This handout contains the slides from the course, and two example BioCOSH risk assessments completed for an HG2 pathogen example and a Human Tissue example.

Fuller guidance is available on the University Safety Office website at www.safety.ncl.ac.uk Please refer to the website as the internal authoritative source of information.

The materials provided in this session have been developed by the University Safety Office and are for internal University use only. If versions of this material are required for in house training please contact the University Safety Office for PowerPoint and other files.
**Objectives**

- Legal requirements for work with biological agents and hazards
- Risks relating to biological agents and hazards at work
- Risk assessment and control for biological agents and hazards

**Risk Assessment**

- Health and Safety at Work Act and Regulations
- Environment Acts and Regulations
- Control of Substances Hazardous to Health Regulations
- Health and Safety Executive (HSE) regulator for biological safety

**BioCOSHH Risk Assessment and Control**

- Responsibility of managers and principal investigators
- Assess risks to human health and environment
- Biological agents and hazards
- Activity
- Who or what might be harmed and how
- Hazard group
- Containment level and controls
- Emergency procedures
- Information, instruction, training and supervision
- BSC and HSE permission
- Review and revise risk assessments

**Biological Safety Committee**

- **University BSC**
  - Chair, School GM Chairs, unions, occupational health physician and practitioner, and biological safety officer
  - Advise on BioCOSHH risk assessments and controls, monitor activities and keep University records
  - Permission system for notifiable biological agents

- **School BSC**
  - School GM Chair and academic researchers
  - Advise on BioCOSHH risk assessments and controls, monitor activities and keep School records
Guidance and Information

Websites
- University Safety Office - Biological Safety
- University Occupational Health Service
- Health and Safety Executive
- Department for Environment, Food and Rural Affairs
- Health Protection Agency

Publications
- Microbiology and biology textbooks
- Scientific papers and internet searches

Hazard and Risks

Hazard
- Biological agents and hazards

Risk
- Biological agents and hazards and potential harm to humans or environment

Guidance and Information

Websites
- University Safety Office - Biological Safety
- University Occupational Health Service
- Health and Safety Executive
- Department for Environment, Food and Rural Affairs
- Health Protection Agency

Publications
- Microbiology and biology textbooks
- Scientific papers and internet searches

Biological Agents

Biological agents are microorganisms, cell cultures, human endoparasites, whether or not genetically modified, which may cause infection, allergy, toxicity or otherwise create a risk to human health

Biological Hazards

Biological hazards are biological agents or anything which contains biological agents or their harmful products

Biological Agents

Viruses
Bacteria
Fungi
Protozoa
Parasites
Cell cultures
TSE agents
GMM

BioCOSHH Risk Assessment

1. University Safety Office website - BioCOSHH Risk Assessment and Pathogen and Toxin Registration
2. Complete BioCOSHH risk assessment form
3. Read and follow guidance (HSE and ACDP)
4. Contact School Safety Officer or Biological Safety Supervisor for advice
5. Permission for work from School BSC, University BSC and HSE where required
Guidance
- ACDP Biological agents: Managing risks in laboratories and healthcare premises
- ACDP Approved list of biological agents
- ACDP Infection at work: Controlling risks
- ACDP Management, design and operation of microbiological containment laboratories
- ACDP Protection against bloodborne infections in workplace: HIV and Hepatitis
- ACDP Working safely with research animals management of infection risks
- WHO Guidance on regulations for transport of infectious substances

Biological Agents
Pathogens
- Biological agents which cause infection and disease
Toxins
- Biological agents or products which cause toxicity
Carcinogens
- Biological agents which cause cancer
Allergens
- Biological agents or products which cause hypersensitivity

Classification of Biological Agents
Biological agents are classified into four hazard groups
- Ability to cause disease or harm to humans or environment
- Severity of disease or harm
- Likelihood disease or harm will spread
- Availability of effective prophylaxis or treatment

- Hazard group 1 (HG1)  - Lowest hazard
- Hazard group 2 (HG2)
- Hazard group 3 (HG3)
- Hazard group 4 (HG4)  - Highest hazard
Classification of Biological Agents

Human Pathogens
- ACDP classification of pathogens based on risks to humans
- Classification into four hazard groups 1, 2, 3 and 4

Animal Pathogens
- DEFRA classification of pathogens based on risks to animals and environment
- Classification into four hazard groups 1, 2, 3 and 4

Plant Pathogens and Pests
- DEFRA classification of pathogens and pests based on risks to plants and environment
- Complex classification groups

ACDP Hazard Groups

<table>
<thead>
<tr>
<th>Group</th>
<th>Description</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Unlikely to cause human disease</td>
<td>B. subtilis, E. coli K12 and BL21 strains and derivatives, S. cerevisiae, Vaccine strains</td>
</tr>
<tr>
<td>2</td>
<td>Causes human disease Unlikely to spread to community Usually effective prophylaxis or treatment</td>
<td>Influenza virus, Adenovirus, HIV, E. coli (except K12, BL21, 0157), S. aureus, N. meningitidis, C. albicans, A. fumigatus, T. gondii</td>
</tr>
<tr>
<td>3</td>
<td>Causes severe human disease May spread to community Often effective prophylaxis or treatment</td>
<td>Pandemic influenza virus, HIV, HBV, HCV, HDV, E. coli 0157, M. tuberculosis, C. immittis, P. falciparum, N. fowleri, T. solium</td>
</tr>
<tr>
<td>4</td>
<td>Causes severe human disease Likely to spread to community Often no effective prophylaxis or treatment</td>
<td>Pandemic influenza virus, Asian influenza virus, Variola virus, Marburg virus, Ebola virus, Herpesvirus simiae</td>
</tr>
</tbody>
</table>

Rules for Hazard Group 1

Possession or use of HG1 biological agents and hazards
- BioCOSHH risk assessment
- School BSC advice
- Implement and monitor controls
- Review and revise BioCOSHH risk assessment
- Keep all records

Rules for Hazard Group 2

Possession or use of HG2 biological agents and hazards
- BioCOSHH risk assessment
- Pathogen registration
- School BSC advice
- Implement and monitor controls
- Review and revise BioCOSHH risk assessment
- Keep all records

Rules for Hazard Group 3

Possession or use of HG3 biological agents and hazards
- BioCOSHH risk assessment
- Pathogen registration
- School BSC and University BSC advice and approval
- HSE notification, advice and approval
- Implement and monitor controls
- Review and revise BioCOSHH risk assessment with advice and approval from School BSC, University BSC and HSE
- Keep all records

Rules for Biological Hazards

Possession or use of biological hazards (eg human, animal and plant tissues)
- BioCOSHH risk assessment
- Pathogen or toxin registration
- School BSC advice
- Implement and monitor controls
- Review and revise BioCOSHH risk assessment
- Keep all records

Rules as for hazard groups if they contain biological agents
**Pathogen and Toxin Registration**

Certain biological agents and hazards must be registered using Pathogen or Toxin Registration Forms before they are brought into University

- Hazard group 2 and 3 biological agents
- Anything which contains HG2 or 3 agents
- Anything which has a high likelihood that it contains HG2 or 3 agents
- Any pathogen or toxin listed in Schedule 5

Detailed guidance on what must be registered on USO website: [www.safety.ncl.ac.uk](http://www.safety.ncl.ac.uk)

---

**Risks to Human Health and Environment**

- How and to what could people or environment be exposed
- What harm to humans or environment
- Route and consequence of exposure or release
- Laboratory or field work
- Bacteria, viruses, fungi, parasites, TSE and microbial products
- Pathogens, toxins, carcinogens and allergens
- Spread to close contacts or community
- Release, survive, spread or displace species in environment
- Could harm be treated or remedied

