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

Name: Chiba University Hospital
Applicant: Masaru Miyazaki
Address: 1-8-1, Inohana, Chuo-ku, Chiba, Chiba Prefecture, Japan

Approved Type 1 Use Regulation

Name of the Type of Living Modified Organism	Nonproliferative and genetically modified Moloney murine leukemia virus that expresses human lecithin:cholesterol acyltransferase gene, and has env protein of mouse amphotropic virus, 4070A (CGT_hLCAT RV)
Content of the Type 1 Use of Living Modified Organism	Used in a clinical facility for human medical treatment, including storage, transportation, disposal and acts incidental to them
Method of the Type 1 Use of Living Modified Organism	Address: 1-8-1, Inohana, Chuo-ku, Chiba, Chiba Prefecture, Japan Name: Chiba University Hospital (1) The solution of CGT_hLCAT RV is to be sealed in containers, transported to the clinical facility in the frozen state, and stored in a freezer in a locked storage room in a P2 level laboratory (2) Thawing, dilution and dispensing of the frozen CGT_hLCAT RV solution is to be performed in a safety cabinet in a P2 level laboratory or in a closed system in the P2 laboratory. Transduction of pre-adipocytes from subjects with CGT_hLCAT RV and culture of the transduced cells are also to be performed in a same manner. Storage of the diluted CGT_hLCAT RV and the transduced cells are to be stored in a refrigerator, a freezer or an incubator in the P2 laboratory. When the diluted solution, its frozen stock, or the transduced cells are required to be transported to another P2 area through open area, these items are to be sealed doubly in a container and transported to the area. (3) The solution (including the diluted dilution) of CGT_hLCAT RV is to be disposed after sterilization according to the infectious waste management protocol of Chiba university hospital (hereinafter referred to as "the infectious waste management protocol"). (4) The transduced cells are to be packed in syringes, which are to be sealed doubly in a container, and transported to an isolated room where appropriate containment measure are taken to prevent the dispersal of the infectious items to the environment (hereinafter referred to as “isolated room”). (5) The transduced cells are to be administered into subcutaneous adipose tissue of the subject in the isolated room. (6) Small objects such as needles, syringes, tubes, so on, which have been contacted with the transduced cells mentioned in (5), are to be disposed after the sterilization according to the infectious waste management protocol. When sterilization of the transduced cells is performed in area

	outside of the isolated room, these items are to be sealed doubly in a container and transported to the area. (7) The subject should be cared for in the isolated room until 72 hours after the administration. When the subject needs to move to another room through open area to take a clinical inspection, he or she is to put on a gown and a mask to prevent the dispersal of the infectious items. (8) Excrement such as urine and stool of the subject are to be disposed after sterilization within the isolated room until PCR test, which is done at the next day or subsequent days, shows no RCR in the subject's blood. Excrement such as blood and urine from the subject that are to be used as clinical samples should be handled in accordance with the handling of the CGT_hLCAT RV solution and the transduced cells as described above. (9) During the stay in the isolated room, invasive devices that have been used in the subject and those that have been in contact with blood, body fluid, and excrement, etc., should be appropriately sterilized and then be disposed in accordance with the infectious waste management protocol. When the sterilization is performed in area outside of the isolated room, these items are to be sealed doubly in a container and transported to the area. (10) Before releasing the subject from the isolated room, it should be confirmed that RCR is negative in blood of the subject. If RCR is detected, he or she should be continually be cared for in the isolated room. (11) If RCR is detected in blood of the subject after releasing the subject from the isolated room, he or she should be immediately transferred to the isolated room under the control, taking the same measures as in (7) to (10) above.