UiO : Universitetet i Oslo
Institutt for medisinske basalfag, Avdeling for komparativ medisin

Standard operational procedure: Import and use of biological material
SOP no: 7-04
Opprinnelig dato: 17.04.2020 Forfattet av: Katarzyna Joanna Zelewska
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IMPORT AND USE OF BIOLOGICAL MATERIAL

1.0 PURPOSE

1.1 Biological material (cell lines, tissues, antibodies, stem cells, media, serum and frog oocytes) may contain undesirable pathological agents such as for instance viruses or bacteria. Undesirable agents may be derived from various sources such as murine/frogs donors or by indirect contact with culture media of murine/frogs origin. Biological material of human origin that has been cultured in vitro can also be a source of unwanted imported pathological agents if culture media or supplements of murine origin have been used. Note that external suppliers of such material, including larger commercial vendors such as ATCC, do not provide sufficient information about undesirable agents in the material they provide.

1.2 The aim of this procedure is to ensure that biological material is screened for the presence of undesirable agents and to prevent any introduction of unwanted murine pathogens via biological material into the KPM rodent and frogs area.

2.0 DISTRIBUTION OF RESPONSIBILITY

2.1 KPM is responsible for creating, maintaining, distributing and revising this procedure. The Head of Department (Designated Veterinarian) is responsible for approving the procedure.

2.2 Each user of the facility is responsible for adhering to the procedure at all times and for arranging the testing of the material in question.

3.0 PROCEDURE

3.1 The user must ensure that all imported biological material, such as a cell clone, originates from a batch or clone that has tested negative for unwanted biological agents. Clones must be stored and cultured without direct or indirect contact with material or culture medium originating from rodents throughout the period after PCR screening. Cells that test positive for Mycoplasma spp. are not allowed into the facility. In the case of Mycoplasma and/or similar pathogens, the cells must be renewed from stock and re-tested before being allowed to enter the facility.

3.2 Biological material to be imported into the KPM facility must be screened by PCR analysis for a panel of murine or frogs agents before being imported into the facility. The user is responsible for arranging the screening in accordance with this procedure, and questions concerning sampling should be directed to the service supplier. Each user must inform in advance PMSK about sending biological

samples to commercial suppliers in advance. Several commercial suppliers can provide such analyses, for instance IDEXX Bioanalytics and Charles River.

3.3 Cell lines to be used shall be screened according to one of these panels, regardless of origin:

- Biological material to be used in mice: IMPACT Mouse I + C.bovis (Idexx) or Mouse Essential CLEAR Panel w/ C.bovis (Crl)
- Biological material to be used in rats: IMPACT Rat V + C. bovis (Idexx) or Rat Essential CLEAR Panel w/ C.bovis (Crl)
- Biological material to be used in both mice and rats: IMPACT Comprehensive Murine Profile + C.bovis (Idexx) or Mouse/Rat Comprehensive CLEAR Panel (Crl)
- Biological material to be used in frogs: Comprehensive Xenopus PCR Panel (Idexx)

3.4 KPM has a quota on the above-mentioned test panels from IDEXX Bioanalytics so that users can benefit from a discount of 15% on their orders from this supplier. The KPM-facility can provide users with the contact details to IDEXX Bioanalytics for further advice and assistance with screening.

3.5 Biological material that has not been screened according to the above specifications cannot be imported into the KPM facility.

3.6 Upon arrival, all cells (regardless of the source of supply) have to be deposited in a cryobank from which cells can be taken when needed.

3.7 Cells that have tested positive for Mycoplasma spp. are not suited for use in experimental animals and the requirements for screening in part 1 include Mycoplasma spp. In addition to a negative test upon arrival, there is a mandatory requirement that the cells are grown in a cell lab that regularly screens for Mycoplasma spp. In the case of a positive test result, the cells must be re-grown from the cryostock before they can be imported into the KPM facility.

3.8 The user is responsible for ensuring that the batch of biological material to be used is exclusively derived from the batch that was screened and that the batch has been stored and grown without any direct or indirect contact with material or media with murine/frogs origin throughout the period after PCR screening.

