

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	Nonproliferative and genetically modified human adenovirus type 5 that expresses Herpes simplex virus thymidine kinase (Adv.RSV-TK)
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	<p>Address: Shikata-cho 2-5-1, Okayama City, Okayama Prefecture Name: Okayama University Hospital</p> <p>(1) The Adv.RSV-TK 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.</p> <p>(2) Thawing, dilution and dispensing of the frozen Adv.RSV-TK solution has to be performed in a safety cabinet in a P2 level laboratory . Storage of the diluted Adv.RSV-TK should be kept in a freezer in the P2 level laboratory. Note that when the diluted Adv.RSV-TK 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.</p> <p>(3) When disposing of the solution (including dilutions) of Adv.RSV-TK, 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").</p> <p>(4) The administration of Adv.RSV-TK to a subject should be performed in a single room that is undergoing appropriate containment measures (hereinafter referred to as "clean room") by injecting the diluted Adv.RSV-TK into the local reoccurrence of advanced prostate cancer in prostate that is resistant to endocrine therapy. Devices such as injection needles, syringes, and tubes, etc., used for the administration of Adv.RSV-TK 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.</p> <p>(5) The subject should be cared for in the clean room until 24 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.</p> <p>(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</p>

	<p>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 Adv.RSV-TK solution as described above.</p> <p>(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 then be disposed of in accordance with the infectious waste management protocol, or be washed sufficiently in the clean room.</p> <p>(8) Before releasing the subject from being taken care of in the clean room, confirm that Adv.RSV-TK is negative in the blood and the urine of the subject. If Adv.RSV-TK is detected, the subject should continually be cared for in the clean room.</p> <p>(9) If Adv.RSV-TK is detected in the blood or the urine of the subject after releasing the subject from being taken care of in the clean room, immediately transfer the subject to be taken care of in the clean room, and take the same measures as in (5) to (8) above.</p>
--	--