Risk assessment made under the
Control of Substances Hazardous to Health Regulations

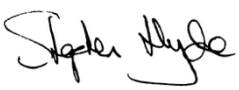
WORK WITH BIOLOGICAL MATERIAL

This form is to be used to identify the handling precautions to be adopted for biological material e.g. blood or blood products, tissues and other clinical samples, protein or RNA fractions, cell lysates, etc. Use the specific risk assessment form for naked DNA work. If the material is going to be used for genetic modification (e.g. cDNA library) an additional risk assessment is required under the Genetically Modified Organisms (Contained Use) Regulations. Guidance on risk assessment of biological agents is provided in University Policy Statement S5/09.

If the material is to be obtained from outside the UK or its use is otherwise controlled by DEFRA then advice should be sought and licences should be obtained as appropriate.

If the material is to be administered to laboratory animals an Animal Care Workers Risk Assessment must be undertaken (see UPS S5/09). Any persons handling the material who might have compromised resistance to disease for any reason should seek further advice regarding the need for additional precautions from the University Occupational Health Physician.

TITLE OF PROJECT:	Screening of NHSBT Blood Samples For Potentially Detrimental Microbes
PURPOSE OF EXPERIMENT:	To test blood donor samples for the presence of pathogens and other non-harmful microorganisms that may be present
LOCATION OF WORK:	Nuffield Department of Clinical Laboratory Sciences, Academic Block, Level 4, John Radcliffe Hospital, Headington, Oxford, OX3 9DU

Supervisor (PRINT): Heli Harvala **Signature:**  **Date: 10/02/2026**	**Assessed by (if not Supervisor) (PRINT): Shannah Secret** **Signature:** Shannah Secret **Date: 03/02/26**
Work approved by (Biological) Safety Committee: YES **Biological Safety Officer: Prof Steve Hyde** **Signature:**  **Date: 2nd June 2026**	**Permission granted by HoD for work to commence (if required): YES** **Head of Department: Prof Deborah Gill** **Signature:**  **Date: 18th June 2026**
Persons involved: Members of the NDCLS/RDM Heli Harvala Laboratory: Shannah Secret Heli Harvala Jaid Debrah Piya Rajendra Vidushi Chugh	

NATURE OF MATERIAL: The material is plasma and cord blood products from NHSBT that have been screened and are negative for HEV/HIV/HBV/HCV. There are some known samples that are positive for Treponema pallidum	
FULL NAME OF SOURCE ORGANISM: Including species, subspecies, strain	Human
HAZARD GROUP OF SOURCE ORGANISM (For micro-organisms):	
Is source organism pathogenic or is material a potential/actual host to pathogenic organisms?	YES
HAZARD GROUP OF CO-PATHOGENS (e.g. For micro-organisms or zoonotic agents in animal or human tissue):	All human samples potentially carry co-pathogens therefore potential risk up to HG3. But source of samples is from healthy donors from blood service and therefore low risk. Some of the samples are known to contain Treponema pallidum (HG2)
If pathogenic can material be biologically inactivated before use? (e.g. Pasteurization for Mycobacterium)	No
If material is pathogenic and cannot be inactivated does it pose an infection risk?	Yes
If infection risk is posed, specify consequences of infection(s) (severity and type or illness caused):	The samples are from healthy blood donors and are already screened negative for HIV, HEV, HCV, HBV. The presence of other infections is possible. Infection with Treponema pallidum can cause syphilis, a chronic systemic disease. Early stages involve painless ulcers (chancres) and rash; untreated infection may progress to latent and tertiary syphilis with severe complications including neurological (neurosyphilis), cardiovascular damage, organ failure, and congenital infection in pregnancy.
IS THE MATERIAL OR THE CO-PATHOGENS PATHOGENIC TO ANIMALS?	No
IS THE MATERIAL OR CO-PATHOGENS ON THE LIST OF SPECIFIED ANIMAL PATHOGENS ORDER?	No
ASSIGN DEFRA HAZARD GROUP	NA
If pathogenic to animals please contact University Biological Safety Officer for further advice as different licences may be required.	
Is the material or co-pathogen listed on Schedule 5 of ATCSA?	No
Route(s) of infection:	Percutaneous
Can material from a less hazardous source be used?	No
If yes, why not use it ?	
Are there any other hazards of the material or its preparation?	No
If yes identify type:	

CONTROL MEASURES:	
Containment Level:	2
Additional precautions: - Wear gloves. at all times - Avoid use of sharps - Use microbiological safety cabinet for aerosols - All material to be handled in microbiological safety cabinet - Centrifugation - Vortexing - FACS Other (specify) **- Good microbiological practice:**	 YES YES YES YES NO NO NO NO YES

LABORATORY / EXPERIMENTAL PROCEDURES (typical volumes, frequency of use, etc.):

Blood/plasma samples (typically 5-10mL) previously screened negative for HEV/HIV/HBV/HCV are stored in a commercial DNA/RNA stabilisation buffer designed to inactivate infectious agents such as viruses, bacteria, fungi & parasites (e.g. Zymo DNA/RNA Shield or similar https://zymoresearch.eu/pages/molecular-transport-media-mtm).

DNA and/or RNA is extracted from (typically 200 µL) aliquots of said blood/ plasma samples using a commercially available DNA extraction kit (e.g. Zymo Quick-DNA/RNA Viral Kit / Viral 96 Kit or similar- such kits use guanidinium based extraction buffers and ethanol washes that render the extract pathogen free). The extraction protocol will follow the manufactures instructions. Nucleic acid samples are stored frozen in aqueous buffers (e.g. water/TE buffer or similar).

