Report on the Ethical Review System in the Healthcare Sector – A Framework to Ensure Ethical Utilization of Healthcare Data

March 2023

The PeOPLe Co-Creation and Utilization Consortium
Task Force on Healthcare Data and Ethics

内容

1. Introduction: Determining suitable regulations for data use in healthcare

With the increased desire for better well-being and the advent of the super-aging society, expectations regarding the use of healthcare data have been rising. That trend was further accelerated during the COVID-19 pandemic.

Simultaneously, a number of issues connected to the handling of such data have arisen. As no concrete rules are in place, there is a risk that proper data use has been hindered because the extent to which legal, ethical, and social concerns must take precedence when applied to privacy, equality, and other values is still unknown.

We formed a task force consisting of experts in various fields as we believe it is necessary to engage in discussion about more appropriate guidelines and regulations for the utilization of healthcare data. Ethical research guidelines are already in place to govern the use of data in the areas of medical research and medical care, but the same cannot be said when it comes to the broader field of healthcare business operations. That is why the task force focused its multifaceted investigation on healthcare businesses in particular. To ensure that the investigation was as efficient as possible, the task force consulted with businesses actually utilizing healthcare data, in addition to working with researchers conducting theoretical studies. This was achieved by harnessing the trusting relationships built between members of the academic and industry communities through such efforts as Keio University's PeOPLe/OPERA operations.

After the first iteration of the task force released its interim report and summary, a broad range of opinions were solicited from various stakeholders – including those overseas – and they were incorporated into the report created by the second task force members. We greatly appreciate all involved in providing us feedback regarding the interim report.

This report brings together theories, results, and analyses acquired through our consultations with organizations working in the field. It was prepared to serve as a useful reference not only for companies engaged in healthcare operations, but also for local and national government bodies. We welcome questions, comments, and critiques from all stakeholders regarding future investigation into the issues touched upon here. We look forward to working with any and all interested in open, frank discussions of this practical research approach.

Healthcare Data and Ethics Task Force Members

First Task Force Members (July 2020-March 2022) (Titles as of time of task force participation)

- Takehiro Ohya, Professor, Faculty of Law, Keio University (Task Force Chairperson)
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Second Task Force Members (April 2022-March 2023) (Titles as of time of task force participation)

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2. Building a Hypothesis: Healthcare data issues, standards, and systems

1) Research targets – The scope of the term "healthcare data"

The term "healthcare data" as used in this report includes body weight, body fat percentage, steps walked per day, activity level, temperature, pulse rate, blood pressure, blood sugar level, heart rate, respiratory rate, sleep records, food consumption records, facial imagery (for facial recognition), and more. In the broadest sense, it includes all data concerning a healthy adult individual that can be continuously acquired, collected, and analyzed with the object being the promotion of better health and well-being.

There are several considerations to be taken into account when handling such data.

First, medical history and other similar data (as defined by Article 2 Paragraph 3 of Japan's Act on the Protection of Personal Information[1]) was temporarily excluded from the scope of data. This included information about medical care, pharmaceutical use, checkup results, health advice and all other information that could reveal the state of an individual's health and potentially reveal or identify an illness. This type of data can be considered equivalent to that which falls under the definition of "medical history" and would therefore require special handling considerations, and so was therefore excluded as a core target for study[2].

Second, we decided to exclude all data concerning minors, dementia patients, or any other individual from whom it would be difficult to obtain "consent" as defined by Article 16, Paragraph 1 of the Act on the Protection of Personal Information[3]. Genomic data is also considered outside the scope of the term as defined in this report as it should be considered subject to special consideration as some of that data is shared with relatives. Similarly, we excluded any data that could be a problem due to group privacy[4] issues. However, though some such data was removed from the scope of usable information, we remained conscious of it while conducting our study. We were particularly careful regarding checkup results, medical treatment history, and other such information because connectivity often has such data handled by single services or apps that bundle it together with other healthcare data.

Third, the data collected had to coincide with an individual in an "ordinary" state, during which they aim to maintain and improve their health. All data considered to be taken in an "emergency" state

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[1] According to the Act on Anonymized Medical Data That Are Meant to Contribute to Research and Development in the Medical Field (the so-called Next Generation Medical Infrastructure Act), "medical data" is deemed to be personal information and defined to include "medical history," as defined in Article 2, Paragraph 3 of the Act on the Protection of Personal Information. However, it can be extremely difficult to distinguish between healthcare data and what is generally considered "medical data." For example, daily blood pressure data would fall under the definition of medical history for those with hypertension.