[www.safety.ncl.ac.uk](http://www.safety.ncl.ac.uk)

---

**Risks to Human Health and Environment**

- Workers
- People sharing workplace
- Visitors
- Public
- Contractors
- Pregnant women
- Lone workers
- Young or inexperienced workers
- Land
- Water
- Air
- Microorganisms
- Animals
- Plants
- Soils
- Food

[www.safety.ncl.ac.uk](http://www.safety.ncl.ac.uk)

---

**Exposure Routes**

- Inhalation
  - Aerosols
- Ingestion
  - Swallowing
- Injection
  - Sharps injuries, animal bites and scratches
- Absorption
  - Intact skin or external mucous membranes

[www.safety.ncl.ac.uk](http://www.safety.ncl.ac.uk)

---

**Pathogens**

Biological agents which cause infection

- Infections may be asymptomatic, acute, chronic or fatal
- Host, agent and environment factors
- Virulence, cell tropism, host range, genotype and immunity
- Infectious dose, dissemination and viability
- Obligate, opportunistic or zoonotic pathogens
- Effects may be delayed (e.g. HIV, HCV, TB)
- Release of microbial, animal, plant or environmental pathogens and pests

[www.safety.ncl.ac.uk](http://www.safety.ncl.ac.uk)

---

**Smallpox Infection**

- Smallpox virus used in laboratory in Medical School at Birmingham University
- Laboratory acquired infection cases in 1978
- Poor safety standards in laboratory
- Last recorded case of smallpox in world
- Smallpox largely eradicated
- People no longer vaccinated and diminishing immunity
- Route of infection through ventilation
- Technician in office outside laboratory was exposed, infected and died
- Spread to close contact in community but they recovered

[www.safety.ncl.ac.uk](http://www.safety.ncl.ac.uk)
Microorganisms can adapt and evolve to become more or less harmful:
- Changes in pathogenicity
- Changes in virulence
- Changes in cell tropism
- Changes in host range
- Changes in toxicity
- Changes in carcinogenicity

New pathogenic agents are continually emerging.

Emerging Pathogens:
- 1967 Marburg virus
- 1976 Ebola virus
- 1977 Legionella pneumophila
- 1981 Human immunodeficiency virus (HIV)
- 1982 Escherichia coli 0157 EHEC
- 1983 Mycobacterium tuberculosis MDR
- 1989 Hepatitis C virus (HCV)
- 1990 Staphylococcus aureus MDR
- 1996 BSE variant CJD
- 2003 SARS virus
- 2005 Avian influenza virus

Marburg Virus Infection:
- Monkeys from Uganda used in laboratory in Marburg
- Laboratory acquired infection cases in 1967
- 31 lab workers and contacts infected with unknown virus
- 25 primary infections of lab workers in contact with monkeys or tissues
- 7 lab workers died of hemorrhagic disease
- 6 secondary infections of doctors, nurses, pathologist and veterinarians wife had direct contact usually involving blood with a primary case but all recovered
- Doctors infected by sharps injury when taking blood from patients
- Newly emerged zoonotic pathogen named Marburg virus

Toxins:
- Biological agents which cause toxicity
  - Microorganisms can produce powerful toxins
  - Toxins can be harmful by various exposure routes
  - Microorganisms do not need to be viable for toxins to be harmful
  - Non-infectious microorganisms can produce harmful toxins

Biological Toxins:

<table>
<thead>
<tr>
<th>Biological Agent</th>
<th>Toxin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Escherichia coli 0157</td>
<td>Cytotoxins</td>
</tr>
<tr>
<td>Shigella dysenteriae</td>
<td>Cytotoxins</td>
</tr>
<tr>
<td>Vibrio cholerae</td>
<td>Cytotoxins</td>
</tr>
<tr>
<td>Streptococcus pyogenes</td>
<td>Cytotoxins</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>Cytotoxins</td>
</tr>
<tr>
<td>Bacillus anthracis</td>
<td>Cytotoxins</td>
</tr>
<tr>
<td>Clostridium difficile</td>
<td>Cytotoxins</td>
</tr>
<tr>
<td>Clostridium botulinum</td>
<td>Neurotoxins</td>
</tr>
<tr>
<td>Clostridium tetani</td>
<td>Neurotoxins</td>
</tr>
<tr>
<td>Cyanobacteria</td>
<td>Neurotoxins and cytotoxins</td>
</tr>
<tr>
<td>Fungi</td>
<td>Neurotoxins and cytotoxins</td>
</tr>
</tbody>
</table>

Biological Toxins - Relative Toxicity
Carcinogens

- Biological agents which cause cancer
  - Mostly viruses
  - Nucleic acids can be carcinogenic
  - Cells, tissues and cell cultures can contain cancer viruses
  - Immune rejection response to non-self tissues but not to biological agents

Allergens

- Biological agents which cause hypersensitivity
  - Animals, plants and microorganisms or their products can cause hypersensitivity
  - Sensitization can occur by acute or chronic exposure
  - Once sensitised very low concentrations of allergens may elicit hypersensitivity reactions
  - Asthma affects breathing
  - Dermatitis affects skin
  - Anaphylaxis causes severe generalised hypersensitivity
  - Hypersensitivity can be mild, severe or fatal

Human, Animal and Plant Cells and Tissues

- Cells, tissues, bodies, body fluids or samples may contain biological agents or products
- Pathogenic viruses, bacteria or fungi or parasites (eg HBV, HIV, HVS, TB)
- Cancer viruses (eg HBV, HCV, HPV)
- TSE agents (eg brain and neural tissue)
- Zoonotic pathogens
- Animal enzootic or epizootic pathogens
- UK prevalence of common bloodborne viruses is 1 in 100 humans (ie HBV, HCV, HDV, HIV)

Primary and Continuous Cell Cultures

- Human, animal or plant cell culture
- Cell cultures may contain adventitious biological agents
- Primary cell cultures generally higher hazard than continuous cell cultures
- Cells, medium or additives may contain biological agents or products
- Cancer cell lines (eg cancer viruses)
- Danger working with own or other worker’s cells with no immunity if source exposed to own cells

Animals and Plants

- Laboratory or fieldwork
- Human infections from animals or plants
- E. coli 0157 (eg cattle)
- Herpesvirus simiae (eg primates)
- Rabies virus (eg dogs, monkeys)
- Bacteria and parasites (eg rats, dogs, pigs, cattle)
- Pathogens in soil
- Laboratory animals often screened for common pathogens
- Experimentally infected animals or plants
- Environmental harm from release of animal or plant pathogens or pests, animals and plants
### Bioreactors
- Microbial, human, animal and plant cell culture
- Adventitious agents
- Potential exposure or release during inoculation, culture, sampling and processing of products
- Potential exposure or release during disinfection and cleaning of equipment and waste disposal
- Aeration may produce large quantity of infectious aerosols
- Accidents may cause exposure or release of large quantity of biological agents

### Environmental Samples
- Environmental samples may contain biological agents or products
- Pathogens in fresh and sea water
- Enteric viruses, bacteria or parasites in sewage or polluted water
- C. tetani or C. botulinum in soil
- Unintentional isolation, concentration or propagation
- Culture may influence selection and survival (e.g., nutrients, temperature, pH, water activity)
- Assume unknown microorganisms are pathogenic

### Fieldwork
- People may be exposed to biological agents during local or overseas fieldwork
- Local or exotic biological agents
- Potential exposure to viruses, bacteria, fungi and parasites or products
- Rabies (60,000 annual mortality mostly dog bites)
- Yellow fever (Yellow fever virus)
- Malaria (P. falciparum)
- Tuberculosis (M. tuberculosis)
- Emerging pathogens
- Risks more difficult to determine and control

