

# A Glass Badge Study That Failed and Betrayed Residents

—A Study with Seven Violations of Ethical Guidelines Can Be No Ground for Government Policies

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## Papers that have been published

Makoto Miyazaki from Fukushima Medical University (herein, FMU) and Ryugo Hayano from the University of Tokyo were supposed to publish a series of three papers in the *Journal of Radiological Protection* (herein, JRP) using individual glass-badge monitoring data and internal exposure data obtained from Date City residents and provided by the mayor's office in Date City, Fukushima Prefecture. In this article, the series of three papers will be referred to as the Miyazaki-Hayano Papers, and individual papers as Paper 1, Paper 2, and Paper 3. It should be noted that Makoto Miyazaki, the lead author, has held the position of municipal advisor on radiation for Date City since January 2015. Paper 1 was published in December 2016 and Paper 2 in July 2017, but Paper 3 has not been published to date. As described in this article, Paper 3 is not to be published even at a later date.\*1

The following 2 papers have been published as part of the Miyazaki-Hayano Papers, and they have been used by the central and local governments as references to support policy making.

### Paper 1

"Individual external dose monitoring of all citizens of Date City by passive dosimeter 5 to 51 months after the Fukushima NPP accident (se-

ries): 1. Comparison of individual dose with ambient dose rate monitored by aircraft surveys" by Makoto Miyazaki and Ryugo Hayano, *J. Radiol. Prot.* **37**(2017) 1-12, <http://doi.org/10.1088/1361-6498/37/1/1>.

### Paper 2

"Individual external dose monitoring of all citizens of Date City by passive dosimeter 5 to 51 months after the Fukushima NPP accident (series) : II. Prediction of lifetime additional effective dose and evaluating the effect of decontamination on individual dose" by Makoto Miyazaki and Ryugo Hayano, *J. Radiol. Prot.* **37**(2017) 623-634, <http://doi.org/10.1088/1361-6498/aa6094>.

## About the "Ethical Guidelines for Medical and Health Research Involving Human Subjects"

The first thing to be pointed out is that the Miyazaki-Hayano Papers, originating from research that used human data, must follow the "Ethical Guidelines for Medical and Health Research Involving Human Subjects"<sup>1</sup> (herein, Ethical Guidelines) established by the Ministry of Education, Culture, Sports, Science and Technology (MEXT) and the Ministry of Health, Labour and Welfare.

The following excerpts from the preamble of the Ethical Guidelines summarize their principles:

The welfare of those research subjects shall be given priority over scientific and social results of research, and human dignity and rights shall be protected.

[The Ethical Guidelines are] based on the Constitution of Japan, the Act on the Protection of

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\*1—Translator's Note (TN): The plan to publish a series of three papers is mentioned in the Introduction section of Paper 1.

Personal Information and other related acts, and the ethical principles as defined in the Declaration of Helsinki adopted by the World Medical Association, etc.

The new [Ethical] Guidelines provide fundamental requirements to be observed by any of those concerned in medical and health research involving human subjects. The chief executive of a research implementing entity is required to make decision on the appropriateness of the research protocol prepared by principal investigator, prior to the implementation of the research, having deliberation by relevant ethical review committee, while investigators, etc. are required to implement their research appropriately in accordance with the research protocol approved by chief executive of research implementing entity.

A research protocol for the research that the Miyazaki-Hayano Papers are based on was submitted to FMU on November 2, 2015 and authorized by the FMU president with reference number 2603 on December 17, 2015.

### Main violations of the ethical guideline in the Miyazaki-Hayano Papers

The Miyazaki-Hayano Papers violate the Ethical Guidelines in several ways. Especially serious violations are:

1. Use of data from the Date City residents who did not consent to the use of their data in the research conducted by FMU.
2. Not informing the Date City residents, i.e., the research subjects, of the research content prior to actually commencing the research, and failing to give them opportunities to withdraw their consent.
3. Not disclosing that the papers were written due to a request by Date City Mayor's Office.
4. Acquisition of Date City residents' data by Miyazaki and Hayano and presentation of the data by Hayano before the research protocol was submitted to, let alone approved by, the Ethics Review Committee and authorized by the FMU president.
5. Research was finished without completing a study on the relationship between internal and external exposure doses even though such a study was included in the research protocol,
6. And including a study, which was originally

not in the research protocol, as the third study in the series of three in the Research Completion Report.

