＜英訳＞

HPB/RDPD Notification No. 0704-1
PSB/PED Notification No.0704-2
July 4, 2024

To: President, Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ)
President, Japan Pharmaceutical Manufacturers Association (JPMA)
Chairman, Japan-Based Executive Committee of Pharmaceutical Research and Manufacturers of America
Chair, European Federation of Pharmaceutical Industries and Associations
Chairman, Japan Contract Research Organization Association (JCROA)
Chairperson, Japan Association of Site Management Organizations (JASMO)

From: Director, Research and Development Policy Division,
Health Policy Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)
Director, Pharmaceutical Evaluation Division,
Pharmaceutical Safety Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)

Request for Utilizing the Japan Common Template for Informed Consent Forms in Clinical Trials

In recent years, due to changes in the environment of the pharmaceutical industry, issues such as the decline in drug discovery capabilities in our country, drug lag, and drug loss have been pointed out. To promptly deliver necessary pharmaceuticals to the public, the importance of further optimizing the development of the clinical trial environment has been emphasized. The "Study Group on the Ideal State of Pharmaceutical Regulations for Strengthening Drug Discovery Capabilities and Ensuring Stable Supply" by the Ministry of Health, Labour and Welfare (report published on April 24, 2024) indicated that one of the measures to further rationalize clinical trial is to standardize and disseminate the

template of informed consent form, which currently differ among sponsors and institutions (referred to as documents stipulated in Articles 9 and 52, Paragraph 1 of the Ministerial Ordinance on Good Clinical Practice for drugs (Ministry of Health and Welfare Ordinance No. 28 of 1997; hereinafter referred to as "GCP Ordinance")).

The Japan Pharmaceutical Manufacturers Association has published the "Japan Common Template for Informed Consent Form (ICF)" (hereinafter referred to as the "Common template") (see the URL below) to standardize the informed consent forms, considering opinions from institutions, patient groups, and other stakeholders. It is expected that the Common Template is aligned to the GCP Ordinance etc., and its utilization by more sponsors and institutions should contribute to the efficiency of clinical trials in our country. Therefore, we ask you to cooperate in informing your member companies of the Common Template and promoting to actively utilize it.

Furthermore, we would like to inform you that we have also requested the cooperation of the Director, Prefectural Health Department (Bureau) in Annexand related parties.

Link to the “Informed Consent Form (ICF) Common Template” (Japan Pharmaceutical Manufacturers Association website)

https://www.jpma.or.jp/information/evaluation/results/allotment/CL_202406_material.html

(Note) In the Japan Common Template, it is allowed to modify contents unique to each clinical trial, however the sections common to all trials (such as general trial explanations) are not permitted. Please consider the importance of utilizing the Japan Common Template.