### Hepatitis C Virus Infection
- Worcestershire Hospital Trust
- Hospital acquired infection case in 2007
- Nurse instructed to take blood from HCV infected patient
- Put used sharps on bench instead of in sharps bin
- Reached over and pricked wrist on needle
- Inadequate information, training and supervision by Trust
- No risk assessment for BBV
- Unsafe working practices
- Nurse was inexperienced new employee only 3 weeks in job
- She was not told about high risk HCV patient
- Nurse is now infected with HCV and may get cancer and die

### Risk Estimation
Risk is estimated by combining severity of harm were it to occur and likelihood of occurrence in specific circumstances
- Severity of harm (severe, moderate, minor, negligible)
- Likelihood of harm (high, medium, low, negligible)

Risk = Likelihood x Severity

Risk = Effectively zero, Low, Low/Medium, Medium or High

### Risk Estimation Matrix

<table>
<thead>
<tr>
<th>Severity of Harm</th>
<th>Likelihood of Harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe</td>
<td>High</td>
</tr>
<tr>
<td>Moderate</td>
<td>High Medium Low</td>
</tr>
<tr>
<td>Minor</td>
<td>Medium Low Low</td>
</tr>
<tr>
<td>Negligible</td>
<td>Effectively zero</td>
</tr>
</tbody>
</table>

Risk = Effectively zero, Low, Low/Medium, Medium or High
### Controls

Protection of humans and environment requires effective containment and control.

Human and environmental exposure to biological agents must be prevented or adequately controlled.

Exposure to biological agents must be reduced to a level which is adequate to protect humans and environment.

### Containment and Control

- Policies, risk assessments and standard operating procedures
- Containment laboratories and controls
- Controls for biological agents, animals and plants
- Biological controls
- Safe work practices for use, storage, transport, inactivation and waste disposal
- Hygiene
- Personal protective equipment
- Health surveillance
- Emergency plans and procedures
- Information, instruction, training and supervision

### Containment Levels

Minimum containment level required is equivalent to hazard group.

- Containment level 1 (CL1) for hazard group 1 (HG1)
- Containment level 2 (CL2) for hazard group 2 (HG2)
- Containment level 3 (CL3) for hazard group 3 (HG3)
- Containment level 4 (CL4) for hazard group 4 (HG4)

### Containment Laboratories

Containment levels required for general, animal and plant laboratories:

- CL1 for low risk work with HG1 biological agents
- CL2 for medium risk work with HG2 biological agents
- CL3 for high risk work with HG3 biological agents
Containment Level 1

- Suitable for low risk hazard group 1 work
- Access limited to authorised persons
- CL1 sign
- Benches, floors and walls impervious, resistant and cleanable
- Autoclave and effective disinfectants
- Hand wash sink with emergency wash hose
- Appropriate PPE (eg lab coats, gloves, specs etc)

Containment Level 2

- Suitable for medium risk hazard group 2 work
- Access to authorised persons only
- CL2 and biological hazard signs
- Benches, floors and walls impervious, resistant and cleanable
- Negative pressure ventilation
- Safety cabinet, isolator or containment used for infectious aerosols
- Autoclave and effective disinfectants
- Hand wash sink with emergency wash hose
- Appropriate PPE (eg lab coats, gloves, specs etc)

Containment Level 3

- Suitable for high risk hazard group 3 work
- Access to authorised persons only
- CL3 and biological hazard signs
- Benches, floors and walls impervious, resistant and cleanable
- Laboratory must contain own equipment
- Negative pressure ventilation and exhaust air HEPA filtered
- Safety cabinet, isolator or containment used for infectious aerosols
- Autoclave in laboratory and effective disinfectants
- Laboratory must be sealable to permit fumigation
- Hand wash sink with emergency wash hose
- Appropriate PPE (eg gowns, gloves, specs etc)
Basic Controls for Microorganisms
- Containment laboratory
- Safe use, storage, transport, inactivation and waste disposal
- Biological controls
- Safety cabinets
- Dedicated equipment and PPE
- Access control and locked rooms

Basic Controls for Animals
- Containment laboratory
- Safe use, storage, transport, inactivation and waste disposal
- Biological controls
- Safety cabinets
- Dedicated equipment and PPE
- Access control and locked rooms
- Isolators and individually ventilated cages
- Pest and vector controls
- Home Office licences for animal welfare
- DEFRA licences required for specific animal pathogens and pests and animals

Basic Controls for Plants
- Containment laboratory
- Safe use, storage, transport, inactivation and waste disposal
- Biological controls
- Safety cabinets
- Dedicated equipment and PPE
- Access control and locked rooms
- Isolators and propagators
- Pest and vector controls
- Removal or bagging of flowers, pollen and seeds
- DEFRA licences required for specific plant pathogens and pests and plants

Biological Controls
- Microorganisms, animals and plants with reduced capacities to survive, propagate, transmit or cause harm
- Attenuated strains (e.g., vaccine strains)
- Host range modified mutant strains
- Reduced replication capacity
- Non-colonising mutant strains
- Multiple disabling mutations
- Reversion frequency and likelihood
- Non-native animal or plant species

Microbiological Safety Cabinets
- Control of biological agents in aerosols (e.g., microorganisms, allergens)
- Class 1, 2 and 3 MSC
- Aerosols captured by airflow through cabinet
- High efficiency particulate air (HEPA) filters capture particles
- Must be located away from ventilation ducts, doors, people and safety cabinets
- Must be properly used and maintained
- Recirculating MSC exhaust air discharged into room
- Fixed ducted MSC exhaust air discharged outside usually on building roof

Class 1 Microbiological Safety Cabinet
- Class 1 MSC provides effective protection of worker but not work
- Partial containment
- Aerosols captured by drawing air into cabinet and filters
- HEPA filtered exhaust air
- Air discharged into room or outside building
- Operator and environmental protection
### Class 2 Microbiological Safety Cabinet
- Class 2 MSC provides effective protection of worker and work
- Partial containment
- Aerosols captured by drawing air into cabinet and filters
- Air passes through grills
- HEPA filtered air circulated over work
- HEPA filtered exhaust air
- Air discharged into room or outside building
- Operator, product and environmental protection

### Class 3 Microbiological Safety Cabinet
- Class 3 MSC provides maximum protection of worker and work
- Total containment
- Aerosols captured by drawing air into cabinet and filters
- Work through glove ports
- HEPA filtered intake air
- HEPA filtered exhaust air
- Air discharged into room or outside building
- Operator, product and environmental protection

### Safety Cabinets
- Check MSC is working properly before use
- Place equipment and disinfectant pot inside cabinet
- Work with sash down
- Sit looking through screen not opening
- Work in centre and not front of cabinet
- Work carefully to minimise disturbance to airflow
- Avoid generating aerosols
- Disinfect equipment and materials before removal from cabinet
- Disinfect spillages immediately
- Disinfect work surfaces after use

### Centrifuges and Incubators
- Failure of machine or equipment, or operational error may lead to breakages and spillages
- Use leakproof containers
- Use sealed buckets and rotors
- Do not open centrifuge or buckets immediately after breakage or spillage
- If necessary open tubes and buckets inside safety cabinet
- Keep clean and disinfect after spillages

### Cells, Tissues and Cell Cultures
- Assume tissues, cells and cell cultures contain pathogens and handle with caution
- Use dedicated laboratory, equipment, sealed centrifuge pots and MSC
- Use PPE
- Avoid use of sharps and generating aerosols
- Use established cell lines with history of safe use
- Never culture your own cells or those of others who could be exposed
- Disinfect equipment and surfaces after use
- Assess if biological agents could persist in products (e.g. DNA, RNA, protein, supernatants)