7. Destroying all the data at the end of the research even though the Ethical Guidelines mandate retention of data as long as possible.

### The Miyazaki-Hayano Papers use some data lacking consent of the Date City residents

Both the Declaration of Helsinki and the Ethical Guidelines make it imperative to obtain informed consent from the research subjects.

In the research protocol submitted to the Ethics Review Committee at FMU, "8. Enrolling criteria of research subjects" clearly states, "Research subjects for the analysis are limited to those who consented to the use of the data by FMU."

Table 1 of Paper 1 shows N=59056 for 2012 Q3 (October-December 2012), and Figure 4(c) also shows n=59056, clearly showing the number of the subjects for this time period to be 59056. This number represents over 90% of the population of Date City, and it is unlikely that all 59056 subjects gave consent. In fact, during the general Q & A session at the September 2018 City Council Meeting, a Date City official stated,

Regarding the number of consent and non-consent, of 58481 individuals who received measurement results for the July-September period, 31151 gave consent, 97 did not give consent, and 27233 did not turn in the consent form. In other words, 53.3% consented, 0.2% did not consent, and the remaining 46.5% never submitted the consent form.

"The July-September period" in this statement refers to July-September 2012, or 2012 Q2. Despite variations at different periods, the statement shows there have been about 59000 glass badge users and only about 31000 of them have given consent. It is an irrefutable fact that the Miyazaki-Hayano Papers are using some data from some residents who never gave consent, and it is obvious that the research protocol was not followed.

What do Miyazaki and Hayano say about this? First, let's examine the December 15, 2018 article in the Asahi Shimbun digital version, "Dose measurement data without consent offered to Fukushima Medical University by Date City." It reports that the paper author Makoto Miyazaki, Vice Director of the Health Promotion Center at FMU, told Asahi Shimbun that "FMU is in no position to have knowledge

of the consent status. I don't see any problem."

It is hard to understand how Miyazaki's statement could be true. The database provided by Date City for the Miyazaki-Hayano Papers was disclosed after it was obtained through an information disclosure request filed by one of the co-authors of this article (TN: and a Date City resident), Akemi Shima. Although individual information such as ID numbers, names, addresses, and dates of birth was blacked out, the column for the consent status was not: the number "1" was assigned for those who gave consent and number "2" for those who did not give consent, with the space left blank if the consent form was not submitted. We checked several percentages of the database and confirmed that about half of the subjects gave consent after counting the number of individuals marked with "1" in this column. Far from being "in no position to have the knowledge" about this, Miyazaki must have simply disregarded this column.

Further, as mentioned in the beginning of this article, Miyazaki is the municipal advisor for Date City, which means that he is in a position to be able to easily ask the city about the consent status of the data provided by the city. Date City has held monthly meetings with Miyazaki as the municipal advisor since January 2015. The minutes for this regular meeting, "Meeting with the municipal advisor (Mr. Miyazaki)," were obtained by Shima through an information disclosure request. The meeting minutes from April 24, 2017 state, "Regarding the data, Mr. Miyazaki used only the data with consent when writing the paper. Individuals were anonymized, and only 6 items were used. (Household ID numbers, addresses, the decontamination area per household, glass badge measurement results, start and end dates for decontamination, and WBC measurement date and results)." It is obvious that Date City and Miyazaki had an agreement to *use only the data with consent in the paper; even though the data offered included some data without consent.*

Next, let us examine what Miyazaki and Hayano said in the December 21, 2018 article by Ryuichi Kino on the AERAdot website, "Date City offers radiation exposure data for over 27,000 residents without permission—a sloppy treatment of personal information."

The article states that Miyazaki said, "It is assumed that the appropriate data was provided based on a trusting relationship with the entrustor, and the fact that we did not confirm (the consent status of the data) is not considered an issue," and that Hayano said, "It was understood that the entrustor provided us with the appropriate data." As data is very important to researchers, there should be no excuse for

using it without confirming the consent status.

