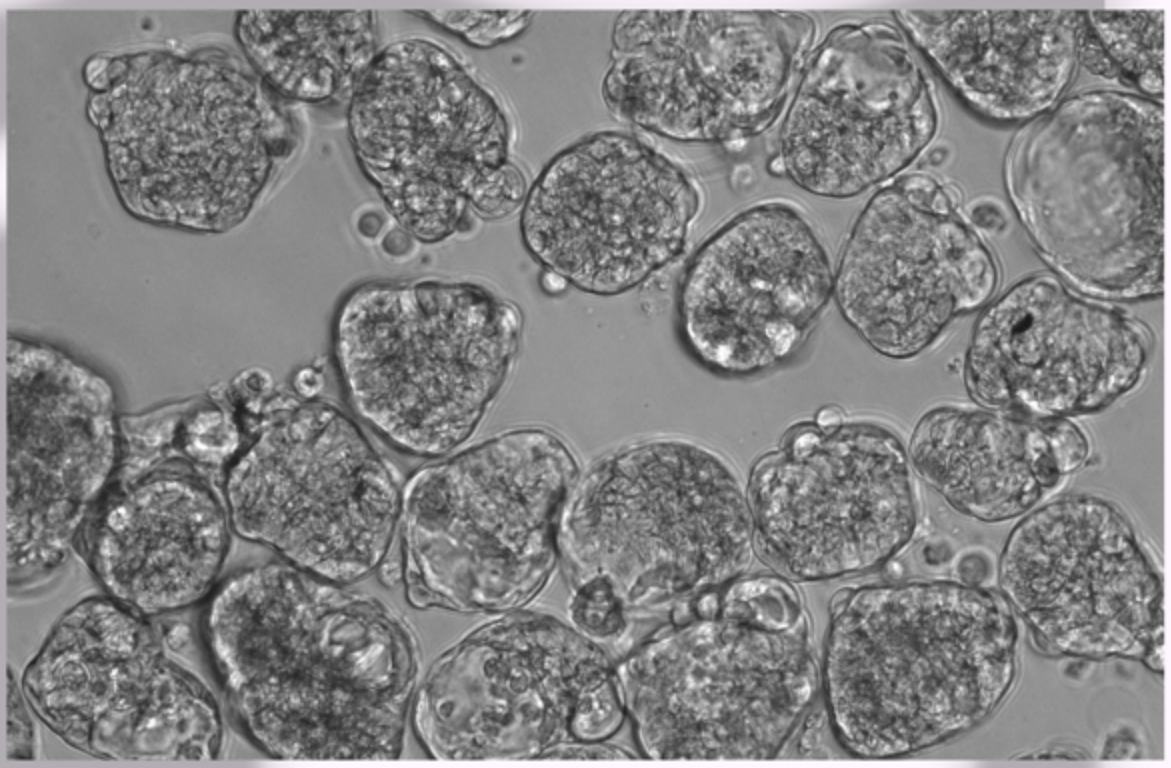

BEST PRACTICES FOR SAFE PRIMARY CULTURE HANDLING

COMPREHENSIVE BIOSAFETY AND SECURITY GUIDELINES

iGEM BIELEFELD

PreCyse

Best Practices for Safe Primary Culture Handling: Comprehensive Biosafety and Security Guidelines

1 Introduction

1.1 Purpose of the guideline

This guideline has been developed to provide clear and comprehensive guidance on the safe, ethical and legal handling of primary cultures. It is intended for all those who work directly or indirectly with primary cultures and aims to ensure that all processes are carried out in accordance with the highest scientific, ethical and safety standards. The guideline covers the entire value chain - from cell procurement, cultivation and use to waste disposal. It aims to protect the health and safety of laboratory staff, the rights and privacy of donors, and the integrity of scientific research. It also serves as a reference document for the training of new staff and for the regular review of existing procedures.

1.2 Area of application

This guide is intended to support all iGEM teams using primary cultures. It applies to all steps in the handling of primary cultures, from tissue collection to archiving and cell destruction. It also covers work with genetically modified primary cultures, if this needs to be done under special safety and regulatory requirements. Other areas of application include handling, storage, data processing and storage, and ensuring compliance with ethical standards. All employees and stakeholders are required to comply fully with this policy and to keep up to date with relevant best practice and regulatory requirements. It is important to note that this policy is not a document that can be immediately applied by every team. It is for guidance only. Different rules apply in different countries, so we encourage all iGEM teams to be aware of the rules and laws in their country!

2 Definitions

2.1 Primary cultures

Primary cultures are cell cultures that are isolated directly from the tissue of an organism and then grown in vitro. These cells represent the original tissue in many respects and retain essential physiological properties that are important for scientific investigation. They differ from cell lines in that they have a limited lifespan and cannot be replicated indefinitely, making their use in research particularly valuable but also challenging. Primary cultures are often used in basic research, drug testing and toxicity assessment because they reflect the behaviour of cells in a more natural state than cell lines. Due to their sensitive nature and the need for specific culture conditions, the handling of primary cultures requires a high level of expertise and care.

2.2 Biological waste

Biological waste is defined as any material that is potentially infectious or otherwise biologically active and that is generated when working with primary cultures. This includes used cell cultures, contaminated laboratory equipment, protective clothing, pipette tips and other consumables. Biological waste poses a significant health risk and must be disposed of in accordance with legal requirements for biological safety standards. This includes sterilisation by autoclaving and proper labelling and storage of waste containers. Disposal procedures must be regularly reviewed and documented to ensure compliance with safety guidelines and to minimise potential environmental impacts.

