

Survey of Participants to Clinical Trial in Fukuoka University Hospital : Relationship between the Participant's Understanding of Informed Consent and their Feeling of Unease for Clinical Trials

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Abstract : Research investigators must fully explain the details of clinical trials so that participants can give their informed consent before such trials begin. In this study, we surveyed both the understanding of informed consent and their feeling of unease in trials at our hospital by mailing written questionnaires, and then analyzed the relationship between these parameters. A poor understanding of informed consent and a feeling of unease in clinical trials were both associated with the insurance compensation, while a better understanding of informed consent with a feeling of unease were associated with adverse effects, efficacy of the drug in trials and limitations of treatment for concomitant diseases, although these relationship did not achieve statistical significance. A poor understanding of informed consent and a less feeling of unease were significantly ($p < 0.05$) associated with placebo use. Research investigators must fully understand the issues that are important to the participants of clinical trials so that any feelings of unease can be immediately resolved.

Key words : Clinical trial, Informed consent, Research investigator, CRC