Pre-Information for Participants in Clinical Trials Provided to Medical Doctors other than the Clinical Investigators as Required by Clause 45 of the Welfare Ministerial Ordinance Number 28 of 27 March 1997

Midori Nishio, Keita Noda, Miki Matsuzaki,
Tomoko Satoh, Etsuko Morita, Ritsuko Asada,
Masaya Takahira, Kaoru Hosoi and Keijiro Saku

Clinical Research Assist Center, Fukuoka University Hospital

Abstract : Pre-information for Participants in Clinical Trials Provided to Medical Doctors other than the Clinical Investigators as required by Clause 45 of the Welfare Ministerial Ordinance Number 28 of 27 March 1997. A ministerial ordinance regarding the standards of implementation for clinical tests of pharmaceuticals (Welfare Ministerial Ordinance Number 28 of 27 March 1997) was published in 1997. According to clause 45, a clinical investigator must inform other medical doctors about their patient's participation in the clinical trial under the participant's informed consent. Our university hospital has performed different kinds of clinical trials. Since many patients enrolled in clinical trials are either elderly or have several complications, the pre-information for participants in clinical trials that is provided to out-of-hospital doctors and/or in-hospital doctors who are not involved in the clinical trial is an important issue. Recently, some applicants for clinical trials prepared pre-information and asked the investigators to give it to the participants. However, we found several problems in both its content and form, which were not consistent with the original aim of Welfare Ministerial Ordinance Number 28 of 27 March 1997. Pre-information needs to be essential and reasonable information to ensure that other medical doctors can help maintain the safe of participants in clinical trials.

Key words : Welfare ministerial ordinance, Clinical good practice, Clinical research trial, Pre-information