

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

Name: National Center for Child Health and Development (NCCHD)

Applicant: Takashi Igarashi

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

Approved Type 1 Use Regulation

Name of the Type of Living Modified Organism	Nonproliferative and genetically modified Molony Murine Leukemia Virus expressing human cytochrome b-245, beta polypeptide (CYBB) that is packaged in the envelope protein derived from mouse amphotropic virus, 4070A (MFGSgp91)
Content of the Type 1 Use of Living Modified Organism	Used in clinical facilities for human medical treatment, including storage, transportation, disposal and acts incidental to them
Method of the Type 1 Use of Living Modified Organism	<p>Address: 2-10-1 Okura, Setagaya-ku, Tokyo Name: NCCHD Hospital and Institute</p> <ol style="list-style-type: none">1) The solution of MFGSgp91 is to be sealed in containers, transported to the clinical facility in the frozen state, and stored in a freezer in a locked storage room at the facility2) Thawing the frozen solution of MFGSgp91, and diluting or dispensing the solution is to be performed within a safety cabinet or using a closed bag-system in a P2 laboratory. Transduction of human CD34⁺ cells with MFGSgp91 and culture of the transduced cells are also to be performed in a same manner. The diluted solution of MFGSgp91 and the transduced cells are to be stored in a refrigerator, a freezer or an incubator in the P2 laboratory. When the diluted solution, its frozen stock, or the transduced cells are transported to another P2 area through the open area, these items are to be sealed doubly in a container and transported to the area.3) The items above are to be disposed after sterilization processing by autoclave or chemical reagents according to the disposal manual of infectious wastes ruled by NCCHD (hereafter referred to as the manual).4) The transduced cells are to be administered to the subject in an isolated room that is equipped with a proper nonproliferation measure of the infectious items to the environment (hereafter referred to as "cell therapy room"). Small objects such as syringes, needles, tubes, so on, which are contacted with the infectious items, are to be disposed after the sterilization processing according to the manual.5) The subject is to remain within the cell therapy room until 72 hours after the administration of the transduced cells. When the subject needs to

	<p>move to another room through the open area to take a clinical inspection, he is to put on a gown and a mask not to spread the infectious items.</p> <p>6) Blood and fluid of the subject during the isolated period are to be disposed after the sterilization processing according to the manual. Excrement such as urine and stool are to be disposed after sterilization with chemical reagents within the cell therapy room until the PCR test, which is done at the next day or subsequent ones, shows no RCR in the subject's blood. Excrement of the subject used as a clinical sample is to be disposed after the sterilization processing according to the manual.</p> <p>7) Instruments invasively used to the subject or ones in contact with excrement during the isolated period are to be sterilized properly in the cell therapy room followed by full washing or disposal according to the manual.</p> <p>8) To free the subject from being isolated in the cell therapy room requires the result of PCR showing no RCR in the subject's blood and plasma. If RCR is positive, the subject is to remain in the cell therapy room until RCR is negative.</p> <p>9) When RCR is detected from the subject's blood or plasma after the decontrol, he is to be immediately moved under the management in the cell therapy room, and the above and the same measure as (5) to (7) are performed.</p>
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