### Sharps Controls
- Exercise caution with sharps to reduce risks of exposure and infection
- Do not use sharps if safer alternatives exist
- Use plasticware instead of glassware
- Never resheath needles
- Store sharps safely
- Put sharps bin where sharps are used
- Dispose of used sharps immediately after use in sharps bin
- Do not push sharps into bins or overfill sharps bins
- Use PPE and cut resistant gloves
- Training and safety procedures minimise risks of accidents
**Sharps Controls**

- **Good Practice**
  - Dispose of sharps immediately after use in sharps bin
  - Take sharps bins to sharps
  - Dispose of bins on reaching level
  - Treat all biological materials as potentially hazardous

- **Bad practice**
  - Use gloves and never resheath needles
  - Never resheath needles
  - Don’t dispose of sharps in clinical waste bags
  - Don’t dispose of sharps in ordinary waste bins
  - Don’t transfer used sharps to other workers

**Personal Protective Equipment**

- Use PPE to protect yourself and other people from potential exposure
- Laboratory coats and gowns
- Spectacles and goggles
- Gloves
- Respiratory protective equipment (RPE)
  - Must be clean
  - Must be properly maintained and cleaned
  - Must be decontaminated if contaminated
  - Discarded if necessary where damaged or contaminated

**Laboratory Coats**

- Microbiological lab coats (Howie) must be worn for hazardous activities
- Wear large enough size to allow for flexibility and shrinkage
- At least two for each person so can be cleaned
- Should be clean and properly fastened
- Must be cleaned by School
- Autoclaved if contaminated with biological hazards

**Gloves and Other PPE**

- Suitable gloves must be worn for hazardous activities
- Nitrile gloves for most biological hazards
- Special gloves for biological, chemical and physical hazards
- Cut resistant gloves for work with sharps
- Laboratory gowns for animal and high risk work
- Disposable clothing (eg gowns, overalls)
- Surgical scrubs for high risk work
- Boots, shoes, aprons, visors used if risk of splashing with biological hazards

**Spectacles, Goggles and Face Shields**

- Eye protection must be worn for hazardous activities
- Suitable spectacles
- Goggles
- Face shields
- Must be clean
- Special spectacles, goggles and face shields for biological, chemical and physical hazards

**Respiratory Protective Equipment**

- RPE may be required for certain hazardous activities
- Disposable mask (FFP1, FFP2 and FFP3)
- Half or full face respirator
- Powered respirator
- Breathing apparatus
- Must be face fit tested to each individual person
- Instructions and training required
- Must be properly maintained and cleaned
Health Surveillance and Immunisation

- University Occupational Health Service provides health surveillance for occupational diseases or conditions for research workers
- Check people not harmed by exposure to biological agents
- Infection, allergy, asthma or dermatitis
- Questionnaire, interview, examination, tests and referrals
- Occupational vaccinations (e.g., HepB, yellow fever, tetanus)
- Health surveillance required for work with laboratory animals and high risk pathogens

www.safety.ncl.ac.uk

Personal Hygiene

- Never do these where you could be exposed to biological hazards
  - Eat
  - Drink
  - Chew
  - Apply cosmetics
  - Store food or drink
  - Avoid touching the face
  - Do not store personal possessions in laboratories (e.g., outdoor clothes, bags)

www.safety.ncl.ac.uk

Hand Washing

- Hands must be washed if contaminated and when work completed
- Handwash sink should be near doors
- Should operate without using hands
- Should have emergency wash hose
- Liquid soap
- Paper towels
- Handwash sink must not be used for lab work
- Emergency wash hose for cleaning eyes, mouth, skin or body in case of injury or personal contamination

www.safety.ncl.ac.uk

Storage of Biological Hazards

- Store properly to prevent accidental exposure or release of biological hazards
- Multiple containment for storing biological hazards
- Use suitable robust containers
- Label items and containers
- Do not overfill fridges and freezers
- Keep accurate records
- Dispose of unwanted material

www.safety.ncl.ac.uk

Internal Transport of Biological Hazards

- Transport properly to prevent accidental exposure or release of biological hazards
- Multiple containment for transporting biological hazards
- Use suitable robust containers
- Hazards warning signs and correct labels
- Use trolleys
- Take spill kit if necessary in case of an accident

www.safety.ncl.ac.uk

External Transport of Biological Hazards

- Complex legal requirements for carriage of dangerous goods
- Category A: High hazard infectious substances harmful to humans (UN2814) or animals (UN2900)
- Category B: Low hazard infectious substances (UN3373)
- Hazardous GMO but not infectious substances (UN3245)
- Use UN approved triple packaging containers
- Package carefully and provide documentation
- Use competent carriers (e.g., Dangerous Goods International or World Courier)
- Communicate details of shipments to recipients
- Ensure consignment is acceptable to carrier and recipient

www.safety.ncl.ac.uk
Category A Biological Hazards

- Category A (See WHO indicative list)
- WHO Guidance on transport of infectious substances
- High hazard infectious substances harmful to humans (UN2814) or animals (UN2900)
- Use UN approved triple packaging instruction containers PI620 for UN2814 or UN2900

www.safety.ncl.ac.uk

Category B Biological Hazards

- Category B
- WHO Guidance on transport of infectious substances
- Low hazard infectious substances harmful to humans or animals (UN3373)
- Use UN approved triple packaging instruction containers PI650 for UN3373

www.safety.ncl.ac.uk

Triple Packaging System

- Primary container (Robust, leakproof with seal)
- Absorbant material
- Secondary container (Robust, leakproof with seal)
- Tertiary container (Reinforced labelled cardboard box)
- Shipping documents and contact details

www.safety.ncl.ac.uk

Inactivation of Biological Agents

- Physical or chemical methods used to kill biological agents
- Disinfection and fumigation
- Autoclaving
- Validation and monitoring of effectiveness is required to prove it works
- Follow manufacturers instructions
- Effectiveness of inactivation affected by many factors (e.g., species, time, temperature, pH, concentration, humidity, organic matter)
- Problems with inactivation of mixed waste (e.g., biological agents, chemicals, radiation)

www.safety.ncl.ac.uk

Disinfection

- Disinfectant must be suitable for biological agents
- No universal disinfectant
- Narrow or broad spectrum activity
- Variable and unreliable
- Disinfectants are harmful
- Use PPE
- Dilute accurately and discard when inactive
- Disinfectant absorbent granules useful for spillages
- Check manufacturers validation of effectiveness
- Disinfection not reliable for inactivation of pathogens (e.g., autoclave)

www.safety.ncl.ac.uk
**Fumigation**

- Fumigation of safety cabinets and laboratories
- Routine and emergency fumigation procedures
- Formaldehyde or hydrogen peroxide
- Fumigants are harmful
- RPE is required
- Laboratories and MSC must be sealable for fumigation
- Fumigate only if essential
- Use safe method of venting fumigant
- Prevent exposure to fumigant and monitor levels before entering laboratory
- Validation of effectiveness required for laboratories

[www.safety.ncl.ac.uk](http://www.safety.ncl.ac.uk)

---

**Autoclaving**

- Autoclaving is most effective method for inactivating biological agents
- Standard 121°C or 134 °C for 15-30 minutes
- Validation of effectiveness using annual thermocouple testing is required
- Monitoring of effectiveness using electronic probes and recorders or chemical indicators is required
- Do not autoclave biological hazards containing radioactive or hazardous chemical substances

[www.safety.ncl.ac.uk](http://www.safety.ncl.ac.uk)

---

**Autoclave Validation and Monitoring**

- ‘All contaminated materials, including waste destined for incineration, will be inactivated by autoclaving (100% kill) prior to disposal of waste or cleaning and recycling of reusable laboratory equipment, such as glassware. Autoclaves will be validated by annual thermocouple mapping and each run will be monitored by continuous chart (or digital) recording of the temperature/time profile’