2.3 Informed consent

Informed consent is a crucial process in the ethical practice of cell collection in which the donor is fully informed about the nature, purpose and potential risks of cell collection. This consent must be given voluntarily and on the basis of full information, without any pressure being placed on the donor. The process includes a written statement, signed by both the donor and the responsible researcher, to document the agreement to use the cells for research purposes. The consent form must be written in a language that the donor fully understands and should include information about the future handling of the cells, any genetic analysis and long-term storage. In addition, the donor must be informed of the right to withdraw consent at any time without giving reasons.

3 Security protocols

3.1 Biological safety & handling of potentially infectious material

The handling of primary cultures carries a risk of exposure to potentially infectious material and therefore strict biological safety measures are required. All work with primary cultures must be carried out in Class II or higher Biological Safety Cabinets to minimise the risk of contamination. These benches are equipped with special filters and airflow systems that prevent the escape of aerosols and particles. In addition, the wearing of personal protective equipment (PPE) such as gloves, lab coats and goggles is mandatory to protect staff from possible infection. All surfaces and equipment must be thoroughly disinfected before starting and after finishing work, using certified disinfectants that are effective against pathogens that may be present in the primary cultures. In the event of a spill or accidental contamination, the affected areas must be immediately decontaminated and a report must be immediately prepared and submitted to the Safety Officer.

3.2 Protective measures for laboratory personnel

The welfare and safety of laboratory staff is of paramount importance. It is essential that all staff are regularly trained in the specific safety protocols for working with primary cultures. This training should take place at least annually and should take into account new scientific knowledge and changes in regulatory requirements. Each employee

must understand the risks and safety measures involved in handling potentially hazardous materials and be able to respond appropriately in the event of an emergency. In addition to general safety measures, specific health surveillance programmes should be established to identify and treat potential exposures at an early stage. This includes regular medical examinations and vaccinations against common pathogens that may be present in the laboratory environment. Any incident or potential exposure must be documented and investigated to minimise future risks and to continually improve the safety protocol.

3.3 Disposal of biological waste

The disposal of biological waste requires special care to prevent any risk to the environment and human health. All biological waste generated when working with primary cultures must be collected in puncture-resistant and leak-proof containers clearly labelled 'biohazard'. These containers shall only be stored in specially designated secure areas to prevent access by unauthorised persons. Prior to final disposal, the waste must be decontaminated by autoclaving or other approved sterilisation procedures to eliminate any potential risk of infection. Disposal must be in accordance with local and national regulations for the disposal of biohazardous materials. All disposal procedures must be documented in a logbook that is periodically reviewed and checked for compliance with applicable regulations. In addition, employees should be regularly informed and trained on the latest best practices for waste disposal to ensure that the highest standards are maintained.

4 Ethical guidelines

4.1 Collection of primary cells

The collection of primary cells from human or animal tissues must be carried out in strict compliance with ethical principles. The donor's full and informed consent must be obtained before tissue samples are taken. The donor must be informed about the purpose of the research, the intended use of the cells, possible risks and the protection of their privacy. This information must be provided in an understandable and non-technical language to ensure that the donor fully understands the implications of his or her consent. The tissue collection itself must be carried out under minimally invasive conditions to maximise the donor's well-being. In addition, it must be documented that the donor has the right to withdraw consent at any time without negative consequences.

4.2 Protection of privacy and confidentiality

Protecting the privacy and confidentiality of donor information is essential when working with primary cultures. All personal data must be anonymised before use in research to ensure that the donor's identity cannot be traced. Anonymisation should be achieved by removing all directly identifiable information and using codes or pseudonyms that do not allow the donor to be identified. Access to identifiable data should be strictly limited to authorised personnel bound by specific confidentiality agreements. Data must be stored in secure systems protected from unauthorised

access by technical and organisational measures. These measures include encryption of sensitive information, access controls and regular security audits. Any breach of confidentiality or security of data must be promptly reported, investigated and remedied in order to maintain the integrity of the research project and the confidence of donors.

5 Regulatory framework conditions

5.1 Legal regulations and guidelines

Working with primary cultures is subject to a wide range of regulatory requirements that govern the handling of biological material, the protection of personal data and compliance with ethical standards. Relevant legal frameworks include national biosafety laws, data protection laws such as the General Data Protection Regulation (GDPR) in the EU, and specific regulations for the use of human or animal tissue samples. Any organisation working with primary cultures must be aware of and comply with all applicable laws and regulations. This includes registering research projects with the relevant authorities, obtaining licences to handle certain biological materials and undergoing regular inspections by regulatory authorities. Failure to comply with these legal requirements can have serious legal consequences, including fines, revocation of licences and criminal prosecution. To ensure compliance, all relevant documents and protocols should be regularly reviewed and updated.

5.2 Monitoring and compliance with ethical standards

Adherence to ethical standards in research is not only a legal obligation, but also a moral imperative that ensures respect for donors and the responsible use of biological materials. All staff involved in research must be trained in the ethical guidelines and must undertake to adhere strictly to them at all stages of the project. Corrective action must be taken immediately when violations are identified.