

The Japanese Society for Pediatric Endocrinology

Bylaws Concerning Conflict of Interest Policy in Medical Research

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Article 5 (About medical research and related organizations)

"Medical research" is a basic and clinical study for humans carried out for the purpose of improving the prevention, the diagnosis and the treatment, the understanding of etiological and pathological condition, and the quality of life of patients.

Medical research targeting humans includes research on human-derived samples that can identify individuals and data that can identify individuals. Whether it corresponds to specimens or data that can identify individuals is as specified "Ethics Guidelines on Medical Research for Human" in the Ministry of Health, Labor and Welfare's.

"Business enterprises, for profit corporate organizations, and commercial entities related to medical research" are defined as follows.

- (1) Sponsors of medical research, or organizations who jointly conduct clinical research, regardless of whether funded or non-funded.
- (2) Organizations sharing the rights including patent rights regarding treatment methods, drugs and/or equipment that are evaluated in medical research.
- (3) Organizations providing drugs and/or equipment for medical research gratis or at an advantageous price.
- (4) Organizations funding or contributing financially to medical research.
- (5) Organizations providing unapproved drug and/or equipment for medical research.
- (6) Sponsors of endowed departments.

Article 6 (Criteria for self-reported COI disclosure)

All COIs must be reported if the amount exceeds the criteria specified below.

- (1) Employment or administrative position, or advisory role in business enterprises,

for profit corporate organizations, or commercial entities that are related to clinical research (hereafter referred to as “Commercial Entity”), if compensation from a single Commercial Entity exceeds 1,000,000 yen per year.

- (2) Stock ownership or options, if profit (total of dividend and gain on sales) of at least 1,000,000 yen from stocks of one Commercial Entity per year, or ownership of 5% or more of total shares.
- (3) Patent royalties from one Commercial Entity, if the royalty fee exceeds 1,000,000 yen per year.
- (4) Honoraria (e.g. lecture fees) paid from one Commercial Entity, for the time and/or labor of an investigator who attended or made presentations at meetings, if exceeding 500,000 yen per year.
- (5) Manuscript fees for promotional materials (e.g. brochures) paid by one Commercial Entity, if exceeding 500,000 yen per year.
- (6) Total amount that the recipient can practically use for research funds paid for medical research (e.g. funded research, collaborative research) paid by one Commercial Entity, if exceeding 1,000,000 yen per year.
- (7) Total amount that the recipient can practically use for subsidy or donation to an individual or a head of department to which the individual belongs received from one Commercial Entity, if exceeding 1,000,000 yen per year.
- (8) Endowed departments provided by a Commercial Entity, if the recipient participates in such a department. Note that the total amount of donations that the recipient can practically use more than 1,000,000 yen per year.
- (9) Others including trips, travel, or gifts, which are not directly related to research, provided by one Commercial Entity, if exceeding 50,000 yen per.