- ‘All contaminated materials, including waste destined for incineration, will be inactivated by autoclaving (100% kill) prior to disposal of waste or cleaning and recycling of reusable laboratory equipment, such as glassware. Autoclaves will be validated by annual thermocouple mapping and each run will be monitored using TST (Time, Steam, and Temperature) test strips (Albert Browne Ltd., TST class 6 emulating indicator 121°C for 20 min)’

[www.safety.ncl.ac.uk](http://www.safety.ncl.ac.uk)

---

**Waste Management**

- Biological hazards must be safely disposed using correct containers and waste route
- Clinical waste bags and bins
- Autoclave waste bags and bins
- Do not overfill waste bags or bins
- Use puncture proof, leak proof, sealable containers for sharps
- Use correct hazardous waste route for mixed wastes (eg biological agents, toxic chemicals, radiation)
- Waste must be safely handled, stored, transported and disposed

[www.safety.ncl.ac.uk](http://www.safety.ncl.ac.uk)

---

**Emergency Procedures**

- Emergency procedures must be prepared in risk assessment and standard operating procedures
- Accidental infections, spillages, release of microorganisms, animals or plants
- Workers must be able to implement emergency procedures
- Assess situation before taking action
- Inform others of accidents and isolate area or evacuate
- Seek assistance and use PPE
- Seek first aid and medical treatment if required
- Decontaminate area or laboratory
- Report accidents and incidents immediately to manager
- Complete USO accident report form

[www.safety.ncl.ac.uk](http://www.safety.ncl.ac.uk)

---

**Spillages**

- Spillage standard operating procedure
- Spillage kits and PPE
- Notify other workers and isolate area
- Evacuate lab if risk of airborne infection
- Contain spills with tissues or granules
- Cover with suitable disinfectant
- Allow sufficient contact time before clean up
- Gather debris but do not use brush
- Pick up broken glass carefully (eg forceps or swabs)
- Put debris in suitable container for safe disposal
- Disinfect contaminated surfaces and equipment

[www.safety.ncl.ac.uk](http://www.safety.ncl.ac.uk)
Personal Contamination or Injury

- Remove contaminated clothing quickly and leave in lab.
- Remove contamination from eyes, mouth and skin by washing with water.
- Minor cuts and small puncture wounds should be encouraged to bleed.
- Wash wounds with water and soap.
- Dress wounds.
- Use PPE when helping injured persons.
- Seek help if required (e.g., First aider, GP or Hospital).
- Emergencies should go to hospital.
- Call ambulance if required (Security x 6666).
- Explain incident and biological hazards to medical staff.

www.safety.ncl.ac.uk
A BioCOSHH risk assessment is required for work with biological agents and hazards. The form should be completed electronically and signed by the principal investigator. Hazard Group 2 and 3 biological agents and hazards must be registered using the Pathogen Registration form and the BioCOSHH form sent by email to the University Biological Safety Officer. The possession or use of any Hazard Group 3 biological agent or the Hazard Group 2 biological agents *Bordetella pertussis*, *Corynebacterium diphtheriae* and *Neisseria meningitidis* requires permission from the University Biological Safety Officer. Guidance on completing this form is provided in the BioCOSHH Risk Assessment section of the Safety Office website.

**Title of project**
Biochemical and immunological analysis of clinical and non-clinical strains of *Candida albicans*.

**Principal investigator / Responsible person**
Professor Alfred N. Other

**School**
School of Molecular Biology

**Date of assessment**
03/02/2010

**Location of work**
HG Building, Rooms 101, 102 and 203.

---

### Section 1 Project or Activity

**1.1: Brief description of project or activity**
We intend to use clinical and non-clinical strains of *Candida albicans* to carry out biochemical and immunological analysis to identify proteins involved in virulence of this common yeast commensal and pathogen. *Candida* strains will be cultured for the isolation of yeast proteins which will be used for gel electrophoresis, western blotting, chromatography, mass spectrometry and immunological studies.

---

### Section 2 Hazards

**2.1: Biological agents or hazards**

| Pathogens (ACDP/DEFRA Hazard Group 1) | [ENTER DETAILS HERE] |
| Pathogens (ACDP/DEFRA Hazard Group 2) | *Candida albicans* – Clinical and non-clinical strains (ACDP HG 2). |
| Pathogens (ACDP/DEFRA Hazard Group 3) | [ENTER DETAILS HERE] |
| Toxins | [ENTER DETAILS HERE] |
| Carcinogens | [ENTER DETAILS HERE] |
| Allergens | [ENTER DETAILS HERE] |
| Human primary or continuous cell cultures | [ENTER DETAILS HERE] |
| Animal primary or continuous cell cultures | [ENTER DETAILS HERE] |
| Human cells or tissues | [ENTER DETAILS HERE] |
| Animal cells or tissues | [ENTER DETAILS HERE] |
| Human blood | [ENTER DETAILS HERE] |
| Patient contact | [ENTER DETAILS HERE] |
| Animals | [ENTER DETAILS HERE] |
| Plants | [ENTER DETAILS HERE] |
| Soils | [ENTER DETAILS HERE] |
| Other biological hazards | [ENTER DETAILS HERE] |

Clinical and non-clinical strains of the yeast *Candida albicans*. Some of these are recently isolated clinical strains and others are laboratory adapted or standard type culture clinical and non-clinical strains.

---

### Section 3 Risks

**3.1: Human diseases, illnesses or conditions associated with biological agents or hazards**
Candida albicans is a common human commensal and pathogenic yeast. It can cause cutaneous, sub-cutaneous and systemic infections. Most infections are minor but it can cause serious infections particularly of individuals who are immunosuppressed or immunodeficient.

### 3.2: Potential routes of infection

<table>
<thead>
<tr>
<th>Inhalation</th>
<th>Ingestion</th>
<th>Injection</th>
<th>Absorption</th>
<th>Other</th>
</tr>
</thead>
</table>

The most significant potential routes of exposure to *Candida albicans* are from the absorption or ingestion routes, but other routes of exposure could also be significant depending on the strain and circumstances. Direct contact with the yeast can cause skin infection which could lead to peripheral or systemic infections. The risks of infection by aerosols are very low for healthy individuals.

### 3.3: Use of biological agents or hazards

<table>
<thead>
<tr>
<th>Small scale</th>
<th>Medium scale</th>
<th>Large scale</th>
<th>Fieldwork</th>
<th>Animals</th>
<th>Plants</th>
<th>Other</th>
</tr>
</thead>
</table>

We intend to use clinical and non-clinical strains of *Candida albicans* to carry out biochemical and immunological analysis to identify proteins involved in virulence of this common commensal and pathogen. *Candida* strains will be cultured in small quantities for the isolation and analysis of yeast proteins. This will involve solid and liquid culture of yeast, centrifugation, microbiological safety cabinets, microscopy, gel electrophoresis, western blotting, chromatography, mass spectrometry and immunological studies.

### 3.4: Frequency of use

<table>
<thead>
<tr>
<th>Daily</th>
<th>Week</th>
<th>Monthly</th>
<th>Other</th>
</tr>
</thead>
</table>

*Candida albicans* yeast strains will be used every day of the week.

### 3.5: Maximum amount or concentration used

<table>
<thead>
<tr>
<th>Negligible</th>
<th>Low</th>
<th>Medium</th>
<th>High</th>
</tr>
</thead>
</table>

*Candida albicans* strains will be grown in small quantities in solid cultures on petri dishes and liquid cultures in flasks and tubes of volumes up to 1 litre.

### 3.6: Levels of infectious aerosols

<table>
<thead>
<tr>
<th>Negligible</th>
<th>Low</th>
<th>Medium</th>
<th>High</th>
</tr>
</thead>
</table>

Some aspects of the culturing and handling of these *Candida albicans* strains will involve the generation of aerosols especially the liquid culture and pipetting of yeast.

