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

Name: Jichi Medical University Hospital
Applicant: Yoshikazu Yasuda
Address: 3311-1 Yakushiji, Shimotsuke-shi, Tochigi

Approved Type 1 Use Regulation

Name of the Type of Living Modified Organism	Nonproliferative and genetically modified Moloney murine leukemia virus that expresses the CD19-specific chimeric antigen receptor gene, and has Env protein of Gibbon ape leukemia virus in its envelope (SFG-1928z)
Content of the Type 1 Use of Living Modified Organism	Used in a clinical facility for human gene therapy, including storage, transportation, disposal, and acts incidental to them
Method of the Type 1 Use of Living Modified Organism	Address: 3311-1 Yakushiji, Shimotsuke-shi, Tochigi Name: Jichi Medical University Hospital (1) The solution of SFG-1928z should be sealed in containers, transported to the clinical facility in the frozen state, and stored in a freezer in a laboratory of biosafety level P2 at the facility (hereinafter referred to as "P2 laboratory"). (2) Thawing of the frozen solution of SFG-1928z, and dilution and dispensing of the solution of SFG-1928z should be performed in a safety cabinet in the P2 laboratory or in a closed system in the P2 laboratory. Similarly, the handling of the dilute solution of SFG-1928z and the cells transduced with SFG-1928z, including transduction of the lymphocytes of patients with SFG-1928z, incubation of the cells transduced with SFG-1928z, etc., are to be performed in a safety cabinet in the P2 laboratory or in a closed system in the P2 laboratory. The dilute solution of SFG-1928z and the cells transduced with SFG-1928z should be stored in a refrigerator, freezer or incubator in the P2 laboratory. Note that when the dilute solution of SFG-1928z, its frozen form or the cells transduced with SFG-1928z need to be transported to another P2 area through an open area, it should be contained inside a sealed container, which should be put in a box etc. for transportation to avoid dropping or breaking it. (3) When the solutions (including dilute solution) of SFG-1928z or the cells transduced with SFG-1928z are disposed, they should be treated with viral inactivation procedures (sterilized by an autoclave, or treated with 0.5% sodium hypochlorite solution or alcohol for disinfection; the same in the followings) and then disposed of in accordance with the medical waste management protocol established by Jichi Medical University Hospital (hereinafter simply referred to as "medical waste management protocol "). (4) Administration of the cells transduced with SFG-1928z to a subject has to be performed by infusion in an individual room with non-positive pressure that is equipped with a proper containment measures (hereinafter referred to as "individual room").

	Additionally, the devices that come in direct contact with the cells transduced with SFG-1928z at the time of administration, such as injection needles, syringes and tubes, etc., should be disposable ones, and these should be appropriately sterilized followed by disposal in accordance with the medical waste management protocol. Note that when sterilization is performed in the outside area of the individual room, the wastes should be contained inside a double sealed container and transported. (5) For three days after administration, the subject has to be cared for in the individual room. When the subject goes to the open area outside the individual room temporarily for examinations etc., viral leakage prevention measures including the wearing of a mask and a gown must be compulsory. (6) Blood and body fluids of the subject during the period of being taken care of in the individual room should be appropriately sterilized individually and disposed of in accordance with the medical waste management protocol. In addition, the excreta of the subject including urine and feces should be appropriately sterilized and disposed of in accordance with Medical waste management protocol until the existence of replication competent retrovirus (hereinafter referred to as "RCR") is denied by the polymerase chain reaction (PCR) test using subject's blood which is performed on or after the day following administration. Note that when sterilization is performed in the outside area of the individual room, the wastes should be contained inside a double sealed container and transported. Also, note that the handling of excreta etc. from the subject that are to be used as clinical samples should be in accordance with the handling of the solution of SFG-1928z or the cells transduced with SFG-1928z. (7) During the period of being taken care of in the individual room, devices etc. that have been used invasively in the subject and those that have been in contact with excreta etc. of the subject should be appropriately sterilized and be disposed of in accordance with the medical waste management protocol, or be sufficiently washed. Note that when sterilization is performed in the outside area of the individual room, the wastes should be contained inside a double sealed container and transported. (8) Before releasing the subject from being taken care of in the individual room, RCR should be confirmed to be negative in the peripheral blood mononuclear cells and the plasma of the subject. If RCR is detected, the subject should continue to be taken care of in the individual room. (9) If RCR is not detected in the first three subjects whom the cells transduced with SFG-1928z are administered to, following subjects are not taken care of in the individual room. (10) If RCR is detected in the peripheral blood mononuclear cells or the plasma of the subject after releasing the subject from being taken care of in the individual room or application of (9), the subject should immediately be transferred to be taken care of in the individual room, and the same measures as in (5) to (8) should be taken.