

III-29. SERUM STORAGE PROGRAM

- I. Purpose: this voluntary program permits NIH employees who may be exposed to biological hazards at work to store serum for potential future reference.
- II. Eligibility: Participation in this program is optional for NIH employees who:
 - A. Work with human pathogens.
 - B. Work with human or nonhuman primate blood or body fluids.
 - C. Work with animals.
 - D. Have patient contact.
- III. Relevant Occupational Medical Service (OMS) Procedure Manual Sections
 - A. Preplacement Medical Evaluation. Chapter III, Section 24
 - B. Nonhuman Primate Body Fluid Exposures. Chapter III, Section 17
 - C. Occupational Injuries and Illnesses. Chapter III, Section 19
 - D. Animal Exposure Program. Chapter IV, Section 2
- IV. Attachments
 - A. Serum Storage Program Overview. Attachment I
- V. Identification of Eligible Employees
 - A. Supervisors identify employees:
 - 1. By indicating work responsibilities for position applicants as part of the preplacement medical evaluation on the Medical Qualification Determination Questionnaire (NIH 750-3).
 - 2. By completing a Human Pathogen Registration Form.
 - B. OMS clinicians offer enrollment in the program to workers who:
 - 1. are named on a Human Pathogen Registration Form and
 - 2. report occupational injuries that involve a potential exposure to a human pathogen, human or nonhuman primate body fluid, or a animal used in research.
- VI. Obtaining the Blood Sample
 - A. Eligible workers are provided with an overview of the serum storage program and invited to donate a 7.5 ml blood sample during as part of the preplacement medical evaluation, after being identified on a Human Pathogen Registration Document, or at the time of an injury involving a human pathogen, human or nonhuman primate body fluid, or an animal used in research.
 - B. Additional blood samples are not collected at regular intervals.
- VII. Storage Procedure

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- A. The serum is separated from the blood sample and divided equally and stored in two 2 ml vials.
- B. The serum samples are assigned a single number and stored at -20 degrees Centigrade in a non frost-free freezer.
- C. Serum samples are retained for ten years.
- D. Samples that are more than ten years old are discarded.

VIII. Access to Serum Samples

- A. Employees may retrieve their stored serum by signing a medical release.
- B. NIH investigators may petition the OMS Medical Director for access to stored sera.
 - 1. A request for a selected employee's serum sample(s) must be accompanied by the appropriate signed medical release from the involved employee(s).
 - 2. A request for grouped sera must be approved by the Director, Division of Occupational Health and Safety. The request must be accompanied by:
 - a. An assessment of the scientific merit of the request by the appropriate Institute peer review group.
 - b. An assessment of the human subject requirement by the Institute Review Board, if applicable. Serum will not be released to investigators involved in such studies if doing so would exhaust the stored serum for any individual employee.
 - 3. Employees and NIH investigators who are provided serum samples from the collection are requested to supply information related to the testing of the serum (see VIII B1).

IX. Medical Records

- A. Samples obtained between January 1, 1992 and December 31, 1995 are manually indexed in two separate filing systems:
 - 1. The first system is indexed by accession number and contains the employee's name and social security number.
 - 2. The second index system is alphabetically arranged by employee's name and also contains the:
 - a. Employee's social security number.
 - b. Employee's date of birth.
 - c. Date the samples were obtained.
 - d. Sample numbers.
 - e. Reasons for storing the serum.
- B. Samples obtained after January 1, 1996 are entered into the OMS computer Labs and Procedures module. The program generates a single accession number for each blood sample and the associated serum samples.
- C. A central manifest (log book) is maintained recording the date that serum was sent to the storage facility, the box number containing the serum, the serum

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sample accession numbers contained in the box and comments related to the samples contained in the box.

- D. The following information is included in the comments section of the central manifest when serum is removed from storage:
- E. Identifying information for the individual receiving the serum (name, address and telephone number).
 - 1. Date the serum is released.
 - 2. The reason the serum was removed.
 - 3. The test results.
 - 4. The test methodology.

Serum Storage Program

- You are encouraged to enroll in the Serum Storage Program, if you are a NIH employee and you work with any of the following:
 - Human pathogens,
 - Human or nonhuman primate body fluids,
 - Patients, or
 - Animals used in research,
- Reference sera may be useful as part of an investigation of a possible work-related infection. Such investigations occur very infrequently.
- If you elect to participate in the program, you will be asked to donate approximately one tablespoon (30 ml.) of blood. An OMS technician will separate the serum from your blood and assign a unique identifying code number to the sample.
- Your serum will be tested only with your permission.
- Your serum will be retained in a non-frost-free freezer for ten years. After ten years, your serum will be discarded.

If you have any questions or concerns regarding this voluntary service, please discuss them with an OMS healthcare provider.