### 3.7: Potential for exposure to biological agents or hazards

<table>
<thead>
<tr>
<th>Negligible</th>
<th>Low</th>
<th>Medium</th>
<th>High</th>
</tr>
</thead>
</table>

The potential for exposure to the *Candida albicans* yeast is significant since fairly large quantities of yeast especially in liquid cultures but also solid cultures are grown up and handled on the bench but the risks of harm to most individuals are generally very low.

### 3.8: Who might be at risk

*Contact the University Occupational Health Service*

- Staff
- Students
- Visitors
- Public
- Young people (<18yrs)
- *New and expectant mothers
- Other

The main risks will be to those doing the work and to other users of the lab and storage facilities.

### 3.9: Assessment of risk to human health

(Prior to use of controls)

<table>
<thead>
<tr>
<th>Level of risk</th>
<th>Effectively zero</th>
<th>Low</th>
<th>Medium/low</th>
<th>Medium</th>
<th>High</th>
</tr>
</thead>
</table>

### 3.10: Assessment of risk to environment

(Prior to use of controls)

<table>
<thead>
<tr>
<th>Level of risk</th>
<th>Effectively zero</th>
<th>Low</th>
<th>Medium/low</th>
<th>Medium</th>
<th>High</th>
</tr>
</thead>
</table>

**Section 4 Controls to Reduce Risks as Low as Possible**

### 4.1: Containment

<table>
<thead>
<tr>
<th>Laboratory</th>
<th>Animal facility</th>
<th>Plant facility</th>
<th>Other</th>
</tr>
</thead>
</table>

### 4.2: Containment level

<table>
<thead>
<tr>
<th>Containment level (CL 1)</th>
<th>Containment level (CL 2)</th>
<th>Containment level (CL 3)</th>
</tr>
</thead>
</table>


All Candida albicans strains will be handled and stored at containment level 2 (CL2).

4.3: Microbiological safety cabinets (MSC)

<table>
<thead>
<tr>
<th>Class 1</th>
<th>Class 2</th>
<th>Class 3</th>
<th>Other</th>
</tr>
</thead>
</table>

Most of the work with this yeast will be done on the bench. All work which might generate significant infectious aerosols such as where large quantities of liquid culture are handled will be carried out inside a microbiological safety cabinet. The surfaces of the microbiological safety cabinet will be disinfected with 1% Virkon after use.

4.4: Other controls

The use of sharps will be avoided unless there is no suitable alternative in which case safe work practices will be used to prevent sharps injuries which might lead to exposure to pathogens. Hands will be washed after the work activity is completed.

4.5: Storage of biological agents or hazards

All Candida albicans yeast strains and samples will be properly stored using suitable containers for microorganisms and their products. Yeast strains, samples, products and sample tubes will be stored inside suitable containers or boxes inside fridges and freezers.

4.6: Transport of biological agents or hazards

Flasks containing large quantities (1 litre) of liquid cultures of Candida albicans will be transported between the centrifuge room and the lab using a trolley and a spill kit.

4.7: Inactivation of biological agents or hazards

Disinfection | Autoclave | Fumigation | Incineration | Other

Disinfection and autoclaving will be carried out where required. All waste materials will be disposed of into the autoclave bags, yellow clinical waste bags or sharps bins as required. All used sharps will be placed immediately after use into a sharps bin. Sharps bins will be located on the bench where the sharps are used so that they can be disposed of directly after use. All Candida albicans infected waste will be autoclaved before disposal.

a) Disinfection.
1% Virkon will be used for disinfection. The surfaces of the microbiological safety cabinet will be disinfected with 1% Virkon after use. Laboratory benches will be swabbed with 1% Virkon after any activity.

b) Autoclaving.
All contaminated materials, including waste destined for incineration, will be inactivated by autoclaving (100% kill) prior to disposal of waste or cleaning and recycling of reusable laboratory equipment, such as glassware. Autoclaves will be validated by annual thermocouple mapping and each run will be monitored by continuous chart (or digital) recording of the temperature/time profile.

Or

All contaminated materials, including waste destined for incineration, will be inactivated by autoclaving (100% kill) prior to disposal of waste or cleaning and recycling of reusable laboratory equipment, such as glassware. Autoclaves will be validated by annual thermocouple mapping and each run will be monitored using TST (Time, Steam, and Temperature) test strips (Albert Browne Ltd., TST class 6 emulating indicator 121°C for 20 min).

4.8: Personal protective equipment (PPE)

<table>
<thead>
<tr>
<th>Lab coat</th>
<th>Lab gown</th>
<th>Surgical scrubs</th>
<th>Disposable clothing</th>
<th>Apron</th>
<th>Spectacles</th>
<th>Goggles</th>
<th>Face shield</th>
<th>Special headwear</th>
<th>Special footwear</th>
<th>Other</th>
</tr>
</thead>
</table>

Lab coats, disposable nitrile gloves and spectacles will be worn to carry out this work.

4.9: Respiratory protective equipment (RPE)

<table>
<thead>
<tr>
<th>Disposable mask</th>
<th>Filter mask</th>
<th>Half face respirator</th>
<th>Full face respirator</th>
<th>Powered respirator</th>
<th>Breathing apparatus</th>
<th>Other</th>
</tr>
</thead>
</table>

Not required.

4.10: Health surveillance or immunisation (If you need advice contact the University Occupational Health Service)

Not required.
4.11: Instruction, training and supervision

All workers will be properly trained and monitored by the principal investigator and suitably qualified laboratory supervisors and no worker will be allowed to work unsupervised in the laboratory until they are suitably and sufficiently trained. Training procedures, which include information on hazards and risks and control measures to be used. Copies of all risk assessments and standard operating procedures will be kept in the laboratory and reviewed regularly and immediately if there are any changes to the risks or the nature of the work.

All workers will be appropriately trained in procedures and safe work practices. All workers will be appropriately supervised until they are competent to safely perform unsupervised all aspects of the work including the emergency procedures. Access to the lab is restricted to personnel approved by the principal investigator.

The principal investigator Professor A. N. Other will carefully monitor all activities to ensure that all control measures are properly and fully implemented and all workers are suitably trained and competent to safely perform the work in the CL2 laboratory.

4.12: HSE consent or DEFRA licence

Not required for this work.

Section 5 Emergency Procedures

5.1: Emergency procedures

Spillages of any Candida albicans or any of their contaminated products will be disinfected with 1% Virkon. In the event of any injection injury or other serious accidental exposure seek first aid or medical attention if required.

5.2: Emergency contacts

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Telephone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prof A. N. Other</td>
<td>Principal Investigator</td>
<td>0191 259 4072</td>
</tr>
<tr>
<td>Dr J. G. Jones</td>
<td>Research Fellow</td>
<td>0191 259 4075</td>
</tr>
</tbody>
</table>

Section 6 Approval

6.1: Assessor

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr J. G. Jones</td>
<td>Jack Jones</td>
<td>11/02/2010</td>
</tr>
</tbody>
</table>

6.2: Principal investigator / Responsible person

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prof A. N. Other</td>
<td>Alfred Other</td>
<td>19/02/2010</td>
</tr>
</tbody>
</table>

Risk Estimation Matrix

<table>
<thead>
<tr>
<th>Severity of harm</th>
<th>Likelihood of harm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High</td>
</tr>
<tr>
<td>Severe</td>
<td>High</td>
</tr>
<tr>
<td>Moderate</td>
<td>High</td>
</tr>
<tr>
<td>Minor</td>
<td>Medium/low</td>
</tr>
<tr>
<td>Negligible</td>
<td>Effectively zero</td>
</tr>
</tbody>
</table>
A BioCOSHH risk assessment is required for work with biological agents and hazards. The form should be completed electronically and signed by the principal investigator. Hazard Group 2 and 3 biological agents and hazards must be registered using the Pathogen Registration form and the BioCOSHH form sent by email to the University Biological Safety Officer. The possession or use of any Hazard Group 3 biological agent or the Hazard Group 2 biological agents *Bordetella pertussis*, *Corynebacterium diphtheriae* and *Neisseria meningitidis* requires permission from the University Biological Safety Officer. Guidance on completing this form is provided in the BioCOSHH Risk Assessment section of the Safety Office website.

