

## **Minutes of 3<sup>rd</sup> Ethics Review Committee on Research Involving Human Biological Subjects**

### Date and Time:

March 15<sup>th</sup>, 2013

15:00 – 16:30 (Japan standard time)

### Venue:

Room 2401, Tokyo HQ

### Attendees:

Chair                      Naruto (Senior Director)

Member                    Funabiki(Senior Director), Yamamoto(General Manager),  
Itagaki(General Manager), Takagi (Assistant General Manager),  
Horinouchi(General Manager), Kaneko(General Manager)

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

Observer                   Yamada(Assistant General Manager for TMC), Tajima(Assistant General  
Manager for TRC), Hirano(Member of the Board for KTS)

Absent                      External member: Satoko Sugawara, Masami Shimamura

### Decision:

- Twenty one research with external Human Biological Subjects and 34 research with internal Human Biological Subjects was registered in fiscal year 2012. 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. The committee received the extended applications for 53 out of 55 research which were registered in fiscal year 2012. With regard to the research which were not applied the extension (2 cases), the Committee asked the study directors the reason and got the opinions from them that their plans could not be fixed due to the continuous discussion with the collaborators by the end of March. From the above reasons, the Committee decided to make a midterm reviewing and evaluation about those 2 research when they were requested to extend.
- Forty nine research was applied to the Committee as Research Involving Human Biological Subjects in fiscal year 2013. The Ethics Review Committee carefully evaluated them from the ethical point of view and approved 45 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)