



Standard Operating Procedure

Biohazard Risk Group Definitions

I. POLICY: The Puerto Rico Clinical and Translational Research Consortium (PRCTRC) ensure the safety and well being of participants and employees in research studies performed in its facilities.

II. PURPOSE: The following information is provided to clarify how biohazards agents are to be classified. Those wishing to use any biological material that is included in the risk groups below must obtain a permit from the Medical Sciences Campus (MSC) Institutional Biohazard Committee (IBC) prior to commencing work with the material.

III. Area(s) of Responsibility: Principal Investigators, lab staff/students, PRCTRC nurses

IV. Definitions:

- **Biohazards** are infectious agents or hazardous biological materials that present a risk or potential risk to the health of humans, animals, or the environment. The risk can be direct through infection or indirect through damage to the environment.
 - Note: The CDC, NIH, and other government agencies and professional organizations provide [list of select agent and toxins](#) Any organism or virus listed in Risk Group (RG) 2, 3, 4 or that requires Biosafety Level (BL) 2, 3 or 4 containment is considered biohazardous.
- **Biohazardous materials** include certain types of recombinant DNA: organisms and viruses infectious to humans, animals or plants (e.g. parasites, viruses, bacteria, fungi, prions, rickettsia); and biological agents (e.g. toxins, allergens, venoms) that may cause disease in other living organisms or cause significant impact to the environment or community;
- **Biological materials** are any materials containing genetic information and capable of reproducing itself or being reproduced in a biological system. Biological materials include (but are not limited to):
 - Microorganisms
 - Recombinant DNA (rDNA) - The NIH Guidelines provide a list of covered experimental uses of recombinant DNA that are considered biohazardous and a separate list of exempt experimental uses of recombinant DNA that are not considered biohazardous. These lists are found in [Section III of the NIH Guidelines](#).
 - Cell lines
 - Animals (live or tissues and biological fluids)
 - Plants

- Human tissue or biological fluids
 - Microbial Toxins
- **Biosafety or Biological Safety** encompasses all aspects of containment to prevent any exposure to and accidental release of infectious biological material. This also includes the containment of plants and animals;
- **Biohazardous waste** is any liquid or solid waste generated through the handling of specimens from humans or animals that may contain infectious agents. Cultures of infectious agents, human anatomical remains, and animal carcasses that may be infectious are also considered biohazardous waste;
- **Hazardous waste** is any hazardous material that is to be abandoned, discarded, or recycled;
- **Human Blood and Body Fluid Waste** refers to items saturated or dripping blood, body fluids contaminated with blood and body fluids removed for diagnosis during surgery, treatment or autopsy. This does not include urine or feces. Material with minimal amounts of non-infectious blood (i.e. does not release blood if compressed) are not considered biomedical waste;
- **Infectious agent** is any microorganism, bacteria, mold, parasite, or virus that normally causes or significantly contributes to increased human mortality. Infectious agents have also been defined as any materials that contains an organism capable of being communicated by invading and multiplying in body tissues (40 CFR 259.10);
- **Infectious waste** contains microorganisms in sufficient quantity which could result in the multiplication and growth of those microorganisms in a host;
- **Pathological waste** is any waste which contains microorganisms capable of causing disease;
- **Select agents and toxins** are agents and toxins <http://www.selectagents.gov/SelectAgentsandToxins.html> as having potential to pose a severe threat to public health and safety, in accordance with section 351A(a)(1) of the Public Health Service Act;
- **Sharp waste** includes devices or objects capable of cutting or piercing, such as hypodermic needles, razor blades, and broken glass;
- **Transgenic materials** include microorganisms, plants, and animals that have been genetically engineered or modified. Recombinant DNA techniques create new genetic combinations by changing, adding, or subtracting DNA genes, but this methodology does not necessarily mean that new organisms are created. With the exception of transgenic bacteria that could be infectious (considered biohazardous waste), transgenic materials generally do not pose a threat to public health or the environment.