**Title of project**
Preparation of human tissues including solid tissue samples and blood samples for analysis.

**Principal investigator / Responsible person**
Professor Alfred N. Other

**School**
School of Molecular Biology

**Date of assessment**
03/02/2010

**Location of work**
HG Building, Rooms 101, 102 and 203.

---

**Section 1 Project or Activity**

**1.1: Brief description of project or activity**
We intend to use freshly isolated human tissues including solid tissue samples of all kinds and blood samples from hospital patients. None of the patients has been diagnosed as having any infectious disease. The preparation of human tissues including solid tissue samples and blood samples will involve processing blood cells and dissection of solid tissues for use in cells culture and other experiments.

---

**Section 2 Hazards**

**2.1: Biological agents or hazards**

| Pathogens (ACDP/DEFRA Hazard Group 1) | [ENTER DETAILS HERE] |
| Pathogens (ACDP/DEFRA Hazard Group 2) | [ENTER DETAILS HERE] |
| Pathogens (ACDP/DEFRA Hazard Group 3) | [ENTER DETAILS HERE] |
| Toxins | [ENTER DETAILS HERE] |
| Carcinogens | [ENTER DETAILS HERE] |
| Allergens | [ENTER DETAILS HERE] |
| Human primary or continuous cell cultures | [ENTER DETAILS HERE] |
| Animal primary or continuous cell cultures | [ENTER DETAILS HERE] |
| Human cells or tissues | Human cells and tissues from hospital patients. |
| Animal cells or tissues | [ENTER DETAILS HERE] |
| Human blood | Human blood. |
| Patient contact | [ENTER DETAILS HERE] |
| Animals | [ENTER DETAILS HERE] |
| Plants | [ENTER DETAILS HERE] |
| Soils | [ENTER DETAILS HERE] |
| Other biological hazards | [ENTER DETAILS HERE] |

Human tissues including solid tissue samples of all kinds and blood samples from hospital patients. None of the patients has been diagnosed as having any infectious disease.

---

**Section 3 Risks**

**3.1: Human diseases, illnesses or conditions associated with biological agents or hazards**
Human tissues have the potential to contain many different pathogens. Generally the most significant biological agents are the bloodborne viruses, human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV) and hepatitis D virus (HDV). These are all dangerous pathogens which can cause serious or fatal infectious diseases and cancers. HIV causes acquired immune deficiency syndrome (AIDS), while HBV, HCV and HDV can cause hepatitis, liver cirrhosis and cancer.

3.2: Potential routes of infection

Inhalation [ ] Ingestion [x] Injection [x] Absorption [ ] Other [ ] Select all that apply

The most significant potential risks of exposure to bloodborne virus pathogens are from the injection route. Other routes of exposure could also be significant depending on the specific pathogen. For example, contact with solid tissues or blood or their products could potentially result in infection of cuts by the absorption route; breathing in any infectious aerosols could potentially result in infection by the inhalation route; swallowing any solid tissues or blood or their products (eg putting contaminated fingers in mouth) could potentially result in infection of by the ingestion route.

3.3: Use of biological agents or hazards

Small scale [ ] Medium scale [x] Large scale [ ] Fieldwork [ ] Animals [ ] Plants [ ] Other [ ] Select all that apply

The preparation of human tissues including solid tissue samples and blood samples will involve processing blood cells and dissection of solid tissues for use in cells culture and other experiments. This will involve dissection of tissues, centrifugation, use of microbiological safety cabinets, microscopy and primary and continuous cell culture.

3.4: Frequency of use

Daily [x] Week [ ] Monthly [ ] Other [ ] Select one

Tissues will be processed several days per week.

3.5: Maximum amount or concentration used

Negligible [ ] Low [ ] Medium [x] High [ ] Select one

[ENTER DETAILS HERE]

3.6: Levels of infectious aerosols

Negligible [ ] Low [x] Medium [ ] High [ ] Select one

Some aspects of the handling of these tissues will involve the generation of aerosols.

3.7: Potential for exposure to biological agents or hazards

Negligible [ ] Low [ ] Medium [x] High [ ] Select one

None of the patients has been diagnosed as having an infectious disease but there is a population risk of biological agents being present in any of these samples. The most significant potential risks of exposure to bloodborne virus pathogens are from the injection exposure route. Other routes of exposure could also be significant depending on the pathogen. The highest risk activity in this work is probably the use of sharps to dissect solid tissues because of the risks of sharps injuries.

3.8: Who might be at risk (*Contact the University Occupational Health Service)

Staff [x] Students [ ] Visitors [ ] Public [ ] Young people (<18yrs) [ ] *New and expectant mothers [ ] Other [ ]

The main risks will be to those doing the work and to other users of the lab and storage facilities.

3.9: Assessment of risk to human health (Prior to use of controls)

Level of risk Effectively zero [ ] Low [ ] Medium/low [x] Medium [ ] High [ ] Select one

3.10: Assessment of risk to environment (Prior to use of controls)

Level of risk Effectively zero [ ] Low [ ] Medium/low [x] Medium [ ] High [ ] Select one

Section 4 Controls to Reduce Risks as Low as Possible

4.1: Containment

Laboratory [x] Animal facility [ ] Plant facility [ ] Other [ ] Select all that apply

4.2: Containment level

Containment level (CL 1) [ ] Containment level (CL 2) [x] Containment level (CL 3) [ ] Select one

All human tissue samples will be handled and stored at containment level 2 (CL2).
4.3: Microbiological safety cabinets (MSC)

All work which might generate infectious aerosols will be carried out inside a microbiological safety cabinet. The surfaces of the microbiological safety cabinet will be disinfected with 1% Virkon after use. The cabinet will be fumigated where a major spillage has occurred.

4.4: Other controls

The use of sharps will be avoided unless there is no suitable alternative in which case safe work practices will be used to prevent sharps injuries which might lead to exposure to pathogens. We will use the following control measures to reduce the risks of sharps accidents and injuries.

- The use of sharps will be avoided unless they are essential.
- Safe techniques will be used when using sharps. Work will be carefully planned to reduce the risks of exposure and sharps injuries.
- Alternative safety sharps will be used where it’s feasible if you can (e.g., syringes with retractable needles and scalpels with retractable blades).
- Forceps will be used to hold tissues or materials rather than gloved fingers and hands where feasible.
- Needles will not be re-sheathed.
- Blunt instead of sharp needles, scissors, and forceps will be used where feasible.
- Core borers will be used instead of scalpels where feasible.
- Personal protective equipment will be used (lab coat, gloves, specs, goggles, or face shield etc) to protect against exposure.
- Double gloves will be used.
- Kevlar or chain mail gloves will be used for all activities involving manual dissection of tissues and where feasible for all activities involving the risks of sharps injuries.
- Materials will not be held by gloved hands or fingers unless it’s essential. Forceps or clamps will be used to hold materials when cutting etc where feasible.
- The distance of the hand without the sharp will be kept as far apart as possible from the hand holding and using the sharp. This reduces the risks of a stab or cut injuries. The further apart your two hands are the less likely workers are to injure themselves in a sharps accident.
- Waste materials and used sharps will be disposed of carefully and using the correct route.
- Puncture resistant sharps bins will be used to dispose of used sharps.
- Used sharps will be disposed of immediately after use.
- The sharps bin will be taken to the sharps not the other way around. The sharps bin will be located where the sharps will be used.
- The lid onto the sharps bin must be locked in place before use and the sharps bins must not be overfilled.
- Equipment and work surfaces will be disinfected or sterilised after use as appropriate.
- Sharps will be properly stored or disposed of after use and not left lying around for other people to have an accident and injure themselves.