3.9 A certificate of analysis from PCR screening must be sent to PMSK (personnel with special screening responsibility) in the KPM facility, who will determine if the biological material can enter the KPM facility. Provided the user confirms in writing (see the attached form) that the conditions and storage of the biological material exclude the possibility of direct or indirect contact with culture media of murine/frogs origin after PCR screening, this same batch of biological material or cell clone can be used in the KPM-facility.

3.10 **Use of biological material harvested inside the KPM facility**

Murine cells and biological material from rodents or frogs inside the KPM facility can be grafted to other rodents or frogs in the facility given the following preconditions:

- The material is directly transferred from donor to recipient.
- The biological material has not been in direct or indirect contact with culture media.
- The biological material was not harvested during a period when the facility health status was lower than the current status.
- Tissues are harvested using aseptic technique (this eliminates the possibility of any infection by Corynebacterium bovis localized on/in the skin, epithelia or fur of infected animals being transferred to harvested cells or tissues).

3.11 When using biological material that has been stored/cultured in vitro, the user must confirm in writing that the material is stored according to the terms of this procedure.

3.12 **Use of biological material of human origin harvested by the user or direct collaborators**

- Fresh cells and tissues that are harvested from patients or healthy individuals can be transferred to rodents providing that the cells/tissues have not been in direct or indirect contact with media of murine origin from the time of harvest to the time of implantation (including any initial use of "feeder cells" or primary fibroblast cell cultures of murine origin). The use of human cells and tissues is subject to prior approval for such use, and the user is responsible for ensuring that the necessary approvals have been obtained.

3.13 All items must be properly disinfected or sterilized before being imported into the KPM facility. See the SOP on "Import of equipment by user" before importing biological material or any other material or equipment into KPM.

4.0 HEALTH, SAFETY AND ENVIRONMENT (HSE)

4.1 Everyone who handles chemicals and biological materials must have adequate training and access to proper protective equipment in order to ensure the safe use of these substances.

4.2 Everyone should be familiar with the Eco Online and Safety Data Sheets for the chemicals and biological materials they may be exposed to.

5.0 EQUIPMENT AND MAINTENANCE

5.1 Equipment may vary.

6.0 HISTORY OF EDITING

6.1 This procedure is based on the current procedure in place at the University of Oslo – InVivo facility IBV – and adapted to local routines in agreement between the facility management, the Head of Department and group leaders, and based on advice from the Designated Veterinarian. The procedure is revised annually, or when new information of relevance becomes available.

6.2 Additions regarding frogs (Katarzyna Joanna Zelewska)

6.3 Added sentence "each user must inform in advance PMSK about sending biological samples to commercial suppliers in advance". 05.04.22 (H. Tandberg and K. Zelweska)

6.4 Reviced 22.05.2023 (Katarzyna Zelewska)

7.0 REFERENCES

7.1 Oirj From Bench to Cageside: Risk Assessment for Rodent Pathogen Contamination of Cells and Biologics

7.2 Procedure for Horizontal Transfer of Patient-Derived Xenograft Tumors to Eliminate Corynebacterium bovis J Am Assoc Lab Anim Sci. 2017 Mar 1;56(2):166-172

7.3 "Pathogenic Corynebacterial Contamination of Biological Materials" – IDEXX Bioanalytics.

7.4 "Biological testing – Quality Assurance Testing Services" – IDEXX Bioanalytics.

Appendix 1.

STATEMENT FOR THE CONDITIONS AND STORAGE OF BIOLOGICAL MATERIAL

Name of the user:

FOTS project number for the biological material:

Location of the storage (the name of Department and room number):

Type and amount of materials to be stored:

Required storage time after receiving pathogen-screening results:

Technical safeguards that will protect the biological materials from unauthorized handling:

I state that the conditions and storage of the biological material exclude the possibility of direct or indirect contact with culture media of murine origin after PCR screening, and that this same batch of biological material or cell clone will be used in the KPM-facility.

Date: Signature: