Charles Sturt University

Biosafety Manual

Booklet 1 - Introduction

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1. Introduction

1.1. Purpose and scope

This Manual is intended to provide guidance to staff, students and visitors (termed 'workers' and 'visitors') of Charles Sturt University handling, or exposed to, potentially biohazardous material during their learning, teaching and research. It contains policies, procedures and guidelines which are intended to *minimise the risk* of infection or injury arising from contact with biohazardous material. It also provides some useful general information in the Appendices. It is *not intended* to be a comprehensive manual on all aspects of the safe handling of biological material. This manual was prepared by Charles Sturt University's Institutional Biological Safety Committee (IBC).

All Schools,Centres and Enterprises at the University working with biological or biohazardous materials are expected to develop their own Safe Work Procedures (SWPs) and Risk Assessments (RAs) which are consistent with the requirements outlined in the policies, guidelines and procedures within this manual. They should also read relevant information and procedures on the Faculty of Science Technical services website at http://science.csu.edu.au/technical .

Researchers should note that Charles Sturt University abides by the '*Australia Code for the responsible conduct of Research*'. (https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2007) and it is incumbent on them to ensure the safety and well-being of all humans involved in research. The code was developed jointly by the National Health and Medical Research Council, the Australian Research Council and Universities Australia.

In addition, with the introduction of the Commonwealth *Gene Technology Act (2000)* and *Gene Technology Regulations (2001)* and subsequent amendments, all workers must obtain the approval of the Institutional Biological Safety Committee for ANY research or teaching which involves the use of Genetically Modified Organisms (GMOs). The act is administered by the Office of the Gene Technology Regulator (OGTR) who produce the regulations and ensure compliance. Experiments that involve the use of GMO's are called 'Dealings' by the Regulator and there are various classes of dealings which require different levels of compliance. CSU may be required to only report annually on certain dealings while other classes may require individual applications (via the IBC) to the Regulator. The various classes of dealings and responsibilities of staff are discussed elsewhere in this manual.

Particular biological agents are classified as Security Sensitive Biological Agents (SSBAs). All workers need to be aware of what these are and if you wish to work with them there are regulations with which you must comply. Their use is governed by the National Health Security (NHS) Act 2007, National Health Security Regulations 2018 and the SSBA standards. Furthermore, biological agents and research information concerning particular biological agents with potential for assisting others produce weapons must be carefully reviewed as they may fall under the Defence Trade Act of 2012 and the Defence Trade Controls Amendment Act 2015. The acts and associated regulations govern what can be exported from Australia and this includes information, (including electronic information), as well as tangible goods.

As a final note, it cannot be over-emphasised that no activity with potentially biohazardous material should be undertaken until a thorough Risk Assessment has been completed (which incorporates procedures for dealing with a range of maximum conceivable incidents/accidents). These should be approved by the relevant Head of School, Centre Director and Facility Manager. It should also be noted that ALL workers at CSU have a duty of care to others inside and outside CSU to ensure all biological agents are worked with safely and that they do not cause harm or injury to humans, animals or the environment. Failure to comply with the various legislations, resulting in accident or injury, can result in severe fines (for staff involved as well as the institution) or possible gaol sentences for those involved.

We acknowledge the use of some content of the Macquarie University and Curtin University biosafety manuals.

Suggestions regarding the content and scope of this manual are welcome and should be emailed to biosafety@csu.edu.au .

1.2. The Institutional Biosafety Committee

1.2.1. Establishment

The Biosafety Committee of Charles Sturt University (the University) was originally established by the Board of Governors on 17 August 1995 (BG95/129). Amended by the University Council on 6 December 2001 (CNL01/235) and again on 30 May 2002 (CNL02/74) to ensure compliance with the Gene Technology Act (2000) and associated Regulations.