### **Not informing the Date City residents about the research content and failing to offer them opportunities to refuse the use of their data**

The research protocol states, "In order to make public the implementation of this research, we plan to have the statement from Attachment 4 posted on the home page and in public relations brochures of Date City." (Note: Attachment 4 is an announcement that the research was approved by the Ethics Review Committee.) However, this dissemination of information never happened in reality. This means that the Date City residents who were the research subjects were not informed of the fact that this research was going on or what type of research it was. Even though the research protocol states, "research subjects or legally acceptable representatives that gave consent may ask to have their consent revoked after the start of this research," there was no way for the residents to take advantage of this clause when they did not even know the research was going on. This is a serious violation of the Ethical Guidelines, which is just as bad, if not worse, as the Ethics Guidelines violation from using the unconsented data of the residents.

The document that announced the approval of this research by the Ethics Review Committee was posted only on the FMU website, never appearing on the home page or in public relations brochures of Date City. "The Guidance on the Ethical Guidelines for Medical and Health Research Involving Human Subjects"<sup>2</sup> states that information for the research "shall be in easily accessible condition for research subjects" in order to ensure opt-outs, i.e., opportunities for the research subjects to refuse the research being implemented or continued. As the subjects for the research were limited to the residents of Date City, putting the information for the research in accessible condition could have involved putting it on the Date City home page, in a public relations brochure, in a community notice, and so on. For his failure to offer the research subjects opportunities to opt out, despite being the municipal advisor, Miyazaki carries a grave responsibility.

### **Not disclosing that preparation of the papers was requested by Date City Mayor's Office**

There is one more issue to be pointed out. That is, Date City Mayor's Office as well as Miyazaki and Hayano never told residents that the research proto-

col states, “This research originated from a request to analyze the data obtained from the radiation dose measurement project in Date City, reporting the results to Date City, and widely disseminating the results as academic papers.” Miyazaki and Hayano completely omitted from the acknowledgement section of the papers the fact that the presentation of the academic results, i.e., publication of the papers in JRP, had been requested by the Date City mayor at the time (Shoji Nishida, 2006-2018) and Date City Office apparently had constant involvement with preparation of the papers through the monthly meetings with the municipal advisor, i.e., Miyazaki. This omission of potential conflicts of interest from the acknowledgement is against the ethical rules to be followed when publishing a research paper. It is a violation of the Ethics Guidelines and also research misconduct.

The request letter from the Date City mayor to the FMU president and Miyazaki is dated August 1, 2015. However, in the August 25, 2015 meeting minutes with the municipal advisor, Miyazaki said, “Regarding the analysis of the glass badge measurements, a formal request from the city is required to disseminate them academically. (...)”

The request letter from the mayor is dated August 1, while the August 25 meeting minutes say, “A formal request from the city is required.” This is incomprehensible and ought to be explained by Miyazaki.

Paper 1 is explained by Miyazaki in Volume 30 of the Date Reconstruction and Regeneration News. However, it does not say who the authors are, what the title is, or which section of what journal it was published in. This alone is against the Creative Commons Attribution 3.0 License which must be complied with as specified by JRP. It also shows a lack of respect for the Date City residents.

Paper 2 is briefly mentioned by Date City mayor Nishida in Volume 31 of the Date Reconstruction and Regeneration News, in the phrase “also according to a recent paper.” Why he had to refer to Paper 2 in a distant manner when he himself was the one that requested the paper be prepared is beyond comprehension.

Miyazaki, Hayano, and the Date City government did a thorough job of hiding from the Date City residents who were the research subjects the facts that preparation of the papers was requested by the mayor and that Papers 1 and 2 had already been published. This is a violation of the Ethical Guidelines by both Date City, the provider of the data, and the researchers, the recipients of the data.

