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STANDARD OPERATING PROCEDURES (SOP) Serum Surveillance Program

1. Scope

The University of Pittsburgh offers faculty, staff, students and other individuals with potential exposure to specified infectious agents in the research environment the opportunity to obtain information about their serum status upon hire and to voluntarily undergo testing to determine their serum status against certain agents on an ongoing basis at no charge to the individuals.

2. Purpose

To provide serologic monitoring for antibodies or to provide other diagnostic tests for specified infectious agents used in the participants laboratory area or research area for which there is a licensed test that is commercially available. Medical monitoring is conducted to provide updated epidemiologic and medical information in conjunction with information on identifying potential worksite exposures to specified agents.

3. Procedures

3.1 Agents

- 3.1.1 Agents included in the Serum Surveillance Program are those that have a commercially licensed test and for which there is sufficient exposure risk to warrant testing. Examples of such agents used at the University are HIV-1, HIV-2, HTLV-1, HTLV-2, SIV, and F. tularensis.
- 3.1.2 To have a potentially infectious agent included in the University of Pittsburgh Serum Surveillance Program a written request should be made to the University Department of Environmental Health and Safety.
- 3.1.3 All proposed alterations will be forwarded to the University Biohazards Committee for discussion and approval.
- 3.1.4 Exceptions can be made by the University Biohazards Committee to the requirement that the diagnostic test be licensed and commercially available, if the diagnostic test is conducted by a nationally recognized institution (eg. CDC).

3.2 Individuals at risk

Individuals with significant potential exposure to naturally or experimentally infected laboratory animals, and individuals with significant potential exposure to specified agents

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in the research environment are eligible. Significant potential exposure is typically defined as manipulation or direct handling of infectious agents, materials or animals.

3.3 Procedures

- 3.3.1 All principal investigators using infectious agents included in this Program must offer all individuals with significant potential exposure the opportunity to participate in the University's Serum Surveillance Program. Department Directors or Chairmen who have staff members with significant potential exposure to specified agents or research animals known to have been infected with specified agents also must notify staff of the availability of the Serum Surveillance Program.
- 3.3.2 Notification of this Serum Surveillance Program shall occur upon hire, and with the employee's consent, a voluntary baseline serum sample will be collected and tested. Collection should occur prior to any exposure to the specified agent in the workplaces of the University of Pittsburgh. Testing of the collected sample will occur expeditiously and the University will not retain an individual's serum (serum banking).
- 3.3.3 Those faculty and staff who work with specified agents for which there is a commercially available test or one which is available from nationally recognized source can voluntarily participate in the Serum Surveillance Program.
- 3.3.4 All serum samples submitted to the University's Serum Surveillance Program will be encoded with a unique and confidential sample identification number (SID). The linking of the SID with the participant's name can only be performed by the medical director or clinical designee from the University-appointed employee health program. The University strictly protects the privacy of participants by withholding their name and other identifying information from all persons not directly connected with the conduct of the University's Serum Surveillance Program.
- 3.3.5 Faculty and staff participation in the University Serum Surveillance Program in no way affects or compromises the employee's ability to receive appropriate and prompt post-exposure evaluation, treatment, or if indicated, prophylaxis. Human retrovirus exposure is well defined in the University Bloodborne Pathogen Exposure Control Program and all reported exposures are evaluated and treated at Employee Health Services.
- 3.3.6 Test results are sent by the medical director or clinical designee to the faculty or staff member's self-designated address in confidence and in timely fashion (no more than three weeks).

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- 3.3.7 Failure to consent to a baseline serum sample or to annual serum surveillance shall have no consequence on the employee's standing or function at the University of Pittsburgh.
- 3.3.8 All participants are advised prior to consent that under State of Pennsylvania Law, the credentialed physician (i.e. University Medical Director) is required to notify Allegheny County Health Department and the State of Pennsylvania of all participants identified as HIV positive via serum surveillance.
- 3.3.9 All participants who are notified in confidence of a positive result shall be offered appropriate counsel, evaluation and available treatment through the University-appointed employee health program.
- 3.3.10 Any positive test result indicating a possible occupational sero-conversion will be reported by the University Employee Medical Director to the Principal Investigator and to EH&S without divulging the employee's name. EH&S in conjunction with the PI will perform a comprehensive review of practice in the laboratory.
- 3.3.11 All Serum Surveillance Program samples are to be collected, prepared for analysis and reported to faculty and staff by the University-appointed employee health program. The University appointed employee health program is currently managed through MyHealth@Work, Medical Arts Building, 3708 Fifth Avenue, 5th Floor, Suite 505; phone: 412-647-4949 or Schedule an Appointment Online.

4 APPROVAL

The University of Pittsburgh's Biohazards Committee and EH&S have reviewed and approved this SOP as attested by the signatures of the Committee Chairperson and the University Biosafety Officer.