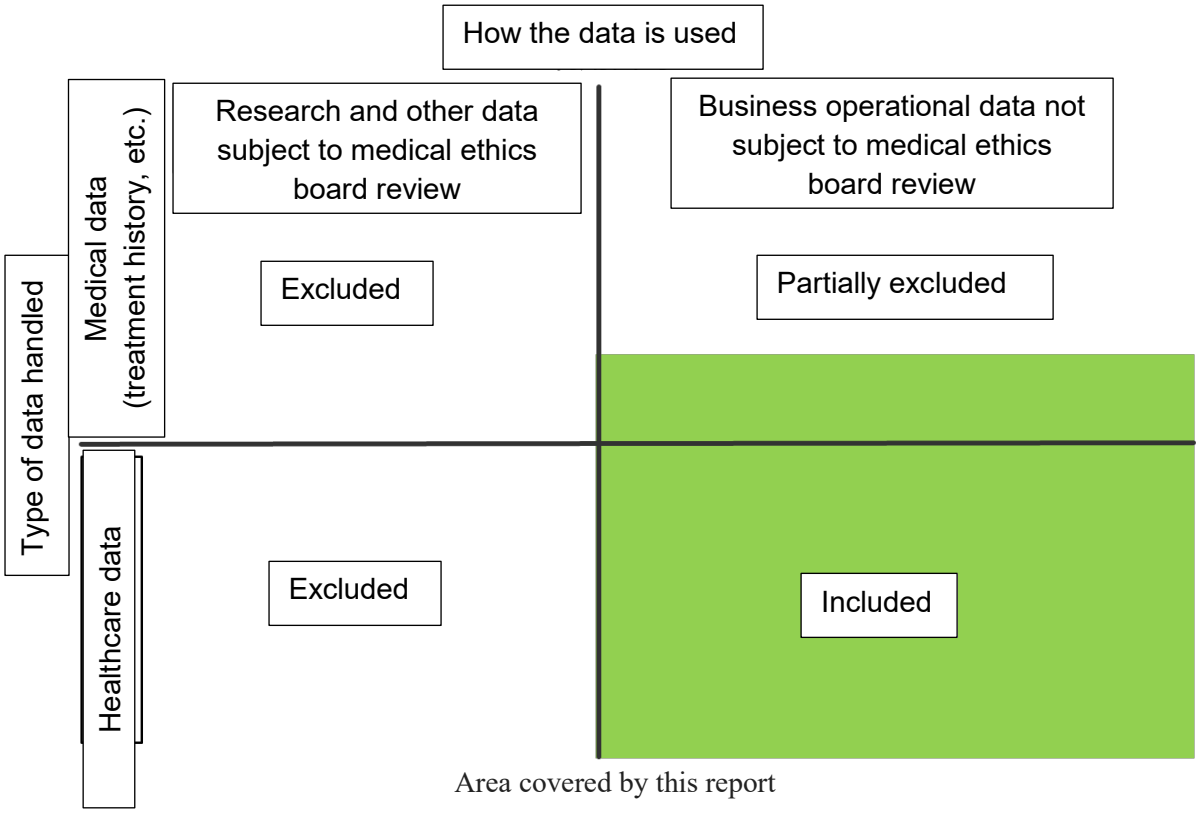
[2] The Health Information Working Group is a part of the Study Group on the Utilization of Health, Medical and Nursing Care Information, a joint effort between the Ministry of Internal Affairs and Communications, the Ministry of Health, Labor and Welfare, and the Ministry of Economy, Trade and Industry. The Study Group released two documents in April 2021, the *Basic Guidelines for the Management of Health and other personal data by Private-sector PHR Business Operators* and the *Report from Study Team on Private Utilization.* Our report coincides with the definitions included in those guidelines and report, which state that companies exclusively handling data on vital signs and other health-related data for individuals were not to be included as targets for study.

[3] With the handling of nursing care data concerning dementia patients in mind, we propose an ethical framework for the handling of data from individuals from whom consent is difficult to obtain in *Good Data: Sharing Data and Fostering Public Trust and Willingness,* Takanori Fujita, Fumiko Kudo et al., World Economic Forum, 2021. https://www.weforum.org/whitepapers/good-data-sharing-data-and-fostering-public-trust-and-willingness

[4] Taylor, Linnet, Luciano Floridi, and Bart Van der Sloot, eds. *Group privacy: New challenges of data technologies. Philosophical Studies Series. 126*. Springer; 2016.