### **Date City residents’ data were used in a presentation before the research protocol was approved**

On September 13, 2015, Hayano made a presentation at the Twelfth ICRP (International Commission on Radiological Protection) Dialogue Meeting, showing some graphs with an analysis of the individual exposure dose data based on the glass badge measurements. It wasn’t until November 2, 2015 that the research protocol, where Hayano’s name as a co-investigator appears for the first time, was submitted to the Ethics Review Committee at FMU. Therefore, as of September 13, 2015, Ryugo Hayano was merely a third party to Date City. For such a third party to have the glass badge measurement data owned by Date City and to conduct an analysis is clearly a violation of the basic principle of the Ethical Guidelines, “to obtain an approval of the Ethics Review Committee prior to commencing the research.”

### **The phantom Paper 3**

The Miyazaki-Hayano Papers were originally planned as a series of three papers, yet Paper 3 never materialized. In fact, Paper 3 will never be published as explained in the beginning of this article. In this section, we are going to examine how this non-existent Paper 3 constitutes a violation of the Ethical Guidelines.

Information disclosure requests filed with FMU by Shima have disclosed a Research Completion Report and a Status Report on the Maintenance of Materials and Data from this research. These reports, submitted on October 23, 2018, state that the research was to be completed as of October 31, 2018 and that the data used in research and materials related to the data would all be destroyed after the completion of the research. The Research Completion Report, which must include a summary of the research findings as a rule, described the main findings as follows:

The analytical results of the data received were published as peer-reviewed papers in an academic research journal in December 2016 and July 2017. (37-1, 2017 and 37-623, 2017 in Journal of Radiological Protection.)

Later, as a study derived from the analytical results themselves, we conducted a temporal estimation of additional individual external exposure doses due to the nuclear power plant accident in Fukushima Prefecture. We compared the results with similar estimates report-

ed by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), and it was published as a peer-reviewed paper in February 2018 (38-310, 2018, Journal of Radiological Protection). We reported to Date City about the details of these analyses and the circumstances of their publication. The commissioned project was completed after the publication of three papers, and the research ended.

The point to be raised here is the fact that the Research Completion Report mentions “three papers” but the third paper (TN: published in February 2018) has nothing to do with this research. The research protocol states,

12. Expected research findings and academic contributions

In this research, we anticipate finding the following from information contained in the database provided by Date City:

- 1) There is a positive correlation between the ambient dose monitoring results and the individual external exposure doses.
- 2) There is no correlation between the individual external and internal exposure doses.
- 3) Decontamination resulted in a decrease in the individual external exposure doses (only limited to area A).
- 4) An estimate of the lifetime doses the residents will receive from continuing to live in Date City.

We plan on publishing them as academic papers, based on the data obtained so far.

Item 1) was published as Paper 1, and items 3) and 4) were published as Paper 2. It was item 2) that was to be published as Paper 3.

Also, the following excerpt from Paper 1 refers to contents of Papers 1-3.

The present authors made use of the large-scale individual dose monitoring data provided by Date City covering the period from 5 to 51 months after the FDNPP accident, analyzed the relationship of the individual doses to the results of airborne surveys conducted by the Japanese Government [10], the effect of decontamination on the individual doses, and the relationship between the external and internal doses. These results will be published in a series of three papers.

“The relationship of the individual doses to the re-

sults of airborne surveys conducted by the Japanese Government” refers to Paper 1, “the effect of decontamination on the individual doses” to Paper 2, and “the relationship between the external and internal doses” to Paper 3.

Why, then, did Miyazaki and Hayano decide not to publish Paper 3? This also is hinted at in the meeting minutes with the municipal advisor. In the February 23, 2018 meeting minutes, Miyazaki said,

Regarding the papers, although we planned to publish a third paper on WBC, we decided there was no need to publish it as a paper since the internal exposure doses were not related to the ambient doses.

This statement is astonishing. One of the expected findings described in the research protocol, “2) There is no correlation between the individual external and internal doses,” was actually found, yet they chose *not* to publish it.

