A No changes made	No amendments. New revision date only	1.0 No new version required.

Loughborough University **The Centre for Biological Engineering**	**Management & Control of Materials**			
Document Ref: RM-POL-006	Version Nº:	1.0	Issue Date:	January 2016

Document Control

The Master Copy of all Controlled Documents is filed by the Departmental Quality Manager. The latest version is maintained on the CBE network. This document is not a controlled copy once printed from the network.

Security Statement

This document is the intellectual property of the CBE within the University of Loughborough and as such, must not be circulated outside of the University without the written approval from the Departmental Quality Manager and the author.