APPENDIX 3

RISK ASSESSMENT WORKSHEET FOR HANDLING HUMAN CLINICAL SAMPLES

Given the number of pathogens that might be associated with human clinical samples there is no known screening technique that can offer complete assurance that such materials are free of pathogens. Consequently protocols should be developed assuming that pathogens are present in at least some fraction of the samples being processed. While Hepatitis B, Hepatitis C virus and human immunodeficiency virus are of most concern they are in no way the only pathogens that might be present

In the laboratory setting, containment Level 2 facility design and operational standards must be in place. Care must be taken to avoid aerosol producing procedures as well as spilling and splashing when working with any of these materials. Pathogens should be presumed in/on all equipment and devices that come into direct contact with any of these materials.

It is still important to obtain as much additional information as possible about the sample before beginning work, in order to develop specific safe work practices or possibly even determine that a different (i.e., higher) containment level is required.

The following worksheet is one way of evaluating risks of handling samples from human blood, body fluids and tissues.

A. Potential Pathogen Assessment

1. Material Sample Source:
- Clinical samples ☐
- Clinical samples from individuals with a diagnosed illness/known pathogen. ☐

Please specify the illness/pathogen

- Normal Donor Pool ☐
- Tissue Bank ☐
- Other: specify

2. Unfixed Material/Sample type:
- Human blood and/or blood products ☐

Specify all in use: e.g. serum, PMNLs, platelets

- Human tissues or organs. ☐

Specify all in use e.g. lung, brain, placenta, muscle

Fixed tissues or organs ☐
Specify all in use and describe how they are fixed.

- Other - please specify e.g. nasal swabs, sputum, semen etc.

3. Numbers of samples to be used over what time period (approx.) _____
Largest amount used: _____ Typical amount used: _____

4. Have the samples been screened for any pathogens? • Yes☐ No ☐

If Yes please specify:

5. For tissue or organ samples can the material be reasonably expected to contain any characterized pathogen in addition to the typical blood borne pathogen?

• Yes ☐No ☐

If Yes – please specify:

For example if sputum or lung tissue were taken from a TB patient it might reasonably be expected that TB was present. Sputum or lung tissue from other sources might be less likely to contain TB and the answer to the question might well be no.

B. Personnel Risk Assessment:
6. All personnel working with or near any clinical materials
• Have had the recommendation to get Hep B vaccinations verbally communicated to them. ☐
• Have had the recommendation to get Hep B vaccinations verbally communicated to them and the department has a record of vaccination being received OR being declined with counselling.☐

7. Are all lab personnel working in the vicinity of the clinical samples aware of the potential risks? • Yes ☐No ☐

C. Facility Design and Operational Practices Risk Assessment Compliance
8. All work with human clinical material is conducted at Containment Level 2, the facility design and operational practices are as detailed in University Biosafety advice? See: - http://www.safety.hku.hk/homepage/pdf/PIS.pdf and section 14.

• Yes ☐No ☐

9. Will sharps be used? • Yes ☐No ☐
If YES, are you using safety engineered sharps? • Yes ☐No ☐
If not, explain:

Needle and syringe assemblies will be placed into a puncture-resistant, autoclavable sharps container with a secure lid, without attempting to clip or recap the needle

• Yes ☐ No ☐ N/A ☐

If No, explain sharps disposal procedure:
10. How and at what stage of the experiment is the infectious agent inactivated or lysed? OR What is the method of terminal inactivation?

11. Is all work carried out in a BSC? • Yes ☐ No ☐
If NO, indicate the type of procedures that will be done on the open bench and describe steps taken to reduce aerosol producing procedures, splash and spill and protect personnel and the environment.
Procedures that would increase the hazard include:
• Aerosol producing procedures including cell sorting, sonication, centrifuging in open containers, shaking or vigorous mixing or pipetting. Blending grinding, opening containers whose internal pressures may be different from ambient pressure?
• Procedures that create a splash, spill hazard
• Procedures with a sharps hazards

12. Will your experiments involve centrifugation? • Yes ☐ No ☐
If yes, are sealed rotors, or sealed centrifuge safety cups available for use ?
• Yes ☐ No ☐

13. Specify disinfectants and decontaminants and decontamination procedures in use.

Disinfectant	Working Concentration	Contact Time (min)	Preparation Frequency	Used Against

Name of assessor Position

Signature Date

Standard precautions for handling clinical samples

(adapted from the UK Advisory Committee on Dangerous Pathogens "Protection against blood-borne infections in the workplace: HIV and hepatitis" ISBN 0-11-321953-9 and INDG 342)

Protocols for the safe conduct of work should be agreed and adhered to strictly;

Each procedure should be conducted in a designated area of the laboratory with sufficient space for working safely;

A microbiological safety cabinet or other form of primary containment should be used when infected material may be dispersed by, for example, tissue homogenization, vigorous mixing etc.;

The designated working area should be kept clear of any unnecessary equipment;

Access of unauthorized persons to the working area should be prevented to ensure that the person carrying out the work is free from the risk of disturbance or accidental physical contact with others;

Protect the eyes and mouth by using a visor/goggles/safety spectacles and a mask where splashing is possible:

Cover all breaks in exposed skin by using waterproof dressings and suitable gloves;

When possible avoid use of, or exposure to, sharps such as needles, glass, metal etc. or if unavoidable take care in handling and disposal;

Consider the use of devices incorporating safety features, such as safer needle devices and blunt-ended scissors;

Control contamination of surfaces by containment and using appropriate decontamination procedures e.g. the bench surface and any equipment used should be decontaminated immediately on completion of a session of work;

Dispose of potentially contaminated waste safely.

Part of this worksheet is modified from a document produced by the University of Manitoba.