

 UNSW THE UNIVERSITY OF NEW SOUTH WALES	Risk Group Determination of Cell Lines
UNSW Guideline	
Control number	OHS651
Linked UNSW policy	This guideline details actions and processes pursuant to the UNSW OHS Policy.
Responsible Officer	Director, Human Resources
Authorisation	Director, Human Resources
Contact Officer	Manager, OHS and Workers Compensation
Effective Date	1 April 2007
Superseded Documents	None
Review	This procedure will be reviewed in accordance with the OHS Management System Review Procedure.
File Number	TRIM 2005/1548

1. Purpose

To assist UNSW researchers identify the appropriate risk group for established human cell lines.

2. Scope

The Guideline applies to all staff and students conducting research or teaching with cell lines

3. Definitions

* A Human Cell LINE is defined as **in vitro** or animal passaged (e.g., nude mouse) cultures or human cells that fulfil traditional requirements of a **cell line** designation. That is, the cells are **immortalised** cells, transformed by spontaneous mutation or natural or laboratory infection with an immortalising agent such as Epstein-Barr virus (EBV). EBV is a bloodborne pathogen. It should be noted that human cervical carcinoma cells or other transformed human cell lines like HeLa cells are sometimes adulterated with laboratory pathogens accidentally introduced by cultivation with other cell cultures, or physically contaminated by other cell cultures handled in the same lab. In order to handle human HeLa cells, without having to comply with risk group 2 precautions noted in AS/NZS 2243.3, human HeLa cells should be documented to be pure HeLa cells and shown to be free of bloodborne pathogens by testing.

**Characterization of human cells, for inclusion or exclusion from compliance with risk group 2 precautions noted in AS/NZS 2243.3, would include screening of the cell lines or "strains" for viruses characterized as bloodborne pathogens by the Standard, including human immunodeficiency viruses, hepatitis viruses or EBV, if the cells are capable of propagating such viruses. Most cell lines are screened for human

mycoplasmas and are free of bacterial and mycotic contaminants. Testing may include antigenic screening for viral or agent markers, co-cultivation with various indicator cells that allow contaminants to grow, or using molecular technology (polymerase chain reaction or nucleic acid hybridization) to identify latent viruses capable of infecting humans such as Herpes viruses (e.g., EBV), or papilloma members of the **Papovavirus group**, etc. Cell lines that are procured from commercial vendors or other sources with documented testing to be free of human bloodborne pathogens and which have been protected by the employer from environmental contamination may be handled as risk group 1 as noted in AS/NZS 2243.3.

*** Human cell STRAINS are defined as cells propagated **in vitro** from primary explants of human tissue or body fluids which have finite lifetime (non-transformed) in tissue culture for 20-70 passages. Human cell "strains" must be handled as potential biohazards (minimum risk group 2) unless characterized by testing to be free of bloodborne pathogens.

4. Guidelines

Established human cell lines* (see Definitions above) which are characterized** (see Definitions above) to be free of contamination from human hepatitis viruses, human immunodeficiency viruses, and other recognized bloodborne pathogens, are not considered to be other potentially infectious materials (OPIM) and are not considered risk group 2 material. Established human or other animal cell lines which are known to be or likely infected/contaminated with human microbes or agents classed as bloodborne pathogens, especially hepatitis viruses and human immunodeficiency viruses are considered a minimum of risk group 2. The final judgement for making the determination that human or other animal cell lines in culture are free of bloodborne pathogens must be made by a Bio-safety Professional or other qualified scientist with the background and experience to review such potential contamination and risk, in accordance with the requirements of the AS/NZS 2243.3. Documentation that such cell lines are not OPIM should be a matter of written record (Risk Assessment and Control Procedure) and on file with the supervisor for review and approval.

All primary human cell **explants** from tissues and **subsequent in vitro** passages of human tissue explant cultures (human cell "strains" ***, see Definitions above) must be regarded as containing potential bloodborne pathogens and should be handled in accordance with AS/NZS 2243.3. Non-transformed, human cell "strains", characterized by documented, reasonable laboratory testing as described in the attachment, to be free of human immunodeficiency virus, hepatitis viruses, or other bloodborne pathogens may be exempted from the standard's requirements. However, if such tissue explants or subsequent cultures are derived from human subjects known to carry bloodborne pathogens, such as hepatitis viruses or human immunodeficiency viruses or are deliberately infected with bloodborne pathogens, they must be handled in accordance with the risk group 2 precautions noted in AS/NZS 2243.3. Likewise, animal tissues, explants or cell cultures known to be contaminated by deliberate infection with human immunodeficiency virus or Hepatitis B virus are also subject to the precautions noted in AS/NZS 2243.3.

All laboratory work with primary human tissues or body fluids is covered by the risk group 2 precautions noted in AS/NZS 2243.3.

5. Legal & Policy Framework

UNSW Biosafety Procedure
UNSW Gene Technology Procedure
AS/NZS 2243.3
Gene Technology Act and Regulation

5.1 Associated Documents

[UNSW Biosafety Webpage.](#)

6. Modifications

Version	Date	Author	Approval	Sections modified	Details of amendments

7. Acknowledgements

US Labour Department Standard Interpretations
[06/21/1994 - Applicability of 1910.1030 to establish human cell lines.](#)