Enrollment of patients in the “Clinical study of autologous induced pluripotent stem cell-derived retinal pigment epithelium (RPE) cell sheets for exudative age-related macular degeneration (AMD)”

The enrollment of additional patients for the above clinical study has been suspended as of March 19, 2015, until further notice while the collaborative research team assesses how to revise their proposed clinical study plan to comply with the new Act on the Safety of Regenerative Medicine. Details of the new plan will be released once finalized.

The Act on the Safety of Regenerative Medicine, which went into effect in November 2014, specifies that for clinical studies carried out using Class I regenerative medical technologies, to which the current clinical study falls under, a medical institution that wishes to offer regenerative medicine applies for and carries out the study, and the processed cells to be used must be manufactured in a government-licensed and -inspected cell processing facility consigned by the said medical institution. In the current clinical study, the IBRI and RIKEN are jointly named as the principal investigating institutions; therefore, the two institutions are working to revise the provision plan to conform to the new law. The new plans include considering collaborations with Kyoto University’s Center for iPS Cell Research and Application (CiRA) for the use of allogeneic iPS cells, with a view to facilitate the smooth transition to practical use in a clinical setting.

The first participant who underwent the transplantation of a cell graft sheet in September 2014 is faring well, and continues to be monitored as per protocol. The follow-up examinations after the initial one-year monitoring period will also be carried out in accordance with the initial clinical study plan.