Title: On "Commentary: The responsibility of the Japanese media, the Fukushima

accident and the use of personal data" by T. Sawano et al.

Authors:

Kyo Kageura

Graduate School of Education, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo, 113-0033,

Japan.

Yutaka Hamaoka

Faculty of Business and Commerce, Keio University, 2-15-45 Mita, Minato-ku, Tokyo, 108-8345,

Japan.

Shin-ichi Kurokawa

Accelerator Department, KEK, High Energy Accelerator Research Organization, Oho 1-1 Tsukuba,

Ibaraki, 305-0801, Japan.

Jun Makino

Department of Planetology, Graduate School of Science/Faculty of Science, Kobe University, 1-1,

Rokkodai-cho, Nada-ku, Kobe, Hyogo, 657-8501, Japan.

Masaki Oshikawa

The Institute for Solid State Physics, The University of Tokyo, Kashiwa, Chiba, 277-8581, Japan.

Yoh Tanimoto

Dipartimento di Matematica, Università di Roma "Tor Vergata", Via della Ricerca Scientifica 1, 00133

Roma, Italy

Contact information of the corresponding author:

Kyo Kageura

E-mail: kyo@p.u-tokyo.ac.jp

Tel: +81-3-6801-7992/+81-70-4195-7921

On "Commentary: The responsibility of the Japanese media, the Fukushima accident and the use of personal data" by T. Sawano et al.

This Commentary, which alleges the media misportrayal of two papers (now retracted), 1,2 not only takes a position that disregards the Declaration of Helsinki, which emphasizes the rights and interests of individual research subjects, but also contains the following errors and misleading statements.

1. "The criticism was due to the way in which personal health data were used, ostensibly without obtaining fully informed consent of participants."

The issue concerned the use of *unconsented* data, not the use of data "without obtaining fully informed consent of participants." The data, collected by Date City and used in the papers, contained fields that indicate whether the participants consented or not.

2. "Consequently, media criticism focused on the presumed failure to comply with research ethics guidelines set by Japan's Ministry of Health and Welfare (MHLW)."

Media criticism also focused on the papers' failure to comply with their own research protocol and on anomalies of scientific content.³

3. "The Ethics Committee of Fukushima Medical University reviewed and approved the research, albeit under the strict condition of excluding all participants who had not provided informed consent for their personal data to be used. Date City government officials provided consent forms to all participants, with over 100 refusing to allow their personal data to be used."

The number of participants who "had not provided informed consent" was 27330, of whom 97 explicitly expressed nonconsent.⁴ The Ethics Committee only approved the use of data with explicit consent. The Date City Investigation Reports confirmed this.^{4,5}

4. "according to the privacy law in Japan, disclosing personal records to any third party in order to conduct necessary analysis allowing the municipal administration to fulfill its responsibilities is legally permitted."

This statement is legally incorrect. Informed consent is required for disclosing personal records; disclosing records without consent is permitted only under extraordinary circumstances, which do not

apply to the two papers. The Date City Investigation Reports confirmed that the papers violated the privacy law and the Date City privacy regulation.^{4,5}

5. "They were given freely to the authors of the papers who were outside Radiation Science specialists engaged to help support the management of radiation exposure in Date City ..."

This statement is misleading, as the first author of the two papers was serving as a municipal advisor to Date City on the issue of radiation management.

6. "The Nuclear Regulation Authority of Japan attached a high value to the results of the analysis."

Multiple anomalies and errors in the numbers and figures of the papers that led to underestimation of the level of radiation exposure have been pointed out.⁶ On 8 January 2019, one of the authors, Ryugo Hayano, admitted that the actual lifetime dose estimate should have been three times the value reported in the papers.

7. "Conflict of interest: None declared."

The last author of the Commentary co-authored several papers with the authors of the two retracted papers. He also served as an advisor to Minamisoma City and Soma City, both municipalities of Fukushima Prefecture.

References

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