

## **Abstract of Presentation**

**Note: This paper should be typed in “Times New Roman” of 12pt.**

**Presentation Title(Should be no more than 20 words):**

Ethics and governance of human genomic research in Japan

**Abstract :**

Since we've been discussed ethical, legal and social implications (ELSI) for the past decades and the human genome is being deciphered, unchallenged empirical data on ELSI has still been existed. Intellectual property issues surrounding access to the use of genetic information, influence of the translation of genetic Information to improved human health, influence surrounding the use of genetic information and technologies in non-health care settings—these themes have been identified as "grand challenges" in the US. (Nature, 422:835-847. 2003). In Japan, at the dawn of the ELSI era, the Ministry of Education, Culture, Sports, Science and Technology (MEXT) issued the first ethical guidelines on human genetic/genome studies in 2002. During a past decade, enormous efforts by scientists have been given to strict compliance of these provisions and most ELSI researchers and the IRB members have played roles as just “gatekeepers”. On the other hand, a comprehensive draft law to prevent genetic discrimination hasn't discussed nor proposed so that the definition of “genetic discrimination” in Japan hasn't been clear yet. A big picture of future ELSI in both health care settings and non-health care settings must be illustrated by the scientific community with various backgrounds promptly.

As a medical sociologist, I've been involved with the Personalized Medicine Project, led by Professor Yusuke Nakamura, and in charge of operating the Ethics and Governance Group since 2007. We have been discussed several issues that have been raised during the first five-year-operation of the Biobank Japan for more clear and transparent policies. Our activities include several inspections on procedures of continuous recruitment of participants and consent withdrawal, activities of scientific communication with participants and scientists, and empowerment for medical research coordinators. I would like to introduce what we've learned from these day-to-day experiences for illustrating a big picture of future ELSI in Japan.