Rules for the handling of blood and other human sample materials

Ref. No 1–505/2022

Valid from 2022-06-28

Karolinska Institutet

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CONTENTS

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With support from 2 chapter, 5 § in the Swedish higher education act (1992:1434) the following is stipulated:

1 Introduction

In the Swedish Work Environment Authority regulations (AFS 2018:4) and general advice regarding risks for infection, there are certain requirements for work with materials with risks for infection and for work where there are risks for exposure to body fluids from humans or animals. These regulations constitute a compilation of the Karolinska Institutet requirements for handling blood and other human sample materials, which safety measures that must be applied and how they shall be implemented. The main principle for these rules is that all blood and blood-contaminated materials must be considered contagious and in biosafety level 2 (BSL-2).

2 Responsibility

The research group leaders and the heads of unit must ensure that employees that are active in the laboratory are trained regarding risks for infection and on how to avoid risks how infections spread, about which protective measures that can be used, what measures that can be used in case of an unwanted incident, and also training regarding additional hygiene measures.

3 Definitions

Definition of ”human blood”	Human blood (whole blood/buffy-coat) also refers to blood products/tissues that have been in contact with blood/blood products that have not been inactivated for infectious agents. Thus, also blood plasma/serum, sputum, primary cells, brain tissue etc, and all laboratory materials, such as pipet tips and needles that have been in contact with these. The rules also include blood, and materials contaminated with blood, from monkeys. When microorganisms from blood are propagated, the rule for each microorganism apply, see AFS 2018:4. See a separate document regarding handling of materials from animals in general (animal biproducts)
Cell cultures	Cell cultures are also included in these rules, if they are of a primary nature and from humans or monkeys.
A permit for handling blood is not required	There is no requirement for a permit for handling blood, under condition that you do not enrich for or grow microorganisms from the sample. The laboratory does not have to be reported to the work environment authority. However, the handling of blood is regulated, and the requirements for handling blood are described in this document and in AFS 2018:4.
Requirements for	The laboratory should be classified at biosafety level

the premises	2 (BSL-2) or higher, depending on the risk assessment. For information on BSL-2 requirements, see[1].
Risk assessment	The responsible manager is responsible for the investigation and assessment of risks for ill health and accidents. The risk assessment is carried out together with laboratory staff with competence in the area, and a safety officer should be given opportunity to participate. It is recommended that the risk assessment is carried out using the risk assessment form HUMRA[1].
Written instructions	There must be written instruction regarding how the blood should be handled. The written instructions must be based on a risk assessment. The handling instructions must at least contain: • Where the work can be carried out, • Who is responsible, • Who can work with the blood (how new staff members are trained regarding risk for infection, routes of infection, how to avoid risk and protective measures, including vaccination prior to starting work), • Risks involved for the particular samples, description of the methods, and which steps has the greatest risks, • Choice of protective equipment (technical tools that are relevant for the work and personal protective gear, in order to prevent cuts and puncture wounds, as well as skin and mucosal exposure), • Which routines that should be implemented, such as particular hygiene measures (see AFS 2018:4) /cleaning/disinfection/routines for leaving the laboratory, • Handling of solid and liquid waste • incident/accident-procedures, including contact information, • procedures for transports within and outside KI, • Other staff that may need to be informed, and how the information should be relayed.
Who can work with blood	The work can only be performed by staff that have received training on risks for infection and how to avoid them, routes of infection, protective measures, actions in case of unwanted events and particular hygiene measures. Laboratory staff must also be informed of the local protective measures through the written measures that must be available for handling blood. At Karolinska Institutet, everyone that handles blood should be offered vaccination against Hepatitis B.[1]
Work technique	In general, particular hygiene measures, according to