Now, let us look at the document called “Radiation Health Management Plan for Date City (Second Phase)”<sup>3</sup> which was released by Date City in April 2017. Page 9 of this document shows the results of the internal exposure monitoring project. The results from Fiscal Year (FY) 2015 show the detection rates of radioactive cesium above the detection limit in subjects aged 19 and older by town: 4.2% in Ryozen, 5.3% in Tsukidate, 2.2% in Hobara, 0.3% in Date, and 1.5% in Yanagawa. These towns are roughly listed in the descending order of the ambient dose rates. Because the external doses are approximately proportional to the ambient doses, these results show a clear correlation between the external and internal doses. The number of subjects, 6833 for FY 2015, increases to 43261 when including the results from FY 2011-2012 which shows as much as a 9.4% detection rate for cesium including children. This points to an even more clear correlation between the external and internal doses. Further, the meeting minutes with the municipal advisor report some cases with very high levels of internal exposure measurements: over 4000 Bq in one resident in the October 26, 2015 minutes, 6400 Bq in the May 30, 2017 minutes, and 5700 Bq in the June 28, 2017 minutes. The true reason for not publishing Paper 3 could be the discovery of a clear correlation between the external and internal doses with some residents showing internal exposure measurements of several thousand Bq even since 2015. Not publishing inconvenient results despite receiving the internal exposure dose data from Date City would have to be considered a violation of the Ethical Guidelines.

Regarding publication of the results, the Declara-



tion of Helsinki states, “Negative and inconclusive as well as positive results must be published or otherwise made publicly available.” The ICMJE recommendation also states, “Some people consider failure to publish the results of clinical trials and other human studies a form of scientific misconduct.”

## **Destruction of the data as scientific misconduct**

The previous section showed that the Status Report on the Maintenance of Materials and Data attached to the Research Completion Report stated that, “the data used in research and the materials related to the data would all be deleted after the completion of the research.”<sup>\*2</sup> If the data were indeed destroyed on October 31, 2018, the end date of the research as indicated in the Research Completion Report, that means the data were destroyed only 15 months after the publication of Paper 2 in July 2017. Destruction of the data merely a little over one year after publication of the final paper is a violation of the Ethical Guidelines and it would have to be considered scientific misconduct. Regarding storage of information for research, the Ethical Guidelines state, “The chief executive of research implementing entity shall endeavor to ensure that information, etc. of the research implementing entity will be retained for as long as possible.” Also, the document called the “Improvement of Integrity in Scientific Research” by the Science Council of Japan states, “Research materials such as experimental data which produced research findings that were published as papers, etc., shall be retained for 10 years after the publication of the paper.”

Further, the “Guidelines for Responding to Misconduct in Research”<sup>4</sup> established by MEXT includes the following clause.

### **2. What is Publication of Research Results?**

Publication of research results is the act of making public the results obtained from research, while presenting data and materials that can be objectively verified, so that the scientific community can examine and judge those results. For the intellectual resources shared by all human beings to be built up soundly through scientific research, a verification system, premised on the integrity of the people carrying out the research and consisting of mutual examination and judgment among researchers, is essential. The publication of research results means par-

ticipation in this verification system. In many cases it takes the form of research paper publishing, and it is largely for the sake of this verification that there are certain fixed rules about writing such papers (presentation of data and materials, logical development, indication of conclusions, etc.).

As a matter of fact, one of the authors of this article, Shin-ichi Kurokawa, submitted critical comments about Paper 2 as a Letter to the Editor to the Journal of Radiological Protection in August 2018. The Letter went through the peer-review process and was “ready to accept” as of November 16, 2018: Publication of the Letter is pending on a response from the original authors, Miyazaki and Hayano, so that the Letter and the authors’ response can be simultaneously published in the same issue.

Thus, researchers must anticipate criticisms regarding their papers, and sincere responses require retention of the data in preparation for any necessary re-analysis. This very issue is described as, “The publication of research results means participation in this verification system. In many cases it takes the form of research paper publishing,” in the “Guidelines for Responding to Misconduct in Research” by MEXT. Any interference with this verification system constitutes scientific misconduct. Hence, destruction of the data by Miyazaki and Hayano would have to be considered scientific misconduct.

There is another major problem with destruction of all the data by Miyazaki and Hayano: Date City does not have the integrated database in its custody as presumed. The research protocol states, “After the analysis, investigators will not retain the database but delete it.”<sup>\*2</sup> Further, the reason this research does not require audit is stated as, “The data is no different from the database owned by Date City, which makes it possible for Date City to double check the results of the analysis. For this reason, audit is considered unnecessary.”