(as defined by the Sections 2 and 3 of Paragraph 1, Article 23 of the Act on the Protection of Personal Information) was excluded from this study.

However, we conducted the study without limiting methods for acquiring and storing data defined as "medical devices" according to Article 2, Paragraph 4 of the Pharmaceutical Affairs Act. It can be difficult to determine the eligibility of medical devices or programs/software[5], but we decided to include a broad range of healthcare related devices and programs/software[6].



Area covered by this report

2) Issue awareness

The healthcare data used in this report is by definition neither invasive nor directly able to be considered personal in nature. However, continued acquisition, collection, and analysis of this data could potentially allow it to be used to learn about or infer the state of illness for an individual at a given moment. For example, daily records on sleep and food consumption fall under the definition of healthcare data, but disturbances to sleep patterns or a sudden tendency to overeat could be used to infer an individual has entered a state of depression.

There are two possible approaches for the handling of such healthcare data. The first carefully treats all information as sensitive from the beginning because it could eventually fall into that category. Although this approach is extremely safe and strong, there is the concern that pre-symptomatic research could become more difficult to conduct. The second approach takes a more flexible, risk-based response. The task force selected the latter approach for this study.

It should be noted that there are strong ethical concerns in the field of healthcare data. Traditionally, the aim of those working in the field of medicine was to maximize patient benefit. Issues such as

[5] See Pharmaceuticals and Medical Devices Agency Document 1228-2 (released 28 December 2018) for information on partial revisions made to section titled "Basic thinking behind applicability to medical devices and programs/software". http://www.jaame.or.jp/mdsi/program-files/301228kanma12282.pdf

[6] In South Korea, software and other non-medical devices used for exercise and health management are also subject to regulation under the country's laws governing medical devices.

information asymmetry and the irreversibility and significance of information related to body and health could be broadly considered partially applicable to healthcare data also.

Therefore, we must find consider a means of data governance that is able to respond flexibly while remaining ethical and compliant to regulations[7].

3) The three research theories

The task force proposed the following three hypotheses for its investigation.

- **Theory A** (Problems): It is not yet clear the extent to which legal, ethical, and social considerations must be taken in the handling of healthcare data, and this may be hindering healthy business growth.
- **Theory B** (Rules): It may be possible to support the growth of healthcare data businesses by giving direction to ethical guidelines and codes of conduct from a third-part expert perspective. This may help to prevent inappropriate business practices.
- **Theory C** (Structure): Implementation may be made easier not only by presenting guidelines and standards, but also by presenting a healthcare data governance structure (e.g. a system of review, procedures, etc.)

Theory A maintains the arguments surrounding potential issues posed in a previous study published in December 2018 titled *Proposal regarding profiling*[8]. It proposed that profiling is not limited to medicine and healthcare, but is in fact spreading beyond advertising and marketing into credit scores, personnel evaluation, and other areas that can potentially have significant impact on an individual's freedom and independence[9]. The paper points out that accordingly, the social companies that introduce or utilize profiling will have greater social responsibilities imposed upon them. In addition, there are no concrete guidelines regarding how a company can fulfill its legal and social responsibilities with regards to profiling in Japan. The authors suggest that this may have a chilling effect on healthy business growth, and made some recommendations regarding rules that could be implemented[10]. It is hypothesized that the above points could also be considered applicable when it comes to businesses operating in the field of healthcare data.

Regarding Theory A, it was pointed out near the beginning of the task force's work that "if the use of healthcare data can be ultimately used to aid in making medical diagnoses and offering treatment, all data gathered should be treated as 'personal information requiring special consideration' and managed extremely carefully."

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[7] The task force does not propose that loopholes be found to subvert conventional medical research and treatment ethical reviews, but in fact suggests that conventional ethical review is required for initiatives that fall within the purview of ethical guidelines designed for research, clinical trials, etc.

[8] Personal Data +α Research Group. Proposal regarding profiling. *New Business Law*. 2018; 1137: 64-85. Shojihomu Co., Ltd.

