

Standard Operating Procedure Immunization and Surveillance	
SOP Number: <u>SOP-IS-02</u>	Category: <u>Lab Process</u>
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	Pages: <u>1 of 2</u>
Issued by: Director, Health Sciences Research	

1.0 POLICY

Users of the W.J. Henderson Centre for Patient-Oriented Research (WJHCPOR) will ensure that they have undergone required screening for immunity to certain infectious diseases prior to conducting clinical research, including clinical trials, for their health, safety and well-being. Screening will be carried out as part of the credentialing process for all users obtaining a Research Hospital Appointment (non-hospital employees) for the first time and for all new hospital employees. Documentation of communicable disease health clearance is required for all users when research hospital appointments or hospital employment exceed ninety (90) days.

2.0 PURPOSE

To prevent the transmission of infectious, communicable diseases among users of the WJHCPOR with research participants, visitors, volunteers, and Kingston Health Sciences (KHSC) employees.

3.0 RESPONSIBILITY

Oversight of the immunization and surveillance program is the responsibility of KHSC's Medical Affairs Office for all users who hold Research Hospital Appointments and KHSC's Occupational Health & Safety Department for all users who are hospital employees. Where exposure to infectious, communicable diseases occurs in the WJHCPOR, KHSC and/or Queen's University (Queen's) will provide occupational health & safety services to manage any exposure through screening, treatment and counselling, facilitate post exposure surveillance, and promote the timely return to suitable work (if applicable). See "Accidental Occupational Exposure and Reporting Workplace Incidents" SOP.

4.0 PROCEDURE

Users of the WJHCPOR must provide documentation of the following communicable disease health clearance requirements to the appropriate oversight body prior to conducting clinical research, including clinical trials, within the WJHCPOR:

IMMUNIZATIONS	REQUIREMENTS	ONGOING REQUIREMENTS
Tuberculous (TB) Screening	A baseline 2-step TB test is required. This involves 2 skin tests performed 1 to 3 weeks apart. If, however one of the following applies, only a single TB test is required: a previous 2 step TB test or a negative 1 step TB test within 12 months. Where only a single TB test is required, it must have been performed within 3 months of a user's start date. For individuals with previous positive TB test, a chest x-ray within 2 years is required along with a symptoms screen.	For users in the following areas of KHSC, an annual TB screen is required: Respiratory Therapy, Pathology, Autopsy, Cytology, Bronchoscopy, Microbiology, Histopathology, Emergency Department, Respiratory Residents, and Critical Care Resource Pool. <i>** Previously positive users will have a symptoms review with KHSC's Occupational Health & Safety Department.</i>
Measles/Mumps/Rubella (MMR)	Documentation of 2 doses of MMR vaccine on or after user's first birthday or laboratory evidence confirming immunity.	A MMR booster is required only where the user is not immune.
Varicella (Chicken Pox)	Documentation of 2 doses of Varicella vaccine on or after employee's first birthday or laboratory evidence confirming immunity.	A Varicella booster is required only where the user is not immune.
Tetanus/Diphtheria/Pertussis (Tdap) or Tetanus/Diphtheria (Td)	Documentation of a one-time, adult dose of Tdap vaccine. Documentation of a Td vaccine within 10 years provided Tdap has been received.	A Td vaccine is required every 10 years once adult dose of Tdap has been given.
Hepatitis B	Required ONLY for users with increased potential of coming into contact with human blood, tissue or bodily fluids. Where Hepatitis B immunity is required, laboratory evidence confirming immunity after the vaccination series has been administered is also required. Where there is no documentation of Hepatitis B vaccination, the vaccine will be administered.	A Hepatitis B booster dose is only required for those users found not to be immune.
Meningococcal	Required ONLY for Medical Lab Technologists working in Microbiology. Where there is no documentation of Meningococcal vaccination within 5 years, vaccination will be administered.	Administered every 5 years.
Influenza	Strongly recommended.	Annual flu shot.

5.0 SOP HISTORY

SOP Number	Date Issued	Summary of Revisions
SOP-IS-01	01-DEC-2017	Original version.
SOP-IS-02	01-MAY-2019	Bi-annual review of SOP completed. SOP header format updated. SOP version number updated. SOP effective date updated. Removed "Contacts" section from SOP. Updated section number for "SOP History". Updated "SOP History" section.