Moreover, the research protocol states as follows regarding the database provided by Date City:

### **2) Compilation of a database**

Date City has compiled the entire results of all the projects conducted so far into individual IDs, establishing a viewable database which includes the measurement results and decontamination information over time. (···) Also, it includes information assigning the grid points (with a mesh size of about 300m x 300m) from the aerial monitoring measurements conducted by the government to the addresses of the subjects.

<sup>\*2</sup>—TN: Note: the research protocol says “delete(d),” but “destroy(ed)” is more appropriate.

Further the letter from Mayor Nishida to Miyazaki requesting the research states,

The database was constructed not only with the existing results from the external and internal dose measurement data, but also residential addresses of the subjects which are incorporated into a GIS (Geographic Information System) and matched with the nearest grid (with a mesh size of about 300 m x 300 m) of the aerial radiation dose monitoring survey conducted by the government.

When Shima filed an information disclosure request with Date City for this integrated database, the response was that such a database was “practically non-existent.” An objection was filed with Date City, and a written explanation was returned from Date City. The written explanation from the Disposition Agency (Date City Mayor, handled by the administrative office of the Department of Health Promotion) is summarized as follows:

1. Hayano was asked by Date City to create the integrated database.
2. Date City verified a sample of the database created by Hayano, but it was deemed unnecessary to have it supplied to the city. Therefore, Date City does not have the database in custody.
3. The database was passed on from Hayano to Miyazaki.

If the statement by the Disposition Agency is accurate, Hayano and Miyazaki were aware that Date City did not have the integrated database in custody. Yet they wrote in the research protocol that Date City had the database, and they proceeded to destroy all the data including this database.

The description of how the integrated database was created, as stated in the written explanation, is simply bizarre from the point of view of personal information protection. One of the previous sections points out that the personal information of Date City residents was provided to a third party, Miyazaki and Hayano, before the research was even approved by the Ethics Review Committee. The investigation committee by Date City must shine a light on the circumstances of the data provision and if it was accompanied by any violation of the personal information protection act.

## Conclusion

As this article points out, the research that formed

the basis of the Miyazaki-Hayano Papers is riddled with many violations of the Ethical Guidelines. In particular, the following actions constitute serious ethics violations: using the unconsented data; depriving the residents of the opt-out opportunities due to failure to inform the residents about the research and its content; acquiring the data from Date City and starting the research before the research protocol was submitted and approved; ending the research before publishing Paper 3 and destroying all the data; and reporting a study not included in the research protocol as research results in the Research Completion Report. Moreover, destruction of all the data is a reckless action that is inevitably considered scientific misconduct.

Date City is culpable of mismanagement as the data provider, but researchers conducting “Medical and Health Research Involving Human Subjects” must adhere to the Ethical Guidelines strictly. How Miyazaki and Hayano conducted this research can only be described as too careless.

Principle 36 of the Declaration of Helsinki includes the following four parts regarding “publication and dissemination of results” (Note: The numbers 1-4 were added by the authors):

1. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports.
2. All parties should adhere to accepted guidelines for ethical reporting.
3. Negative and inconclusive as well as positive results must be published or otherwise made publicly available.
4. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication.

Principle 36, then, concludes, “Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.”

The Miyazaki-Hayano Papers disregard all four parts of Principle 36. This means that the Miyazaki-Hayano Papers are exactly the “reports of research not in accordance with the principles of this Declaration,” and thus “should not be accepted for publication.”

Lastly, let us point out that the ethical policy of the Journal of Radiological Protection which published the Miyazaki-Hayano Papers, includes full adherence to the Declaration of Helsinki in investigations involving humans.

## References

- 1—<https://www.mhlw.go.jp/file/06-Seisakujouhou-10600000-Daiji-nkanboukouseikagakuka/0000080278.pdf>
- 2—<https://www.mhlw.go.jp/file/06-Seisakujouhou-10600000-Daiji-nkanboukouseikagakuka/0000166072.pdf>
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