

Corporation obtaining approval, the name of its representative, and the address of its main office

Name of Entity: National Center for Child Health and Development

Name of Applicant: Takashi Igarashi, President

Address: 2-10-1 Okura, Setagaya-ku, Tokyo

### Approved Type 1 Use Regulation

Names of types of living modified organisms	Non-proliferative genetically modified human immunodeficiency virus type 1, in which the major portion of U3 region of 3'LTR has been deleted, and human Wiskott-Aldrich syndrome protein is expressed under the control of WAS gene promotor and post-transcriptional regulatory element of variant woodchuck hepatitis virus, and G protein derived from vesicular stomatitis virus is in its envelope (WASP LV)
Content of Type 1 Use of living modified organisms	Use for the purpose of human gene therapy, storage, transportation, disposal, and other acts attendant with these.
Method of Type 1 Use of living modified organisms	<p>Transportation and Storage</p> <p>(1) Human CD34 positive cells which were infected with the living modified organisms in an external institution (to be called "WASP LV-infected cell" hereinafter), shall be transported to a medical facility while being enclosed in a sealed bag indicating that it contains living modified organisms, and stored in an appropriately controlled storage within the facility.</p> <p>Administration</p> <p>(2) WASP LV-infected cells shall be administered in an individual room in the medical facility. When administering, connect a bag which contains WASP LV-infected cells to the central venous catheter indwelling in the patient's body, then inject WASP LV-infected cells.</p> <p>Infectious Waste Management</p> <p>(3) When disposing medical instruments such as injection needles, bags and catheters, which have been in direct touch with WASP LV-infected cells, as well as medical equipment stained with patient's blood, follow the Rules regarding the medical waste management, provided by the medical facility, based on the Waste Disposal and Public Cleansing Act (Act No. 137 of 1970), which is called "Medical Waste Management Rules" hereinafter.</p> <p>Handling of Patient's Specimen</p> <p>(4) Specimen collected from the patient for test shall be handled according to the rules provided by the medical facility, and disposed according to the Medical Waste Management Rules.</p>

	When the test is entrusted to an external institution, ensure that the infection activity of the living modified organisms does not exceed the detection limits by performing an appropriate infectivity test before taking it out of the facility.
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