

Accident - an incident that results in personal injury or property damage.

Activity - means a set of tasks, situation, condition, or process that is conducted by a user.

Aspirate - to draw liquid up into the pipette tip.

<u>Audit</u> – an examination, verification or review of all activities, documents, facilities, equipment, records, and other resources associated with clinical research, including clinical trials, to determine whether all research activities were conducted in compliance with the study protocol, site-specific and/or sponsor-specific SOPs, institutional and REB policies, good clinical practice (GCP), and other applicable regulatory requirements and guidelines. Audits are typically conducted to help ensure compliance with applicable standards, to correct errors before the research is completed, to identify low or high rate of adverse events when research sites are compared, and to verify the data is accurate and of quality.

Biohazardous Waste - waste that in all probability contains pathogenic agents that because of their type, concentration and/or quantity may cause disease in individuals exposed to the waste. Wastes that are saturated with blood or bodily fluids (i.e. could drip or be wrung out) are considered biohazardous and require use of biohazardous waste containers whereas wastes which are non-saturated (i.e. used bandages or gauze) are disposed of via regular garbage waste containers.

<u>Blow Out</u> - The piston moves to the lowest position in order to blow out the residual liquid from the pipette tip. During pipetting operations, the liquid from the blow-out is part of the dispensing volume.

Body Fluid - a liquid produced by the body; includes blood, cerebral spinal fluid, synovial fluid, pleural fluid, peritoneal fluid, amniotic fluid, seminal fluid, vaginal secretions, human tissue, or any body substance containing visible blood.

<u>Bomb</u> - any device, which by design produces an explosion, or due to additional incendiary, toxic, or radiological substances, some dangerous environmental condition upon activation.

Buddy System - a system of organizing users into work groups so that each user of the work group is designated to be observed by at least one other user in the work group.

<u>CBRN</u> - is an acronym for Chemical, Biological, Radiological & Nuclear event.

<u>Check in Procedure</u> - an established procedure of communication between a user and a designated individual with the goal of accounting for the user working alone. Medium and high risk activities will require that a check-in procedure be established when working alone or in isolation.

<u>Class II Type A2 Biological Safety Cabinet (BSC)</u> - is the primary barrier protection for individuals working with low to moderate risk biohazardous materials designed to discharge HEPA-filtered exhaust air directly into the laboratory or into an exhaust system ducted out of the building with a thimble connection. When ducted out of the building, this BSC may be used for applications involving minute quantities of volatile toxic chemicals. During operation, room air is drawn into the inlet grill of the BSC. The air in the plenum beneath the work surface of the BSC is a mixture of unfiltered room air and air that has just passed through the work area of the BSC.



This contaminated air is drawn by the blower through the back plenum of the BSC, where approximately 70% of the air is recirculated through the supply HEPA filter and back over the work area. The balance of the contaminated air is discharged to the environment after passing through the exhaust HEPA filter.

<u>**Critical Injury</u>** - an injury of a serious nature that places life in jeopardy, produces unconsciousness, results in substantial loss of blood, involves fractures or amputations, involves burns to major portions of the body or the loss of sight.</u>

Decontamination - is the process of cleansing the human body to remove contamination, or the possibility (or fear) of contamination, by hazardous materials.

Disaster - A sudden natural or man-made event that causes widespread destruction and distress.

<u>Disaster Management</u> - requires the allocation of limited resources for the greatest good of the greatest number of casualties.

Dispense - to discharge the liquid from the tip

<u>Effective Means of Communication</u> - a radio, telephone, or other electronic communication device.

Emergency- a serious, unexpected, and often dangerous situation requiring immediate action.

Emergency Eyewash Station - a device used to provide tepid fluid to irrigate and flush both eyes simultaneously at a velocity low enough not to be injurious to the user. The main type of emergency eyewash station in the WJHCPOR is a plumbed (primary) eyewash station- an eyewash unit permanently connected to a source of potable water.

Flood - a very large amount of water that has overflowed from a source such as a river or a broken pipe onto a previously dry area. An accumulation of fluid that wets fixed porous materials such as drywall, carpeting, ceiling tiles, wooden furniture, etc. and/or covers a water-impervious area that will require more than 10 minutes to remove the water.

<u>**Hazard</u>** - a danger or risk that has the capability of producing adverse effects to the health, wellbeing and safety of an individual.</u>

Hazard Assessment - a procedure, which helps integrate required Kingston Health Sciences Centre (KHSC) Occupational Health & Safety and Queen's University (Queen's) Environmental Health & Safety principles and practices into a particular work task. Each basic step of the task is examined to identify potential hazards and required control measures to determine the safest way to do the work.