1.2.2. Membership and Terms of Reference

Please refer to the Biosafety Webpage for the current Membership and Terms of Reference.

https://research.csu.edu.au/integrity-ethics-compliance/biosafety/membership-information

1.2.3. Biosafety Committee members

A current list of members of the IBC can be found at https://research.csu.edu.au/integrity-ethics-compliance/biosafety/membership-information

1.2.4. Useful Websites

ORGANISATIONS

Biosafety Committee Home Page..... https://research.csu.edu.au/integrity-ethics-compliance/biosafety

Department of Agriculture /Biosecurity ..... https://www.dpi.nsw.gov.au/biosecurity

National Health and Medical Research Council ..... http://www.nhmrc.gov.au/

Office of the Gene Technology Regulator ..... http://www.ogtr.gov.au

Department of Health..... http://www.health.gov.au/

Department of Health (Security Sensitive Biological Agents) ..... http://www.health.gov.au/ssba

NSW Ministry of Health..... http://www.health.nsw.gov.au/Pages/default.aspx

Association for Biosafety of Australian and New Zealand ..... https://www.absanz.org.au/

Defence Trade Controls Act…… https://www.legislation.gov.au/Details/C2015A00031

FORMS

Accident/Incident Report Online Form..... https://www.csu.edu.au/division/hr/incident-or-hazard

Exempt Dealing Application form and Notifiable Low Risk Dealing forms can be found at https://research.csu.edu.au/integrity-ethics-compliance/biosafety/forms-and-resources

STANDARDS

Australian Standards..... http://www.standards.org.au/Pages/default.aspx

Australian Standard documents can be obtained from the CSU Library databases (Standards online)
http://www.csu.edu.au/division/library/services/find-books-and-other-resources/databases

AS/NZS 2243.1:2005 Safety in laboratories Part 1: General

AS/NZS 2243.3:2010 Safety in laboratories Part 3: Microbiological aspects and containment facilities

AS/NZS 2647:2007 Biological safety cabinets – Installation and use

AS/NZS 2982.1:2010: Laboratory design and construction – General requirements

GUIDELINES AND POLICIES

NSW Health Policies ..... http://www.health.nsw.gov.au/policies/pages/default.aspx

Australian Immunisation Handbook… ..... https://immunisationhandbook.health.gov.au/

OGTR Guidelines for Certification of Facilities/Physical Containment Requirements
http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/certifications-1

OGTR Guidelines for the Safe Transport of GMOs http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/transport-guide-1

Material Safety Data Sheets for various risk group micro-organisms..... https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html

WHO Biosafety Manual..... http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf

CSU Human Biological Specimen laboratory use policy…….. https://policy.csu.edu.au/document/view-current.php?id=196

Approved code of practice for control of work related exposure to Hepatitis and HIV Australian Government
……https://www.safeworkaustralia.gov.au/doc/national-code-practice-control-work-related-exposure-hepatitis-and-hiv-blood-borne-viruses-nohsc

OTHER SITES OF INTEREST

Cartagena Protocol on Biosafety ..... https://bch.cbd.int/protocol

CDC Biosafety in Microbiological and Biomedical Laboratories https://www.cdc.gov/biosafety/publications/bmbl5/index.htm