[9] The paper defined profiling as any action involving "the use of personal data and algorithms to analyze or predict a specific individual's interests, preferences, abilities, credit capability, knowledge, behavior, etc." The EU's General Data Protection Regulations (GDPR) began to be implemented in May 2018, and it provides this definition: "…'profiling' means any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to a natural person, in particular to analyse or predict aspects concerning that natural person's performance at work, economic situation, health, personal preferences, interests, reliability, behaviour, location or movements;…". (See GDPR Article 4(4).)

[10] *Proposal regarding profiling* was later updated, with *Final proposals regarding profiling* released 22 April 2022 (Available at https://wp.shojihomu.co.jp/shojihomu_nbl1211), but this description from the original paper was used as it was what the task force referred to during its investigation.

Theory B is based on actual practical application of what was proposed in *Proposal regarding profiling*, mentioned above. Its *Interim report including proposals* takes a more definite direction regarding ethical guidelines and codes of conduct with the included "Checklist for voluntary efforts." The People Analytics and HR Technology Association announced principles actually based on the proposals in 2020, titled *Principles for utilization of personnel data*[11], which promoted the formation of an industry body that would provide self-regulation[12].

This theory was also based on suggestions received when investigating systems built for reviewing medical research and treatment to use as reference points for this study[13], namely that medical research and medical treatment ethical review boards may be unable to fully investigate issues related to privacy protection. The reason given for this was that ethical review in these fields is fundamentally designed to protect subjects and patients from highly invasive physical procedures, so challenges may arise by expanding review to encompass other types of values (e.g. protection of personal information, equality, social value of research, etc.)

This theory proposes therefore that it may be necessary to re-state the direction of ethical guidelines and codes of conduct specific to the utilization of healthcare data.

Theory C is also based on suggestions obtained while investigating review systems in use in medical research and medical treatment. Currently, ethical review boards in Japan are decentralized, which helps ensure independence and autonomy. On the other hand, there is no system in place to collect or receive feedback based in the knowledge of different individuals, so experience is only gained on the local level. In addition, a series of institutional reforms were implemented throughout the 2010s to improve the issues surrounding the so-called "The 3000 Ethics Committees Problem." They were expected to allow for greater consolidation and better quality assurance, but it is difficult to say whether or not either objective was achieved[14].

That is why this theory proposes that it may be necessary to come up with a review system, procedures, and other elements of a system of governance designed to handle the issues presented above.

References: Preliminary work conducted before formation of the task force

- 18 February 2020 – Held a study session on ethical review systems in the fields of medical research and medical treatment in the era of AI medicine
    - Lecturers: Yutaka Tomiyama (Researcher, Graduate School of Humanities and Sociology, University of Tokyo), Yusuke Nagato (Specially-Appointed Assistant Professor, Research Center on Ethical, Legal and Social Issues, Osaka University)Moderator: Takehiro Ohya (Professor, Faculty of Law, Keio University)
    - https://www.people-tonomachi.com/report/2019/200218.html

[11] "Request for distribution of *Principles for utilizing personnel data – Ver. 1* and its Explanatory Video," The People Analytics and HR Technology Association, 19 March 2020 Available at https://peopleanalytics.or.jp/news/2025/

[12] In *Ethical Issues Regarding the Use of Profiling Services for Recruiting: The Japanese Rikunabi Data Scandal*, Fumiko Kudo et al studied whether or not the "Checklist for voluntary efforts" mentioned here would have had any effect on reducing or removing risk during the scandal surrounding issues with Rikunabi job offers. See *Proceedings of the Annual Conference of the Japanese Society for Artificial Intelligence*, 2020.

[13] See Appendix 1 for an overview.

[14] Tashiro, Shimon. Trends in Reform of the Ethics Review Board System in Japan. *Journal of Health Care and Society.* 2018; 28 (1): 79-91

- 5 June 2020 – Held a study session of the formation of rules governing the use of personal data
    - Lecturer: Fumiko Kudo (Visiting faculty, Research Center on Ethical, Legal and Social Issues, Osaka University)
    - Moderator: Takehiro Ohya (Professor, Faculty of Law, Keio University)
    - https://www.people-tonomachi.com/report/2020/200605.html

3 Theory testing and analysis: Suggestions obtained from opinions in the business field

1) Opinions of people in the field

The first task force held six discussion meetings over the course of its investigation. Details can be found below.

