

SUMMARY OF RESEARCH SPECIMENS COLLECTED

Sample Collected	Quantity	Collection Time-points^a
Throat swab	1 swab	Weekly during acute phase
Nasopharyngeal swab	1 swab	Weekly during acute phase
Skin/mucosal lesions	Up to 3 swabs	Weekly during acute phase
Blood – serum	1 tube (into 500 uL)	Weekly during acute phase
Urine	30 mL (in 1 mL aliquots)	Weekly during acute phase
Rectal swab	1 swab	Weekly throughout study
Semen (if applicable)	2-5 mL	Weekly throughout study
Vaginal swab (if applicable)	1 swab	Weekly throughout study
Breastmilk (if applicable)	1-5 mL	Weekly throughout study
Blood – serum for serology	1 tube (1 mL aliquots)	Baseline, End of acute phase, Final visits
Environmental swabs	Up to 8 swabs per outpatient visit Up to 20 swabs per inpatient	Optional per visit as determined by study site

^a For items listed as ‘weekly during acute phase’, a subset of participants (initial target n=20, plus any hospitalized participants) will be sampled more intensively (three times per week) rather than weekly.

BIOBANK SUMMARY

<p>Description of the bank and its objectives</p>	<p>Bank objective: Storage of body fluids, tissues and swab samples for future testing related to monkeypox virus, co-infections, and the host response to monkeypox infection.</p>
<p>Administrative Management</p>	<p>• Where is the bank located? University of Toronto’s Combined Containment Level 3 (C-CL3) Unit Emerging and Pandemic Infections Consortium (EPIC) 1 King’s College Circle Toronto ON M5S 1A8 Phone: 416-574-8073 Fax: 416-854-5302</p> <p>• Ownership of the bank. The Co-Principal Investigators of the Monkeypox Prospective Observational Cohort Study (MPOCS) are the owners of the bank: Darrell H. S. Tan, St. Michael’s Hospital Sharmistha Mishra, St. Michael’s Hospital Adrienne Chan, Sunnybrook Hospital Sharon Walmsley, Toronto General Hospital</p> <p>• How long will the samples remain in the bank? The retention period of the samples is 7 years after study closure.</p>
<p>Privacy and Confidentiality</p>	<p>• Description of coding process. Each study participant will be coded with a six-digit number. The first three digits correspond to a clinical research site number, assigned by an existing clinical research network (CIHR Canadian HIV Trials Network, or CTN) to which all contributing sites already belong. The second three digits are to be numbered sequentially at each site beginning with 001.</p> <p>• Physical security measures. Samples from contributing sites will be securely sent by courier to the CL3 lab at EPIC on a regular basis, and within 24 hours of specimen collection. The CL3 lab is a secure facility that has operated as a fully certified biocontainment level 3 facility for work with Risk Group 3 (RG3) pathogens for more than 20 years. The facility that houses the freezers is controlled by FOB access only, and the freezers themselves can be opened only by key access; both these levels of security controlled only by the Facility Manager.</p> <p>• Confidentiality of codes and data.</p>

	<p>Only coded samples will reside in the bank and the master linking logs potentially linking the codes to specific individuals will be securely retained at the investigator sites.</p> <ul style="list-style-type: none"> • Will it be possible to link subjects’ data with samples? Samples can be traced or linked back to the participant by the site investigator/staff via the master linking logs. This log will remain at the investigator site. Any other authorized parties working with the samples will not be able to directly link the sample to personally identifiable information independently.
<p>Access to samples for future research</p>	<ul style="list-style-type: none"> • Who could use the samples for future research? Investigators who are part of the MPOCS study team may potentially use the samples for a period of up to 7 years for the purposes described in the study protocol and consent. The Principal Investigators may work with other researchers under formal agreements to carry out this research. "Other researcher" refers to anyone that has a contract with the Sponsor, for example, collaborators or external labs. Ethics approval will be sought as needed for future projects to ensure alignment with consent, protocol and regulatory requirements. • What will samples be used for? Samples will be used for future testing related to monkeypox virus, co-infections, and the host response to monkeypox infection. Specific tests related to monkeypox virus that are envisioned include: monkeypox PCR testing (including using additional PCR primers / platforms), whole genome sequencing and RNAseq. Specific tests related to co-infections include: serology for herpesviruses (eg. Herpes simplex virus, varicella zoster virus). Specific tests related to the host response to monkeypox infection include: serology, inflammatory biomarkers. • Criteria to evaluate a research project using the bank. Any research proposal will be evaluated by the MPOCS Steering Committee (section 10.1 of the protocol) to ensure that the use is aligned with the study protocol and consent, and feasible. Decisions will be made by consensus. • Agreement of bank users to comply with bank policy. All collaborating researchers working with the biobank owners on future research will be required to adhere to the contract.
<p>Removing of a participant or of specific samples</p>	<ul style="list-style-type: none"> • Process to find and destroy samples if requested: An Excel based laboratory information management system (LIMS) is used to track and identify samples for storage, testing and destruction. Any request must be communicated to the Biobank owners by the site investigator and include reference to the sample ID.

End of the Bank	<ul style="list-style-type: none">• Sample destruction After the specified storage period (7 years after study closure) or upon withdrawal of consent, samples will be destroyed using standard procedures for biowaste at the C-CL3. (or at other researcher’s institution as part of the formal agreement) and a full record of chain of custody will be maintained.
------------------------	---