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

Name: Kyusyu University Hospital
Applicant: Sachiyo Suita, Director
Address: Maidashi 3-1-1 Higashi-ku Fukuoka City

Approved Type 1 Use Regulation

Name of the Type of Living Modified Organism	Nontransmissible and genetically modified Sendai virus that expresses human basic fibroblast growth factor (hFGF-2) (SeV/dF-hFGF2)
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 of Clinical Facility: Maidashi 3-1-1 Higashi-ku Fukuoka City, Fukuoka Prefecture Name of Clinical Facility: Kyusyu University Hospital (1) The SeV/dF-hFGF2 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 SeV/dF-hFGF2 solution has to be performed in a safety cabinet in a P2 level laboratory. The diluted SeV/dF-hFGF2 should be stored in a freezer in a P2 level laboratory. Note that when the diluted SeV/dF-hFGF2 or its frozen form 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 SeV/dF-hFGF2 solution (including dilutions), 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 SeV/dF-hFGF2 to a subject has to be performed by direct injection of the diluted SeV/dF-FGF2 into the skeletal muscle of the lower limb of a patient with arteriosclerosis obliterans or Buerger's disease in a single room that has appropriate containment measures (hereinafter referred to as “clean room”). Injection needles, syringes, gauze, and sterilized sheets, etc., used in the administration of SeV/dF-FGF2 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) The subject should be cared for in the clean room until one week after administration. 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 gown must be compulsory. (6) The excreta, etc. (including blood, body fluids, urine and feces) of the subject during the period of being taken care of in the clean room should be appropriately disinfected in the clean room and then disposed of in accordance with the infectious waste management protocol. 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 SeV/dF-hFGF2 solution as described above. (7) 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. (8) Before releasing the subject from the clean room, confirm that SeV/dF-hFGF2 is negative in the blood and the urine of the subject. If SeV/dF-hFGF2 is detected, the subject should continually be cared for in the clean room. (9) If SeV/dF-hFGF2 is detected in the blood or the urine 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 (8) above.