American Biological Safety Association (ABSA) .....https://absa.org/

2. Responsibility and Management

Deputy Vice Chancellor (Research and Engagement)	The Deputy Vice Chancellor is responsible to the Vice Chancellor for the CSU IBC and that committee's requirement as specified by the OGTR.
Institutional Biosafety Committee	Under OGTR legislation, all work involving GMO's must be reviewed by IBC. CSUs IBC responsibilities are included in the terms of reference:
Technical Services, Laboratory Managers and Facility Managers	Technical Services, laboratory managers and facility managers are responsible for monitoring facility access and authorisation. They are to ensure that staff and students and visitors teaching, working or conducting research in their laboratories have undergone the appropriate laboratory safety induction prior to commencing. Managers of certified facilities (OGTR and quarantine) are to maintain all facility documentation required for their certification.
Deans and heads of school	Deans and Heads of School are responsible for ensuring that all employees and students receive appropriate information and training necessary for them to work and conduct their research safely.
Chief investigator and academic supervisors	Chief investigators (including principal investigators, academic supervisors, research supervisors and subject coordinators and conveners) are responsible for the health and safety of the undergraduate, masters and postgraduate students they supervise in addition to visitors, volunteers and staff employed under them. They are to ensure that their students and staff have received the appropriate laboratory safety induction and training to enable them to undertake their work safely and that associated risk assessments have been completed.
Staff, students and visitors	Staff, students, visitors (including volunteers) working with biological hazards must ensure that they follow safety guidelines and complete safety training set out by the university and their respective facility manager and chief investigators. They should ensure that their actions do not put themselves, or others at risk.
Responsibilities of all workers	There are laws, regulations (enforceable by law) and standards for working with biologicals and biological agents. The term 'biological agent' is defined here as any organism including bacteria, plant, virus, fungus, parasite, prion or any biological material including toxins that may cause harm to human/ animal health or the environment. It is critical that all staff and students handling biological agents and their supervisors observe the standards and regulations and understand their obligations under them. The term 'biological' means any organism or substance derived from biological systems (natural or synthetic). The Australian Standards e.g. AS/NZS 2243:3; 2010 are not required by law unless they are incorporated within an Act of Parliament. They are however recognized in common law as defining minimum requirement for best practice for laboratory safety. This should be interpreted as a warning that if injury or infection of persons, animals or the environment results from non-compliance with these standards then Charles Sturt University and individuals concerned may be liable for civil damages. Regulations are mandated by Acts of Parliament and must be adhered to by law. Non-compliance with these regulations can attract severe penalties. For instance if a laboratory deals with genetically modified organisms (GMOs) then all work within the laboratory is regulated by the *Gene Technology Act 2000* *and subsequent amendments*. Breaches of this Act may be dealt with in the criminal courts. Penalties that can result are significant terms of imprisonment and substantial fines. These can be applied to Charles Sturt University and to those individuals within the organization deemed responsible for the breaches.

3. Health management

3.1. Staff and student vaccination and inoculation requirements- (For staff and students who come into contact with human tissues, body fluids, cadavers or any human clinical specimens).

Charles Sturt University is required by law to ensure the health, safety and welfare of all staff, students and visitors. All staff and students working in healthcare settings in NSW within or outside the university are required to ensure they comply with the 'Occupational Assessment, Screening and Vaccination Against Specific Infectious Diseases' policy. Compliance is mandatory.

Similar regulations exist in other states; please see (https://www2.health.vic.gov.au/public-health/infectious-diseases) for Victoria. This includes all students on work placements, practicums and staff working in clinics including dental, podiatry, physiotherapy clinics and hospitals. It is the responsibility of the faculty/schools and divisions to ensure that their students and staff comply with these regulations. The cost of vaccination where this is required of staff for their normal duties should be borne by the staff members cost centre. Students are required to bear the cost of vaccinations or immunological tests themselves. The university 'Human Biological Specimens Laboratory Use Policy' can be found at https://policy.csu.edu.au/document/view-current.php?id=196 and the university's infectious disease policy can be found at https://policy.csu.edu.au/document/view-current.php?id=185 .

In brief it says that use of human biological specimens in teaching and research falls outside this policy and an application in writing to the IBC must be made to conduct the work. Written approval from the IBC must be received before that work can be commenced.

Anyone coming into contact with non-screened human biological specimens, during the course of their work should be or have been immunised against Hepatitis B and preferably Hepatitis A viruses. It is the responsibility of the supervisors to ensure this is the case and documentation is available.

3.2. Staff and student vaccination and inoculation requirements (For staff and students who come into contact with animal tissues, body fluids, cadavers or any animal clinical specimens where there is a risk of transmission of a zoonosis).

