

JMTO Rules (hereinafter referred to as The Rules) Governing Conflict of Interest Management in Clinical Research

(Purpose)

Article 1

The Rules aim to define JMTO requirements for the appropriate management of conflict of interest in clinical research.

(Definitions)

Article 2

Terms used in The Rules are defined in each of following items.

- (1) Researcher; the person who conducts clinical research.
- (2) Conflict of Interest; a situation in which, due to financial interest with an external entity or person, the fair and appropriate judgement of a researcher may be compromised (or the perception of unfair interest is observed by a third party).
- (3) Financial interest; establishment of any relationship that allows the researcher to receive payment from organisations other than the research organisation in which the researcher belongs to and conducts research.
- (4) Salary or other payments; anything of monetary value, including but not limited to salary or other payments for services (consulting fees or honoraria), such as acceptance through industry-academia cooperation (commissioned research, technology training, acceptance of visiting fellow/post-doctoral fellow, acceptance of a grant, testing/analysis, or provision of equipment), shares, and intellectual property (royalties from patents, copyrights and similar intangibles). Honoraria paid by public organisations are not included in Financial Interest.

(Scope of clinical research subject to The Rules)

Article 3

Clinical Research involving JMTO are subject to the provisions of The Rules.

(Duty of the Principal Investigator to provide a conflict of interest status report to JMTO)

Article 4

JMTO will manage Conflict of Interest relating to research in accordance with Guidelines on the Management of Conflict of Interest in Health and Labour Sciences Research decided by Director of Health Science Division in Notification No. 0331001, on March 31, 2008 (“the Conflict of Interest Guidelines”). A Principal Investigator must conduct relevant clinical research in accordance with appropriate Conflict of Interest Management and report Conflict of Interest management status to JMTO Chair in writing.

(Checking Conflict of Interest Management Status)

Article 5

JMTO Chair may check Conflict of Interest Management status subsequent to the Principal Investigator's report and confirm in writing with the Principal Investigator matters relating to Conflict of Interest.

(Protection of Personal, Research or Technical Information)

Article 6

In order to appropriately protect personal, research and technical information, JMTO Chair or interested parties must not divulge any such material.

(Dissemination)

Article 7

JMTO Chair will work to disseminate The Rules and Conflict of Interest Management Policy to the Principal Investigator.

(Accountability relating to Conflict of Interest)

Article 8

1. Upon disclosure request of Conflict of Interest, JMTO Chair must fulfil to a reasonable and adequate extent accountability to the public.
2. In the event of public disclosure of information, JMTO will ensure to protect relevant personal information.

(Delegation of JMTO Chair's Authority relating to Conflict of Interest Management)

Article 9

When the Chair conducts clinical research as a researcher, the JMTO Chair will delegate its authority relating to Conflict of Interest Management to the JMTO Vice Chair.

(Preservation of Relevant Documents)

Article 10 JMTO will preserve documents relating to Conflict of Interest Management for five (5) years.

(Office Procedures Relating to Conflict of Interest Management)

Article 11

JMTO Operations Office will conduct office procedures relating to Conflict of Interest Management.

(Establishment, Amendment and Abolishment of The Rules)

Article 12

Establishment, amendment and abolishment of The Rules will be proposed to the JMTO's Board of Directors and executed with the approval of the Board.

Established on March 24, 2014