

Serum Banking Policy *For Research and Support Staff*

Introduction and Rationale

Serum banking is the collection and frozen storage of serum samples obtained from employees who may be at risk for an occupationally acquired infection. Serum is the protein-rich liquid that separates out when blood changes to a solid or semisolid state (coagulates). The purpose of serum banking is to assess whether there was exposure to a research agent by providing the ability to compare serum obtained after an acute illness or exposure with serum obtained before the illness or potential exposure.

The National Institutes of Health and the Centers for Disease Control and Prevention require serum banking for employees who work with specific biological agents. [Biosafety in Microbiological and Biomedical Laboratories](#), published by the US Department of Health and Human Services, states in the 5th edition, Section VII, that employers should consider collecting and storing serum when occupational exposure to human pathogens is a risk.

The University has three levels of serum banking requirement:

1. For work with most biological agents, serum banking is neither required nor offered.
2. For work with some biological agents (e.g., *Coxiella burnetii*), the UW Employee Health Center (EHC) must offer serum banking, but employees are not required to participate in order to work with those agents.
3. For work with a select few biological agents (e.g., highly pathogenic avian influenza virus), serum banking is required for all employees (research and support staff) who work with or may be exposed to the biological agent. University employees may not work in areas where these agents are in use unless they participate in serum banking.

Determination of which biological agents include required or offered serum banking is made after review of the research protocols by the EH&S Biological Safety Program staff, EH&S EHC medical staff, and the University's Institutional Biosafety Committee (IBC), and in consultation with the principal investigator or supervisor. The University conducts serum banking only when: (1) it is required by federal regulations or suggested by evidence-based occupational health practice standards; and (2) there is a plan to analyze the data as part of a risk assessment strategy.

When serum banking is required or offered, it becomes part of the medical management protocols for that biological agent. The cost of serum banking is charged to the budgets of research projects with employees who participate in serum banking.

Protocols for Collecting and Storing Serum

The following steps are taken to collect and document the serum collection:

1. The serum is collected at the EH&S Employee Health Center (EHC) during the preplacement medical evaluation before the employee works with or near the biological agent.
2. Before the sample is drawn, the EHC occupational health nurse reviews the serum sample consent form with the employee and answers any questions.
3. Serum specimens are labeled with an EHC lab number and are logged into the UW Medical Center (UWMC) laboratory database.

The University takes the following measures to ensure all collected serum is properly stored:

1. The serum is labeled and stored in a locked -70° Celsius freezer in the UWMC.
2. The EHC has a key, and a back-up key is located in an office in the Warren G. Magnuson Health Sciences Center.
3. The freezer is monitored by alarm system. If the temperature is too high, an alarm notifies the alarm system company, which notifies UWMC Engineering.
4. If UWMC Engineering determines there is a problem with the freezer, the EHC manager is notified.

Ownership and Use of the Serum

The stored serum is the property of the University of Washington. The University uses the following protocols to ensure stored serum maintains its integrity and is used for only the purposes for which it was collected:

1. The stored serum is used solely for occupational health purposes related to the employee's participation in the biological research for which the serum was originally collected.
2. The serum sample results, if tested, become part of the employee's confidential medical record maintained by the EH&S Employee Health Center.
3. Serum is destroyed after 10 years or sooner if the study is complete. If the study continues for longer than 10 years, a new baseline serum sample will be collected.
4. To destroy serum, it is autoclaved and disposed in the manner required by applicable health and safety regulations.

Employee Consent for Serum Sampling

Serum banking is required for employees with the potential for direct contact with Risk Group 3 influenza viruses (e.g., H5N1). This NIH requirement applies to those who: work directly with the agents; work with animals experimentally challenged with the agents; enter research laboratories working with influenza viruses; are present when agents are being worked with/handled in the lab; and perform biohazard waste collection and handling. Please refer to the UW Serum Banking Policy in the Institutional Biosafety Manual for additional information on serum banking.

Baseline serum samples for all at-risk employees will be collected and stored in accordance with the University's Serum Banking Policy. The samples will be stored for at least the time period you work with the agent at biosafety level 3 containment or 10 years, whichever is greater. After that time period your serum sample will be disposed. Serum obtained will be labeled and stored in a locked, -70° Celsius freezer at the UW Medical Center. The freezer is monitored by a temperature alarm system to maintain the integrity of the sample.

UW may test your serum, only as deemed professionally necessary or advisable relative to potential hazardous occupational exposures. Your serum will not be used or tested for any other purposes. Results of the tests become part of your confidential employee health medical record, which is maintained at the UW Employee Health Center and can be released only with your written permission.

I, _____ (printed name of employee), a UW employee, hereby grant permission to the UW occupational health nurse or lab medicine employee to collect a baseline blood sample and additional samples as deemed appropriate following an occupational exposure.

CONSENTING employee's signature

Date