It is incumbent on the university to ensure that all staff, students and visitors are compliant with any policy relating to vaccination or immunological testing recommended for their normal activities within or outside of the university, to protect them against infection, including animal borne, zoonotic diseases. The cost of vaccination for staff should be borne by their cost centre and students are required to cover the costs themselves. At present immunological testing and vaccination (if sero-negative) for Q fever is required for all staff and students who come into contact with animals regardless of the school they work in. For staff or students who may come into contact with bats, which can carry Lyssavirus, a rabies vaccine is required. A tetanus vaccination for those that work with animals is also advised.

3.3. Common notifiable diseases

Tetanus, Hepatitis A, Hepatitis B and Q fever are notifiable diseases in all states and territories in Australia. In NSW if an employee contracts Q fever it must be reported to NSW Health.

Tetanus	Tetanus is a disease caused by a toxin produced by *Clostridium tetani*. Any tetanus-prone wound can become contaminated with *C. tetani*. Tetanus-prone wounds are those other than clean, minor cuts and include: • wounds where disinfection has been delayed by more than 4 hours • compound fractures • bites • deep penetrating wounds • wounds containing contamination or foreign bodies (wood, dust, soil, manure) Those at risk of tetanus include: • anyone at risk of scratches, bites and cuts from animals or their cages

	• anyone handling *C. tetani* or its toxin • outdoor workers (e.g. those working on farms)
Hepatitis	Hepatitis B is one of several different hepatitis viruses that can cause infections and damage to the liver. Hepatitis B is a potentially life threatening disease caused by the Hepatitis B virus. The Hepatitis B virus is spread through contact with blood and other bodily secretions. Hepatitis A is caused by the Hepatitis A virus and it is highly contagious and can be particularly dangerous for people with pre-existing liver problems. The virus is spread by the faecal oral route and can survive on hands, in food and in water for prolonged periods of time. Immunisation is an effective way of protecting against Hepatitis A and B viruses. Currently for Hepatitis C there is no immunisation or completely effective treatment. Those at risk of hepatitis infections include anyone who: • handles a hepatitis virus • is exposed to human faecal material, blood, liver tissue and bile and other bodily secretions • works with non-human primates • first aiders
Q fever	Q fever is amongst the most serious infective hazards and is a NSW Health-reportable illness in NSW. Q fever is a zoonotic infectious disease caused by the bacterium *Coxiella burnetii*, which can be harboured in numerous domesticated and wild animals. *C. burnetii* is highly infectious and is transmitted to humans via aerosols (often in dust particles which are inhaled) from dried contaminated body fluids of infected animals. People considered at risk of exposure are those working with or handling: • *Coxiella burnetii* as part of their work • Animals potentially infected, especially pregnant animals, including native animals (e.g. kangaroos), companion animals (cats and dogs) and stock animals (pigs, sheep, cattle) • Unfixed tissues, including carcasses from potentially infected animals • Unfixed human samples (blood or tissue) that could be from individuals with Q fever

3.4. Precautions for pregnant women and immunocompromised individuals

Minimising laboratory risks for pregnant women (due to the sensitivity of the foetus to specific biological agents) and immunocompromised individuals is especially important. All lab workers should know the hazards associated with the materials with which they work and it is important to recognise that an individual's susceptibility to those hazards may change due to factors such as pregnancy. In all cases, a pregnant women and immunocompromised individuals should discuss their laboratory environments with medical care professionals and their supervisors and provide specific information about potential exposures.

3.5. Personal hygiene

To prevent the spread of laboratory contaminants, it is important to use good microbiological techniques, correct techniques for application, wearing and removal of the provided personal protective equipment (PPE) and thorough handwashing before leaving a laboratory or facility. How to remove PPE and surgical handwashing techniques are given in appendices 3 and 4 (Booklet 3).

3.6. Rights and obligations

Whilst individuals reserve the right not to partake in screening or vaccinations, the University is obliged not to place staff into areas or tasks where the risk level or outcome is unacceptable, especially where no preventative vaccination has

been undertaken. It should be noted that a record of screening/ vaccinations against NSW Health Department listed infectious diseases is a prerequisite for approval to access their sites.