- 21 August 2020 (1st meeting): Discussed and decided task force objectives, administrative rules, and how to proceed
- 29 September 2020 (2nd meeting): First hearing to survey of opinions in the field
- 6 November 2020 (3rd meeting): Second hearing to survey of opinions in the field
- 9 November 2020 (4th meeting): Third hearing to survey of opinions in the field
- 14 December 2020 (5th meeting): Discussed and decided how to proceed based on opinions gathered
- 5 February 2021 (6th meeting): Discussed interim report proposal

It was decided that opinions gathered and discussed during the 2nd to 5th meetings would be handled in accordance with the Chatham House Rule. In principle, access to documents and other materials was limited to members of the task force. Consequently, this report contains only an outline of the information obtained.

2) Additional investigations by second task force

An interim report was created to release the results of the six meetings of the first task force. The second task force built upon that work through the four meetings detailed below, which were held during its investigation.

- 10 August 2022 (1st meeting): Discussion of whose (experts/businesses) perspectives should be included in the interim report
- 15 December 2022 (2nd meeting): Hearing to survey of opinions in the field
- 28 December 2022 (3rd meeting): Review of opinions gathered in the field
- 27 February 2023 (4th meeting): Discussion of final report and future direction

As was the case for the first task force, it was decided that opinions gathered and discussed by the second task force would also be handled in accordance with the Chatham House Rule. In principle, this meant that access to documents and other materials was limited to members of the task force, and therefore this report contains only an outline of the information obtained.

In addition, a summary of the interim report was translated into English (Appendix 2), and we solicited opinions on it from experts overseas (Appendix 3). This report reflects the results of these additional investigations.

3) Theory testing and analysis

The following three theories were verified using the results of the investigations conducted by the first and second task forces.

- **Theory A** (Problems): It is not yet clear the extent to which of the legal, ethical, and social considerations that must be taken in the handling of healthcare data, and this may be hindering healthy business growth.
    - There is a chilling effect on businesses concerned about the potential risks to their reputation due to the lack of any concrete rules. (Conventional ethical reviews do not necessarily consider potential reputational risks.)
    - Because of this chilling effect, healthcare data tends to be subjected to the same strict handling rules designed for personal information requiring special consideration.
    - On the other hand, there is an incentive to avoid such difficulties by underestimating the applicability of stricter rules to personal information because the procedures involved in the handling of medical information are complicated.
    - We initially envisioned that businesses would be the primary users of healthcare data, but later realized that other important stakeholders include businesses operating platforms that distribute smartphone apps, government bodies, and other public sector organizations[15].
- **Theory B** (Rules): It may be possible to support the growth of healthcare data businesses by giving direction to ethical guidelines and codes of conduct from a third-part expert perspective. This may help to prevent inappropriate business practices.
    - Ethical guidelines and codes of conduct can go some way towards managing risk to reputation.
    - It would be more effective to provide a defined code of conduct based on actual usage cases rather than a set of abstract ethical guidelines. (It may be difficult to create a code that can be sufficiently generalized to meet different situations.)
    - For example, there is definite need for a code of conduct on the utilization of employee healthcare data.
    - There is already a lack of knowledge about such issues, not only among individual employees, so it will be important to educate people not only within companies but also on local and national levels.
    - Clearer guidelines regarding personal health promotion and privacy issues are already being formulated, but there is still a need for further consideration of and discussion about other values (e.g. equality, social value of utilizing such data, etc.)
    - The relationship between this type of data and the medical research data considered outside of the scope of this study should also be shown.
    - It was initially assumed that these regulations would apply to data acquisition and use, but it may be beneficial to also consider what regulations may be needed regarding the use of unjustifiable premiums in labeling, advertising, etc.
    - It is important to design guidelines that comply with norms.
- **Theory C** (Structure): Implementation may be made easier not only by presenting guidelines and standards, but also by presenting a healthcare data governance structure (e.g. a system of review, procedures, etc.)

[15] See Appendix 4 below for further discussion on how stakeholders are categorized.