Hazardous Drug – a hazardous drug is any drug that has the capability of causing toxicity to personnel and others who come in contact with them. Hazardous drugs may include antineoplastics, cytotoxic, biologic, antiviral or immunosuppressive agents. NIOSH (2016) recommends that all investigational drugs be regarded as potentially hazardous until information establishes their safety. Drugs may be classified as hazardous when they possess any one of the following characteristics:



- Genotoxicity the ability to cause a change or mutation in genetic material; a mutagen.
- Carcinogenetic the ability to cause cancer in animal models, humans, or both; a carcinogen.
- Teratogenicity the ability to cause birth defects in fetal development or fetal malformation.
- Fertility impairment in either men or women.
- Serious toxicity at low doses in experimental animal models or treated patients.
- Chemical structure and toxicity profile that mimic existing drugs as treated as hazardous by the five previous criteria, until properly classified.

<u>Hazardous Material</u> - any substance or compound that has the capability of producing adverse effects to the health, well-being and safety of an individual.

<u>Hazardous Spill</u> - the escape from containment of any substance, which by its nature presents a threat to life or safety of the person or the environment through contact, absorption, inhalation or ingestion or a secondary threat of fire or explosion effects to the health, well-being and safety of an individual.

<u>**HEPA Filter**</u> - HEPA stands for High-Efficiency Particulate Air. HEPA filters are defined as aircleaning devices that have a proven minimum removal efficiency of 99.97% of particles in the air, equal to 0.3 μ (microns) in diameter, with higher efficiency for both larger and smaller particle sizes.

Incident - an unplanned event.

Infectious Disease - Infectious diseases are caused by pathogenic microorganisms, such as bacteria, viruses, parasites or fungi; the diseases can be spread, directly or indirectly, from one individual to another individual. Examples include Hepatitis B Virus (HBV), Human Immunodeficiency Virus (HIV), and Hepatitis C Virus (HCV).

Inspection – an official examination by regulatory authorities (i.e. HC,FDA or EMA) of all activities, documents, facilities, equipment, records, and other resources deemed by the regulatory authorities to be relevant and related to the clinical research, including clinical trials, to determine whether all research activities were conducted in compliance with the study protocol, site-specific and/or sponsor-specific SOPs, institutional and REB policies, good clinical practice (GCP), and other applicable regulatory requirements and guidelines. Inspection typically occurs at the research sites; however, inspection can also occur at the sites of the Sponsor, CRO, funding entities, REB and/or other locations deemed appropriate by the regulatory authorities. Following an inspection, an official written report is provided that lists all observations, deviations, and deficiencies noted during the inspection.

<u>Man-Made Disaster</u> - resulting from man-made hazards (threats having an element of human intent, negligence, or error) or involving a failure of a man-made system. May be the result of sociological hazard (crime, civil disorder, terrorism), technological hazard (industrial, structural, fire, hazardous material), or transportation hazard (aviation, rail, road).

<u>Mass Casualty</u> - any event resulting in number of victims large enough to disrupt the normal course of emergency and health care services.



<u>Natural Disaster</u> - is the effect of a natural hazard (i.e. flood, tornado, hurricane, volcanic eruption, earthquake, or landslide). It leads to financial, environmental or human losses depending on the vulnerability of the affected population.

NIOSH - the U.S. National Institute of Occupational Safety and Health. An American safety institute that publishes standards related to many topics including hazardous drugs.

<u>**Remediation**</u> - general clean up, repair, or replacement of building components after water intrusion.

Routes of Entry - means by which a substance gains access into the body; includes ingestion (mouth), inhalation (lungs) or absorption (contact). Examples include needle stick injuries (percutaneous), splashes to the mouth, nostrils or eyes (mucous membranes) and exposure to skin or open wound (i.e. cuts, abrasions, dermatitis).

<u>Safety Plan</u> - a documented plan of safe work practices with a goal to prevent incidents, accidents, and critical injuries and to minimize risk.

<u>Sharps Waste</u> - any wastes that involve needles, medical sharps (e.g. scalpels, lancets, saws, etc.), glass blood/specimen collection tubes or broken glass.

<u>Supervisor</u> - a person that directs or oversees a user, user group, user department, user organization, or user operation for KHSC and/or Queen's.

Tepid - moderately warm or lukewarm water; temperature of water is between 60°F (15.5°C) and 100 °F (38°C).

<u>User</u> - a researcher, student, trainee, KHSC employee, Queen's employee, agent, contractor, or a person in an unpaid position who is performing/carrying out research activities under the direct supervision of a KHSC employee and/or Queen's employee/Faculty member.

<u>Water Intrusion</u> - entry of environmental (rain), potable (broken water pipe), damaged infrastructure systems (HVAC or sprinkler) or sewage (pipe break or backup) into a building's interior spaces, requiring actions beyond simple removal.

<u>Working Alone</u> - when a person works in isolation or in a remote location (referred to as isolated or remote work) for a period of time and they do not have direct contact with another user or co-worker or a supervisor and in the event of injury, illness or emergency, immediate assistance is not readily available.