

大阪大学医学部附属病院における 臨床研究法への対応

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Efforts to align with the Clinical Trials Act at Osaka University Hospital

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Abstract

In Japan, the Clinical Trials Act went into effect in April 2018. Under the Clinical Trials Act, clinical studies are reviewed by the Certified Review Board that is authorized by the Minister of Health, Labour and Welfare (MHLW). In addition, the studies must be registered in the Japan Registry of Clinical Trials (JRCT) maintained by the MHLW.

In August 2017, in preparation for the enforcement of the Clinical Trials Act, Osaka University Hospital conducted a questionnaire survey among the researchers belonging to the Hospital and the Faculty of Medicine at Osaka University to understand the status of studies being carried out in the hospital. In February 2018, a Brush-Up Meeting was established in the Academic Clinical Research Center to support the consultation of on-going studies subject to the transitional measures, and prepare the researchers in advance of the Clinical Trials Act.

In the Brush-Up Meeting, interviews with almost all of the researchers were carried out to confirm whether or not their studies fell under the Clinical Trials Act, and the process of the specified clinical trials was explained to these researchers. A flowchart for the preparation of the applications was also developed so that the smooth implementation of the studies can be carried out.

More than six months have passed since the Clinical Trials Act went into effect. However, we are still working on many of the issues to be addressed under this Act, including education, protection of research subjects, and practical implementation.

We believe that our efforts to improve the current issues are essential for future clinical research in Japan.

Key words

Clinical Trials Act, Certified Review Board, specified clinical trials

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