- Healthcare data is less physically invasive so it falls outside of the purview of ethical review boards in the fields of medical research and medical treatment. There is therefore room to review and restructure the system because there is a risk that insufficient consideration will be given to privacy protection and other concerns. For example, a possible approach would be to outsource to or work with the Personal Information Protection Commission, so-called "Authorized Personal Information Protection Organizations," and other bodies that ensure personal information is handled appropriately.
- A decentralized ethical review system must have a means of maintaining review quality. For example, information about the experience and knowledge of ethical review board members must be collected, and feedback provided to each review board.
- It is also necessary to ensure that actual operations run smoothly and promptly, all while maintaining the ability to collect a certain amount of information. A related issue would be to ensure best practices are followed by determining terms of use beforehand to distinguish between what sorts of information can be decided upon using automated methods and what sorts of information require actual adjudication through careful ethical review.

4) Suggestions received

The key findings of the investigations conducted by the first and second task forces are summarized below.

4-1) Include diverse operational strategies

We observed that some companies are adopting business policies that take into account their social reputation to differentiate themselves from other companies – in a similar way to how companies try to create a "green" brand image. For such companies, the lack of clear and concrete guidelines governing the use of healthcare data poses a potential risk to their reputation, and to a certain extent, likely imposes a chilling effect on the decisions they make. This observation partially validates Theory A and Theory B.

At the same time, we found that companies employ a diverse range of business strategies. In other words, each company has to make various decisions about whether to thoroughly comply with existing regulations, or to proactively embark on a course of rule-making. Although it may be difficult in practice, any examination of what guidelines would be most appropriate should respect the business decisions each company makes.

4-2) The role of platform operators

We also confirmed the role played by Apple, Google, and other platform operators. Such operators can serve as gatekeepers when reviewing apps to ensure they observe the rules governing healthcare data. In addition, it was confirmed that they play an important role in providing health interventions in the realm of COVID-19 countermeasures. However, there needs to be a guarantee that platform operators will act appropriately.

It was for this reason that we revised Theory A to include platform operators as subjects.

See Appendix 4 below for more information regarding the stakeholders involved in designing a review system for healthcare data utilization.

4-3) The role of the public sector

We observed companies utilizing data from the point of diagnosis with the aim of monetizing such work and expanding their businesses. In other words, we are noticing a trend in operators adopting business strategies resembling the B2B2C model, with the customer touchpoint being the time of diagnosis[16]. Accordingly, there is a tendency to treat data as personal information requiring special consideration because it is linked to diagnostic information, and to implement strict guidelines for information management and utilization, so there have been no problems in the field regarding healthcare data. This is a partial rejection of Theory A.

However, this could also be interpreted as showing a need for the public sector to formulate rules regarding healthcare data. In brief, from a medical economic perspective, it is important to take an approach that promotes the improvement and maintenance of good health and allows for pre-symptomatic data use (not only after symptoms have been discovered), and there is demand for the acquisition, collection, and analysis of healthcare state data of individuals while they are still healthy. The reason for this is that there is always the possibility that project operators will not take it upon themselves to formulate guidelines independently.

Therefore, we decided to revise Theory A and include government bodies and other public sector organizations as subjects. It is a fact that there are cases in which healthcare data is not subjected to the same sort of ethical review that is conventionally required in the academic sector – e.g. in health promotion projects – and ethical reviews should be conducted to ensure personal protection in a way similar to those conducted by companies. The public sector also has a role to play in providing education to improve knowledge of the issues, and in providing incentives.

4-4) Regulation in line with objectives and risks

One view expressed during the hearings was that if life-saving is the priority, data governance can be used to achieve that goal. This may also coincide with Article 23, Paragraph 1, Item 2 of the Act on the Protection of Personal Information. It is only reasonable to assume that a different form of governance will be needed in ordinary times when the objective is health maintenance and improvement (when compared to times of emergency). Moreover, even in ordinary times, data management can be divided up into data management for treatment, data management for disease discovery, data management for daily health, and other types of data management.

There were also concerns about what should be considered when the purpose of the data utilization is changed due to subsequent operational developments.

Regarding Theory B, it was suggested that ethical guidelines and codes of conduct should be organized in response to healthcare data usage objectives and risks, while keeping in mind concrete use cases. Yet, healthcare data can be used in ways that do not require the ethical review described in this report, so further clarification is required in this area also.

[16] We received a comment suggesting that it would initially be more cost-effective to use indirect marketing aimed at doctors and medical institutions that influence consumer and patient decisions rather than target the general public directly from the beginning.

4-5) Using employee healthcare data

During the hearings process, it was discovered that there is a demand for the utilization of employee healthcare data. For example, healthcare data acquired while an employee is working remotely could be used to maintain physical and mental health, and to prevent turnover.

