**Clinical Trial Test Article Hazard Profile/Exposure Response Guide**

This document is intended to serve as a reference for personnel who may be handling a test article containing recombinant DNA molecules or a viable biological agent as part of preparation, administration or disposal of such materials. A copy of this document should be provided to all such parties as well as VEHS Biosafety & Occupational Health before first doses are prepared.

|  |  |  |
| --- | --- | --- |
| **Title** | **Name** | **Contact Numbers** |
| Principal Investigator |  |  |
| Study Nurse |  |  |

The above section should have contact information for the Principal Investigator and the study personnel with direct oversight of the people administering the agent. This is usually the head nurse for the study or the study coordinator.

|  |  |
| --- | --- |
| **Test Article** |  |
| **Description of Test Article** | The description of the test article goes here. This should be the same language as in the biorisk summary. |
| **Material Handling Considerations** | Information on how to handle the test article goes here. This should address handling procedures for the staff preparing the test agent for administration and for the staff who will be administering the agent to the patient.  If the study materials describe handling procedures for the agent, copy or paraphrase them here. This information may be in the Protocol, Investigator’s Brochure or Pharmacy Manual buried in the descriptions for preparing or administering the study agent.  If the study materials do not describe handling procedures, then a biosafety risk assessment of the agent must be made and handling procedures suggested by the protocol analyst or Committee members. Here are some common examples:  Agent contains human-derived cells: Agent should be prepared in a biosafety cabinet under BSL-2 conditions. Personnel administering the agent should use universal precautions.  Agent is a Risk Group 2 infectious agent (bacteria, virus, etc that causes treatable disease) or is derived from one: Agent should be prepared in a biosafety cabinet under BSL-2 conditions. Personnel administering the agent should use universal precautions.  If the agent contains recombinant DNA, the waste will need to be disposed of in a waste stream where the DNA is rendered non-viable before final disposal. For example, the recombinant DNA containing waste could be autoclaved or sent for incineration.   * All personnel handling CRS-207 must be provided with and complete awareness training regarding the risks associated with this product (elevated exposure risk for pregnant personnel). Only personnel who have completed this training may be dispatched for responding to spills involving this product. |
| **Exposure Response Actions** | * In the event of a needlestick or contact with test article through broken skin or mucous membranes, flush the exposed area with running water for 15 minutes. * For a cut, puncture or scratch, cleanse the area with soap and water. * Seek further medical attention or a medical evaluation at the Vanderbilt Occupational Health Clinic, 1211 21st Ave. South, Suite 640 Medical Arts Building, Monday - Friday, 7am-6 pm. The OHC phone number is 936-0955. If the exposure occurs after hours/on weekend, call this number for instructions regarding post-exposure evaluation unless the exposure involved human-derived materials/cells. (In the instance of an exposure involving human-derived materials, report to the Vanderbilt University Hospital Emergency Department immediately.) * The PI or the PI’s designate must notify the Institutional Biosafety Committee for Human Subjects in the event of an exposure. The point of contact is the Biological Safety Officer phone: 322-0927 | fax: 343-4951 robin.trundy@vumc.org   The points above are stock language that applies to any study agent. There may be other actions added by either the study PI or Occupational Health. |
| **Post-exposure medical assessment considerations** | This section is provided by the study PI and then refined by Occupational Health. If the study PI or Occupational Health calls for specific follow-up events, such as specific tests, they are detailed here. This is also where instructions for personnel with an exposure incident would go, such as monitoring for specific symptoms. |

**Study Timeline**

|  |  |  |  |
| --- | --- | --- | --- |
| Anticipated start date  (when doses will first be prepared) |  | Anticipated end date |  |

Response Guide prepared by/date: