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

Name: Tsukuba University Hospital
Applicant: Iwao Yamaguchi, Director (Seal)
Address: Amakubo 2-1-1, Tsukuba City, Ibaraki Prefecture

Approved Type 1 Use Regulation

Name of the Type of Living Modified Organism	Nonproliferative and genetically modified Moloney murine leukemia virus that expresses Herpes simplex type 1 thymidine kinase and human intracellular region-deleted low affinity nerve growth factor receptor, and has env protein of mouse amphotropic virus 4070A in its envelope (SFCMM-3)
Content of the Type 1 Use of Living Modified Organism	Used in clinical facilities for human gene therapy, including storage, transportation, disposal and acts incidental to them
Method of the Type 1 Use of Living Modified Organism	Address: Amakubo 2-1-1, Tsukuba City, Ibaraki Prefecture Name: Tsukuba University Hospital (1) The SFCMM-3 solution should be sealed in containers, transported to a clinical facility in the frozen state, and stored in a freezer in a P2 level laboratory at the facility. (2) Thawing, dilution and dispensing of the frozen SFCMM-3 solution has to be performed in a closed system in a safety cabinet in a P2 level laboratory or in a P2 level laboratory itself. Similarly, the diluted SFCMM-3 and the cells to which SFCMM-3 was transferred, including the transfection of the donor lymphocyte with SFCMM-3, incubation of the cells to which SFCMM-3 was transferred, etc., are to be handled in a closed system in a safety cabinet in a P2 level laboratory or in a P2 level laboratory itself. This diluted SFCMM-3 and cells to which SFCMM-3 was transferred should be stored in a refrigerator, freezer or incubator in a P2 level laboratory. Note that when the diluted SFCMM-3 or its frozen form or the cells to which SFCMM-3 was transferred is transported to another P2 level area through an open area, it should be kept inside a doubly sealed container. (3) When disposing of the solution (including dilutions) of SFCMM-3 or the cells to which SFCMM-3 was transferred, these should be sterilized and then disposed of according to the infectious waste management protocol defined by the facility (hereinafter referred to as "the infectious waste management protocol"). (4) Administration of the cells to which SFCMM-3 was transferred to a subject has to be performed by infusion in a single room that has appropriate containment measures (hereinafter referred to as “clean

	room”). Additionally, devices that come in direct contact with the cells to which SFCMM-3 was transferred at the time of administration, such as injection needles, syringes, and tubes, etc., should be disposable ones, and after use, these should be appropriately disinfected in the clean room, followed by disposal in accordance with the infectious waste management protocol. (5) Until the third day after administration, the subject should be cared for in the clean room. When the subject enters the open area outside the clean room for examinations, etc., viral leakage prevention measures including the wearing of a mask and a gown must be compulsory. Blood and body fluids of the subject during the period of being taken care of in the clean room should be appropriately disinfected individually and disposed of in accordance with the infectious waste management protocol. In addition, the excreta of the subject including urine and feces should be appropriately disinfected in the clean room and disposed of in accordance with the infectious waste management protocol until the existence of replication competent SFCMM-3 (hereinafter referred to as “RCR”) is denied by the polymerase chain reaction (PCR) test using subject blood, which is performed after the day following administration. Note that the excreta, etc., from the subject that are to be used as clinical samples should be handled in accordance with the handling of the SFCMM-3 solution or the cells to which SFCMM-3 was transferred. (6) During the period of being taken care of in the clean room, invasive devices that have been used in the subject and those that have been in contact with excreta, etc., should be appropriately disinfected in the clean room and disposed of in accordance with the infectious waste management protocol, or be washed sufficiently in the clean room. (7) Before releasing the subject from the clean room, confirm that RCR is negative in the peripheral blood mononuclear cells (PBMC) and the plasma of the subject. If RCR is detected, the subject should continually be cared for in the clean room. (8) If RCR is detected in the PBMC or the plasma of the subject after releasing the subject from the clean room, immediately transfer the subject back to the clean room, and take the same measures as in (5) to (7) above.