and hygiene	AFS 2018:4, are in place when handling blood. Briefly, the laboratory worker must avoid the formation and spread of aerosols, as well as spills and splashing, and the use of integrated safety measures when sharp objects are used. Large amounts of aerosols are formed when liquids are poured from one vessel to another, and this must therefore be avoided, or be performed in a microbiological safety cabinet. All materials and all surfaces must be disinfected after work is ended, and the hands of the worker should be disinfected.
Waste management	The waste is classified as infectious according to Karolinska Institutet waste regulations. Briefly, fluids/materials cannot be placed in the drain or household garbage without prior inactivation using a verified method. The waste containers for sharp objects must be secure regarding penetration of sharp objects and they cannot be reused. According to paragraph 15 of AFS 2018:4, a fine of 150 000 SEK must be paid if such a container is not in use while using sharp objects that have been in contact with blood or other human sample materials.
Handling spills	It must be taken into account that viruses in dried serum can remain infectious for several days. In case om smaller spills, 70% ethanol or 45% isopropanol + tensid (DAX Ytdesinfektion Plus) can be used. In case of larger spills, an oxidant, such as bleach or virkon, must be used, since blood has a buffering effect. Please note that bleach/virkon is classified as hazardous waste according to the KI waste management rules.
Accident/first aid	Splashing into eyes/mouth/mucosas: Rinse abundantly using an eye wash fountain or sterile saline solution, preferably, alternatively, tap water can be used. Remove any contact lenses and rinse again. Puncture/cut, and skin exposure: Wash immediately using large amounts of soap and water, followed by disinfection using hand sanitizer or 70% ethanol. If there is a suspicion of exposure to blood contagions, the immediate supervisor should be informed at once. Also, the KI occupational health service should be contacted during their office hours, or the infection clinic at the Karolinska Hospital, outside regular office hours.
Accident/ work related injury	Immediately contact the KI occupational health service in case of a puncture wound or cut with exposure to blood or other human sample material, in order to take a test at time zero. Report the incident to the immediate supervisor/other responsible person, who, after possible consultation with the KI occupational health service, will determine whether the incident should be reported to the Swedish work environment authority as a workplace injury, or only

	be reported to the internal KI incident reporting system. In case of a puncture wound or cut with a known contagion or where there is a strong suspicion of infection in blood or other human sample material, the research group leader or head of unit must immediately report this according to the routine for reporting incidents at KI.
Transport	This type of samples should be transported as "Biological substance, category B, UN 3373" or alternatively, "exempt medical sample" when it is transported outside the respective campus.[1]

Personal protective equipment and technical equipment

Protective clothing	A lab coat must be used. The coat must not leave the work area. If the coat has been contaminated or if there is a suspected contamination with blood, it must be decontaminated before it is submitted for washing, for example by autoclaving.
Protective gloves	Gloves must be used for protection against exposure with all handling of blood. Hand washing and hand disinfection must always be performed after the gloves are removed. The disinfectant destroys the protective qualities of the glove. The choice of gloves must be adapted to the work task and the exposure level. Gloves suited for laboratory purposes and blood handling must be used (marked SO 374-5:2016 virus).
Spray protection	Protective goggles and a protective mask/visor must be used when there is a risk for aerosol formation or spray. A plexiglass shield or a microbiology safety cabinet may be used as alternative spray protection.
puncture/cut protection	Sharp objects, such as needles, razor blades and sharp glass objects should be avoided as much as possible while handling blood. Sharp objects should be equipped with a functioning integrated safety function, if such a product has been developed for this purpose and is available on the market. If this product is not available, other available products that reduce the risk for punctures/cuts, such as blunt needles, should be used. If a needle is used, the sheath for the needle must never be put back on the needle. Instead, the exposed needle should be placed directly into the container for sharp waste (preferably using a needle remover).

Hepatitis B **Hepatitis C**	Hepatitis B infection constitutes the greatest risk when handling blood. It is estimated that there is a 6-30 % risk to be infected after an inoculation with Hepatitis B positive blood. Laboratory workers that may be exposed must therefore be offered a pre-exposure vaccination. The Hepatitis B vaccine is offered for free via the KI occupational health service. There is no vaccine or post-exposure prophylaxis against Hepatitis C. There is an estimated 3% risk of infection after an inoculation with Hepatitis C positive blood.
HIV	There is no vaccine against HIV, but post-exposure treatments are available. There is an estimates 0.3% risk of infection after

	an inoculation with HIV-positive blood.
Other risks for infection	Hepatitis D and G, HTLV1 and 2 and other viruses, and also bacteria, parasites, prions, misfolded protein aggregates and unknown contagions may constitute risks.