The aforementioned *Principles for utilization of personnel data* could provide some direction in personnel matters. However, special consideration and handling should be observed for data connected to mental health as it could be a source of marriage-based or employment-based discrimination.

In addition, employee data made be used internally in the development of products, but consent in such cases may not be sufficiently voluntary. It is necessary to ensure that such consent is truly voluntary by guaranteeing the ability to refuse and preventing peer pressure, and otherwise preventing such data from being put to other uses based on weak consent. Moreover, the utilization of employee data should be considered from the perspective of data reliability as well, by taking care to eliminate any biases that favor particular product development.

It was suggested that business development could be aided by adding a sub-item to Theory B that provides a code of conduct that covers commensurability between personnel data and healthcare data.

4-6) Regulations on labeling and advertising

Concerns were raised during the hearings about the harm caused to consumers by non-scientific claims made by the makers of "dubious" healthcare apps, and about overregulation resulting from those concerns.

This issue is reflected in Theory B. Consideration could be given to revising the Pharmaceutical Affairs Act and other related legislation to include another category alongside "foods with function claims" and "foods with specified health uses" in the medical device and program/software section. In addition, we can expect a review of regulations governing unjustifiable premiums in labeling, advertising, and other such areas in order to protect consumers. It is important to consider a review of incentive implementation as well. This should be studied for its use as a system to ensure product reliability, for example through implementing policies to shift burden of proof, as proposed in the Act against Unjustifiable Premiums and Misleading Representations.

4-7) Invasiveness, privacy, and other values

It was pointed out that ethical review boards in the medical research and treatment fields may be unable to give full consideration to privacy protections. Physical invasiveness is generally considered to be low in the context of the utilization of healthcare data, and thereby such considerations fall outside the area of focus for medical ethics review boards.

One comment suggested that a possible approach would therefore be to outsource to or work with the Personal Information Protection Commission, so-called "Authorized Personal Information Protection Organizations," and other bodies that ensure personal information is handled appropriately.

It was suggested that this alone may not be enough as there has been little progress made in the formulation of guidelines and practical application for equality, social value of utilizing such data, and other such non-privacy related values. For example, there remain a number of questions about how to sort out data and algorithm biases, and how evaluations should be made from the medical economics perspective, and more.

In addition, there must be appropriate and well-informed oversight of outsourcing and cooperating organizations, rather than avoiding responsibility and simply strengthening bureaucratic authority.

This partially validates Theory B and Theory C.

There was also a proposal that it could be beneficial for a supervisory body to take a dual approach involving administrative guidance and penalties if problems were to still arise after guidelines that take into account a diverse range of values were formulated and promoted within the healthcare data industry. A system for reporting issues when they arise should also be considered.

4-8) Reviewing bodies and feedback

It was suggested that it remains uncertain who will undertake the work of conducting ethical reviews of healthcare data utilization, and there is no means of assuring quality. For example, in the case of research ethical reviews, it can be expected that a medical board will make appropriate judgements fitting a situation even without policies governing that specific situation in place. However, boards reviewing work conducted in other faculties without prior experience in ethical review may end up being more defensive in their judgements. Another comment stated that it will be necessary to also prevent so-called "forum shopping[17]". The opinion was expressed that specific guidelines would be necessary to prevent such actions.

This partially validates Theory B and Theory C.

As discussed above, the adoption of a decentralized review system makes it more difficult to accumulate knowledge and could lead to inconsistent standards. This lesson was learned from the ethical review system in place for medical research and medical treatment. It is necessary to absorb and gather the knowledge and experiences of each ethical review board, and to provide feedback to each.

Here it was suggested that financial incentives for auditing bodies be considered. For example, software platform operators review apps as a part of their business, so it can be said that they have a financial incentive to do so. However, it is still necessary to ensure that the reviews conducted by platform operators are appropriate.

4-9) Standard and substantive reviews

It was decided that smooth, prompt processing should be considered. For example, it was noted that tens of thousands of applications are submitted regarding genome analysis, so consent acquisition and other usage terms based on consent are processed regularly and automatically matched.

