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

Name: Okayama University Hospital
Applicant: Kiyoshi Morita
Address: Shikata-cho 2-5-1, Okayama City

Approved Type 1 Use Regulation

Name of the Type of Living Modified Organism	Telomerase-specific replication-competent oncolytic adenovirus (Telomelysin)
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: Shikata-cho 2-5-1, Okayama City, Okayama Prefecture Name: Okayama University Hospital (1) The Telomelysin 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 Telomelysin solution has to be performed in a safety cabinet in a P2 level laboratory. Storage of the diluted Telomelysin should be kept in a freezer in the P2 level laboratory. Note that when the diluted Telomelysin or its frozen form is transported to another P2 level area through an open area, it should be kept inside a container that is doubly sealed. (3) When disposing of the solution (including dilutions) of Telomelysin, 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) Telomelysin sould be diluted in phosphate-buffered saline in a safety cabinet in a P2 level laboratory. The Telomelysin solution inside a container that is doubly sealed should be immediately transported to a single room that is undergoing appropriate containment measures (hereinafter referred to as “clean room”) or computed tomography (CT) room. Devices such as injection needles, syringes, and tubes, etc., are used for the administration of Telomelysin. (5) Advanced head and neck, esophageal or lung cancer patients who have the unresectable tumors or the inoperable local recurrence after operation are enrolled. Intratumoral injection of Telomelysin is administered to three cohorts of patients (1×10^{10}, 1×10^{11}, 1×10^{12} viral particles). Telomelysin is injected directly into the tumor, either endoscopically, endobronchially or percutaneously under CT or ultrasonography guidance. The administration of Telomelysin is performed on days 1, 18, and 32 of treatment. The leakage of Telomelysin solution after injection

	should be carefully prevented. (6) The injection site after Telomelysin administration should be disinfected. For viral leakage perevention, the subject who wears a mask and a gown should be transported to the clean room. (7) Devices for the administration of Telomelysin 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. The floor in the clean room or CT room should be cleaned. Note that air in the clean room should be changed to HEPA-filtered fresh air 12 times per hour. (8) The subject should be cared for in the clean room until 48 hours 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 a gown must be compulsory. (9) 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 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 Telomelysin solution as described above. (10) 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 then be disposed of in accordance with the infectious waste management protocol, or be washed sufficiently in the clean room. (11) Before releasing the subject from being taken care of in the clean room, confirm that Telomelysin is negative in the sputum, saliva and urine of the subject. If Telomelysin is detected, the subject should continually be cared for in the clean room. (12) If Telomelysin is detected in the sputum, saliva or urine of the subject after releasing the subject from being taken care of in the clean room, the necessity to transfer the subject to be taken care of in the clean room should be considered. If the transfer of the subject is decided, the same measures as in (8) to (11) above should be taken.