Hands will be washed after the work activity is completed.

4.5: Storage of biological agents or hazards

All tissue samples will be properly stored using suitable containers for all tissues and their products. Samples and sample tubes will be stored inside suitable containers or boxes inside fridges and freezers.

4.6: Transport of biological agents or hazards

Human tissue samples will be transported from the hospital to the CL2 laboratory inside a primary leak-proof container with a secure lid. The primary container will then be placed inside a cooler box fitted with a secure lid and carry handle. The primary containers and cooler box will be disinfected as required and if contaminated.

4.7: Inactivation of biological agents or hazards

Disinfection | Autoclave | Fumigation | Incineration | Other

Disinfection and autoclaving will be carried out where required. All waste materials will be disposed of into the yellow clinical waste bags or sharps bins as required. All used sharps will be placed immediately after use into a sharps bin. Sharps bins will be located on the bench where the sharps are used so that they can be disposed of directly after use.

a) Disinfection.

1% Virkon will be used for disinfection. The surfaces of the microbiological safety cabinet will be disinfected with 1% Virkon after use. Laboratory benches will be swabbed with 1% Virkon after any activity. The microbiological safety cabinet will be...
fumigated where a major spillage has occurred.

b) Autoclaving.
All contaminated materials, including waste destined for incineration, will be inactivated by autoclaving (100% kill) prior to disposal of waste or cleaning and recycling of reusable laboratory equipment, such as glassware. Autoclaves will be validated by annual thermocouple mapping and each run will be monitored by continuous chart (or digital) recording of the temperature/time profile.

Or

All contaminated materials, including waste destined for incineration, will be inactivated by autoclaving (100% kill) prior to disposal of waste or cleaning and recycling of reusable laboratory equipment, such as glassware. Autoclaves will be validated by annual thermocouple mapping and each run will be monitored using TST (Time, Steam, and Temperature) test strips (Albert Browne Ltd., TST class 6 emulating indicator 121ºC for 20 min).

4.8: Personal protective equipment (PPE)

<table>
<thead>
<tr>
<th>Lab coat</th>
<th>Lab gown</th>
<th>Surgical scrubs</th>
<th>Disposable clothing</th>
<th>Select all that apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apron</td>
<td>Spectacles</td>
<td>Goggles</td>
<td>Face shield</td>
<td></td>
</tr>
<tr>
<td>Gloves</td>
<td>Special headwear</td>
<td>Special footwear</td>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

Lab coats, disposable nitrile gloves and spectacles will be worn to carry out this work. We will use Kevlar or chain mail gloves under our disposable nitrile gloves for work involving manual dissection of solid tissues with sharps.

4.9: Respiratory protective equipment (RPE)

<table>
<thead>
<tr>
<th>Disposable mask</th>
<th>Filter mask</th>
<th>Half face respirator</th>
<th>Full face respirator</th>
<th>Select all that apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Powered respirator</td>
<td>Breathing apparatus</td>
<td>Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

[ENTER DETAILS HERE]

4.10: Health surveillance or immunisation (If you need advice contact the University Occupational Health Service)

Human tissues may contain pathogens including bloodborne viruses so HepB vaccination is required for protection against HBV and HDV. Health surveillance is required for all workers using human tissues. Because we intend to work with human tissues all workers will be offered HepB vaccination. Health surveillance and vaccinations will be carried out by the University Occupational Health Service.

4.11: Instruction, training and supervision

All workers will be properly trained and monitored by the principal investigator and suitably qualified laboratory supervisors and no worker will be allowed to work unsupervised in the laboratory until they are suitably and sufficiently trained. Training procedures, which include information on hazards and risks and control measures to be used. Copies of all risk assessments and standard operating procedures will be kept in the laboratory and reviewed regularly and immediately if there are any changes to the risks or the nature of the work.

All workers will be appropriately trained in procedures and safe work practices. All workers will be appropriately supervised until they are competent to safely perform unsupervised all aspects of the work including the emergency procedures. Access to the lab is restricted to personnel approved by the principal investigator.

The principal investigator Professor A. N. Other will carefully monitor all activities to ensure that all control measures are properly and fully implemented and all workers are suitably trained and competent to safely perform the work in the CL2 laboratory.

4.12: HSE consent or DEFRA licence

Not required for this work.

Section 5 Emergency Procedures

5.1: Emergency procedures

The following emergency procedures must be followed in the event of a spillage or personal injury or contamination with any human tissues or their potentially contaminated products.

a) Spillage procedure.
- Instructions, spills kits, PPE must be used where required.
- Instructions on laminated sheet near equipment.
- Notify other workers and isolate area (if required).
- Evacuate lab if risk of airborne infection.
- Allow aerosols to settle.
- Contain spills with tissues or granules.
- Cover with disinfectant (liquid or granules).
- Allow sufficient contact time before clean up.
- Sweep up debris gently (do not use brush).
- Pick up broken glass carefully (eg forceps or swabs).
- Put debris in a suitable container for safe disposal.
- Disinfect contaminated surfaces.

Spillages of any tissues or their products will be disinfected with 1% Virkon.

b) Personal injury or contamination procedure.
- Remove contaminated clothing as quickly as possible and leave in lab.
- Remove contamination from skin, eyes and mouth by thorough washing with water.
- Minor cuts and small puncture wounds should be encouraged to bleed.
- Wash wounds with soap and water.
- Dress wounds.
- Use PPE if required when helping injured persons.
- Seek help where required - First aid, GP or Hospital.
- Emergencies should be taken straight to hospital and call ambulance if necessary (Security x 6666).
- Explain incident and biological agents or hazards to medical staff.
- Report all accidents immediately or as soon as practicable.

The exact procedures for dealing with accidents, injuries (eg sharps injury or personal contamination) and spillages of human tissues (eg blood) or their contaminated products will be typed as bullet points on laminated A4 sheets of paper and will be placed above the main benches where the work is carried out. In the event of an accident or spillage the procedure will be immediately implemented. In the event of any injection injury or other significant accidental exposure seek medical attention immediately.

### 5.2: Emergency contacts

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Telephone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prof A. N. Other</td>
<td>Principal Investigator</td>
<td>0191 259 4072</td>
</tr>
<tr>
<td>Dr J. G. Jones</td>
<td>Research Fellow</td>
<td>0191 259 4075</td>
</tr>
</tbody>
</table>

### Section 6 Approval

**6.1: Assessor**

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr J. G. Jones</td>
<td>Jack Jones</td>
<td>11/02/2010</td>
</tr>
</tbody>
</table>

**6.2: Principal investigator / Responsible person**

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prof A. N. Other</td>
<td>Alfred Other</td>
<td>19/02/2010</td>
</tr>
</tbody>
</table>

### Risk Estimation Matrix

<table>
<thead>
<tr>
<th>Severity of harm</th>
<th>Likelihood of harm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High</td>
</tr>
<tr>
<td>Severe</td>
<td>High</td>
</tr>
<tr>
<td>Moderate</td>
<td>High</td>
</tr>
<tr>
<td>Minor</td>
<td>Medium/low</td>
</tr>
<tr>
<td>Negligible</td>
<td>Effectively zero</td>
</tr>
</tbody>
</table>