Collection of Human Samples for Research Purposes.

Purpose:
Safe handling of human samples in a research setting is monitored by the York University Biosafety Committee through a formal risk assessment and permitting process. The collection of human samples also requires approval from the Human Participants Review Committee (HPRC). The purpose of this document is to ensure safe practices are followed during the collection of human samples for research purposes.

This does not apply to:
- School of Nursing
- Flu Clinics
- Blood Donor Clinics
- Any other organized human sample collection event where samples will not used for research-purposes.

This applies to the following “human samples”:
- Blood/blood products
- Tissues
- Saliva
- Urine

Collection by collaborators:
If any of the above samples are collected by a collaborator (e.g. not directly involving York faculty, staff and students), then ensure the following:

1. Determine general health status of the individual(s) from which the sample is derived. This should be included in consent forms, when relevant (e.g. for blood borne pathogens). If samples will be received at York, include this information on your biosafety permit application/amendment. If samples are not collected, handled or stored at York, a biosafety permit is not required.

2. Determine what related documentation (e.g. material transfer agreement, import permit) must be in place. Read the health and safety requirements for receiving the biological agents/materials and ensure they are met.

3. Inquire if a biosafety permit is in place at your collaborator’s institution. If a biosafety permit is also completed, provide the name of the permit holder and permit number in Section H of your York biosafety permit application including any other external approval requirements.

4. If shipping or receiving human samples, determine if TDG (Transportation of Dangerous Goods) regulations apply.
Collection at York University:

In keeping with the safe handling of biohazards in the research lab, similar “best practices” must be followed:

1. Know the risks (type of exposure, routes of transmission) regarding the collection of the particular type of sample(s) you will collect and the steps required mitigating those risks.

2. Review and follow, where relevant:
   a. *York University Biosafety Guideline: Safe Handling of Human blood/body fluids.

3. Limit the number of individuals who will perform the sample collection(s). Where possible (e.g. fingerprick, saliva), have the participant collect the sample themselves.

4. Medical surveillance requirements must be met for individuals collecting human blood and other body fluids/tissues that may contain blood borne pathogens. Refer to the *Medical Surveillance Protocol: Experimental Animals and other Biohazards.

5. For any procedure deemed a “delegated medical act”, a Medical Directive will be required and reviewed by the HPRC. Contact the Office of Research Ethics for more information.

6. All surfaces are easily cleaned and disinfected. Carpets and cloth-covered chairs must not be used. If collecting saliva or obtaining fingerpicks, this is still recommended.

7. An assessment/treatment plan must be in place for participants regarding the potential adverse reactions that may occur. Minimize the risks by excluding participants with a history of experiencing adverse reactions in the past (e.g. someone who typically faints when having blood drawn). Make this part of the exclusion criteria, but still be prepared for all potential scenarios.

8. Incorporate the assessment/treatment plan into your overall emergency response protocols. The following will help in the development of a plan:
   a. *Biological Materials Exposure and Spills Response Flowchart
   b. *Contingency Plan for Emergency Situations
   c. *Accident Investigation Program (includes information of incident response, investigation and reporting requirements at York)

9. Gloves and a lab coat must be worn for the collection of any human sample. If collecting saliva or obtaining fingerpicks, a lab coat is still recommended. Proper glove removal procedures must be followed, followed by proper hand-washing.

10. Hand-washing sinks must be available and it must be used immediately after each sample collection. Sinks should be located in the same room, or one must be easily accessible. In some cases, a hand sanitizer may be used as an interim measure after
proper glove removal for sinks accessible but in another room. Before collection begins, it must be ensured that soap and paper towels are available for use at the designated hand-washing sink.

**Collection in the “field”:**

Sample collections may require visiting participants where the collection environment is not controlled. The following precautions must be followed:

1. Wear suitable clothing. A “uniform” with York-related markings is recommended, and an identifier (e.g. YU card).

2. Bring related documentation such as copies of certificates/approvals, collection protocols and emergency response procedures.

3. Ensure all items required for the collections and for emergency spills are on hand:
   - Nitrile gloves, absorbent, 5-10% bleach solution, waste bag, CSA-approved sharps container, collection tubes, sealable bags and secondary container, proper labeling (for samples and for transport), Human blood: Transportation of Dangerous Goods (TDG) certification, safety-engineered needles.

4. Determine the location of a sink before the collection commences. Bring hand sanitizer as an interim measure until the hands can be washed.

*Note all referenced documents are available at: [www.yorku.ca/dohs/biosafety](http://www.yorku.ca/dohs/biosafety), except The Accident Investigation Program which is available at: [http://www.yorku.ca/dohs/programs.htm](http://www.yorku.ca/dohs/programs.htm)*