# Minutes of 4th Ethics Review Committee on Research Involving Human Biological Subjects

## Date and Time:

March 11th, 2014

17:00 - 17:30(Japan standard time)

# Venue (TV meeting):

- Room 2401, Tokyo HQ
- Room 402, Tokyo 2<sup>nd</sup> HQ
- Room 205, Technology Center 1<sup>st</sup> Building, Shiga Plant
- Small Conference Room, Pharmaceutical Laboratories, Kamakura Basic Research Center

#### Attendees:

Chair Naruto (Senior Director)

Member Funabiki(Senior Director), Yamamoto(General Manager), Itagaki

(General Manager), Takagi (Assistant General Manager), Kaneko

(General Manager)

External member Satoko Sugawara, Masami Shimamura

Secretariat Yamane(Senior Staff), Yamada(Senior Staff), Ozawa(Manager)

Observer Torii (Senior Staff for TMC), Anaguchi(Senior Staff for TRC)

Absent Miyashita (Assistant General Manager), Takizawa(Senior Staff)

## Decision:

- Twenty four research with external Human Biological Subjects and 31 research with internal Human Biological Subjects was registered in fiscal year 2013. The self-inspection by the study directors and the evaluation by secretariats of the Ethics Review Committee were performed. The Ethics Review Committee confirmed that all research were performed properly in the ethical point of view.
- Seven research with external Human Biological Subjects and 21 research with internal Human Biological Subjects was applied as Research Involving Human Biological Subjects in fiscal year 2014. The Ethics Review Committee carefully evaluated them from the ethical point of view and approved 24 of them. The rest of them (4 cases) were on hold because of the insufficient information to evaluate and requested the revision of the application. (Based on the revised application, the Committee approved all of them later).