Nucleic acid detection assays (typically 5-20µL) are performed using said extracted DNA/RNA samples to detect Treponema pallidum or similar pathogens (methods include but are not limited to PCR, qPCR, ddPCR, methods may include analysis of both DNA and/or RNA). Other standard laboratory analytical techniques (e.g. determination of nucleic acid content may be performed as appropriate).

MOST LIKELY & WORST CASE SCENARIO. INDICATE MITIGATING CONTROLS:

In the worst-case scenario, the most likely risks are from percutaneous infection by: **Treponema pallidum**. This is the infection commonly known as syphilis. The symptoms of syphilis are not always obvious and may eventually disappear, but infected individuals usually remain infected unless they are treated. Some people with syphilis have no symptoms. Symptoms can include: small, painless sores or ulcers that typically appear on the penis, vagina, or around the anus, but can occur in other places such as the mouth, a blotchy red rash that often affects the palms of the hands or soles of the feet, small skin growths (similar to genital warts) that may develop on the vulva in women or around the bottom (anus) in both men and women, white patches in the mouth, tiredness, headaches, joint pains, a high temperature (fever) and swollen glands in your neck, groin or armpits. If it's left untreated for years, syphilis can spread to the brain or other parts of the body and cause serious long-term problems.

In the likely-case scenario, T. pallidum is rendered inactive by cold storage. Syphilis is not considered to be a major risk to transfusion recipients in the UK and other services where cold storage is utilised for a longer period [Jayawardena T, Hoad V, Styles C, Seed C, Bentley P, Clifford V, Lacey S, Gastrell T. Modelling the risk of transfusion-transmitted syphilis: a reconsideration of blood donation testing strategies. Vox Sang. 2019 Feb;114(2):107-116; PMID: 30565234]. In addition, any infectious agents in the primary blood samples are inactivated via the use of the commercial DNA/RNA stabilisation buffer at the point of sample collection. Such reagents are specifically designed to minimise the risks from the adventitious agents described.

Mitigating controls: PPE will be worn when handling blood products. Blood products will be handled in a Biological Safety Cabinet. All waste will be disinfected with 2% Virkon solution. No sharps will be allowed or used in the area this work is taking place. Workers will be adequately trained in good microbiological practice.

Mitigating controls: all the samples have been screened and are negative for blood borne pathogens (HEV, HIV, HBV, HCV) and deemed very low risk.

DISINFECTION PROCEDURES:

In the laboratory, used equipment will be immersed in a suitable disinfectant (2% virkon) before cleaning or disposal. Disinfectants will be used in accordance with the departmental disinfection policy. Examples of suitable disinfectants include hypochlorites and Virkon. Use of 70% alcohol is not recommended.

At the start and end of the procedure, the cabinet will be cleaned using 2% Virkon and then surfaces will be wiped with 70% alcohol.

In addition all surfaces will be disinfected immediately following any spillage, at the end of the working day and before any maintenance or cleaning staff are permitted to work in the area where work with blood or blood products has been carried out. Permanent cleaning or maintenance staff will be trained in the correct procedures and non-technical visitors will be instructed in the work to be carried out and, where any hazard may be present, suitably supervised.

EMERGENCY PROCEDURES:

For spillage in Class II Biological Safety Cabinet, assess based on volume of spillage.

For small spills (<1ml): Stop the work and immediately clean up with 2% Virkon followed by 70% IPA/Ethanol.

For larger spills (>1ml): Stop the work. Keep the cabinet running. Ask for support if you think you would like support cleaning up. Decontaminate by liberally adding Virkon granules (or equivalent) to the spill (do not use Virkon solution as this will increase the volume of spill). Allow 10 minutes contact time for the granules. If virkon granules are not available place enough dry paper towel(s) over the spill to mop up all of the spill, then spray the towel with 2% virkon solution and allow 10 minutes contact time. Clean up the Virkon treated spill with disposable tissue/paper towel and then wipe surfaces with 70% alcohol.

WASTE DISPOSAL PROCEDURES:

All contaminated waste must be disposed of safely. Local rules must specifically state laboratory procedures and arrangements for disposal of contaminated materials. All contaminated equipment, surfaces, protective clothing etc should be decontaminated after use.

STORAGE: Samples will be stored in NDCLS laboratory 4A10 located at below address;
Nuffield Department of Clinical Laboratory Sciences,
Academic Block, Level 4
John Radcliffe Hospital,
Headington, Oxford,
OX3 9DU
They are stored in the Harvala -70 degree freezer clearly labelled with the contents and a biohazard sticker

ADDITIONAL INFORMATION: (Please consult University Policy Statement S5/09 if handling human blood, blood products or tissues)

We will follow "University Policy Statement S5/09" and "Handling Precautions For Laboratory Work With Blood, Blood Products And Other Human Tissues (AT Handling prec Blood)"

HEALTH SURVEILLANCE All workers must register with the University Occupational Health Service when working with human and primate samples. Vaccination may be offered.

VACCINATION(S):

Is an appropriate vaccination available? NO

Will it be offered? NO

If "no" why not?

Additional controls may be required if the following techniques are being used as part of this project (highlight):

Generation of aerosols: ~~Centrifugation~~ ~~Sonication~~ Mixing ~~Vigorous pipetting~~ ~~Any other action generating splashes or aerosols~~	Wear appropriate eye protection (spectacles, goggles, visor) Use microbiological safety cabinet. ~~Implement any other necessary controls (list):~~

Dissection - ~~Use of syringe needles~~ ~~Use of other sharps or glass~~	N/A
Consider all other potential routes of infection: Not applicable	**Implement appropriate controls:** Not Applicable