In Japan, there are more than 3,000 institutional review boards (IRBs)/Research Ethics Committees (RECs). However, the quality of the review as well as their operational speed and efficiency especially in multi-center studies have been questioned. To improve the situation, Japan Agency for Medical Research and Development (AMED) has started a new project called "Project for Development of Central Institutional Review Board." Osaka University Hospital was chosen as one of the selected five hospitals in this project for fiscal year 2016, and have been promoting centralization of IRBs for Japanese-GCP-based clinical trials, guideline-based clinical trials and observational studies.

In our hospital, as the reviewing institution, we modified the clinical research electronic application system to reduce a burden of secretariat work due to the increase in the number of consignment and entrustment business. In addition, we re-examined the review fee to promote multi-center studies, and created materials to enable the relying institutions to learn how to use central IRB, as well as the visit to some institutions for inquiry.

The issues to be addressed for centralization of IRB/REC include the ways to assure the quality of research and the tools required for identifying non-compliance of the regulations to be used at relying institutions. To improve the current issues, we shared operational procedures and relevant formats with relying institutions, as well as developed an e-learning system to learn relevant regulations, basic knowledge for implementing clinical research and human research protection.

Central IRB/REC is one of the topics attracted world-wide attention. We'd like to share our challenges and welcome any comments.