A dual system could also be considered for healthcare data as well – through standardized handling of consent confirmation and terms of use – followed by more in-depth review of items that takes into account uncertain potential risk, flexible personal interest of the reviewee, etc. We can envision a post-inspection model in which project research is launched and problems dealt with when they arise, and a pre-inspection model in which projects cannot be launched without being subject to social review. Consent and conditions of use must be regularly confirmed for healthcare data as well, but a dual system can be considered for when future risk is uncertain, or when review is conducted based on more flexible interests of the reviewee. Regarding promptness and simplification, the opinion was expressed that perhaps it would be possible to make up a notification system in advance to ensure no target cases are overlooked, and then make it possible to conduct audits afterward.

[17] Forum shopping is a term generally used in legal contexts to refer to a plaintiff choosing a court more likely to rule in the plaintiff's favor when a case could be held in multiple jurisdictions.

For Theory B and Theory C, one suggestion proposed that once conditions of use are decided, it would be beneficial to determine which parts will be determined automatically and which will undergo substantive ethical review, while other issues were raised regarding how reviews would be assessed.

4-10) Internal and external auditing

As mentioned previously, ethical guidelines and codes of conduct should be designed in accordance with the objectives of healthcare data use and any potential risks. It was suggested that it would be subsequently possible to have a selection of auditing frameworks available, including internal and external audits, and audits conducted by third-party committees. In addition, there are multiple options available for the auditing of holding companies and other groups of connected companies, from where to establish the review board, to whether to provide only a report of target operations or to go as far as providing a full audit, etc.

It was also suggested that attention should be paid to maintaining diversity among auditing personnel, securing the personnel needed to conduct audits, and securing administrative functions. Some rules in place for clinical trials were noted. For example, in clinical trial review, board members must include an individual whose expertise lies outside of the realm of medicine, dentistry, and pharmacology and who has no specialized knowledge regarding clinical trials. Another rule states that the board must include an individual independent of the medical institution conducting the trial[18]. Another proposal stated that in addition to the forming of ethics committees to regulate data usage, it is also conceivable to have data use promotion committees that advocate for the social value of data utilization. Other ideas received include the establishment of numerous expert sub-committees, and structuring the main committee such that it provides summaries of all projects being undertaken.

The methods by which votes are placed, whether through unanimous decision, supermajority, etc., can also have a major effect on actual operations.

4-11) Other concerns, issues, and ideas

It was noted during the hearings that other factors that serve as hindrances to the healthcare data business include issues surrounding standardization and data interoperability. Interoperability may need to be achieved under the guidance of the public sector. (This is connected to Theory B.) Also, technical standards that incorporate Privacy by Design and other ethical aspects are being formulated. We would like to discuss this point in cooperation with JIS and other working groups in the future.

It was also pointed out that other obstacles include the difficulties in coordinating data sharing between national governments, local governments, and the private sector. This became particularly apparent when data was being shared between local governments while introducing countermeasures to combat the spread of COVID-19. However, work is being done to address this issue through the 2021 Amendments to the Act on the Protection of Personal Information, which aim to unify data usage rules that are adaptable to the characteristics of different data handling organizations. There are also international issues surrounding the linking of medical research and treatment data with healthcare data. However, there has been greater movement toward collecting and utilizing such data together since the COVID-19 crisis began, and those trends should be watched.

[18] Article 28 Paragraph 1 Items 3,4 of the Ministerial Ordinance on Standards for Conducting Clinical Trials of Pharmaceuticals https://www.pmda.go.jp/int-activities/int-harmony/ich/0076.html

5 Conclusion

This report is built upon the results released in the interim report in which theories on the ideal ethical review system for the field of healthcare were proposed; consultations were undertaken to obtain the opinions of businesses actually working in the field; and the results were reviewed and analyzed. This report improves upon the original by reflecting the opinions of various stakeholders both in Japan and around the world.

The future plan is to formulate practical guidance for those working in the field by creating questionnaires (check sheets) for use in self-evaluation and third-party evaluation and organizing a data handling framework for the rules and systems covering healthcare data usage and ethical concerns while keeping concrete use cases in mind, and thereby continue with a multistakeholder perspective. In parallel with the publication of this report, we are also creating educational materials for use in the field, but we believe that the addition of check sheets and other such tools will only them more useful and enriching as educational materials.

This is an experimental endeavor and therefore we expect various questions, opinions, and critiques to arise. We warmly welcome all feedback.

There is great potential for the utilization of healthcare data, yet there is naturally some concern about how it will be used. In order to build (or re-build) public trust, industries, governments, academia, and the various other stakeholders must cooperate in the creation of more appropriate guidelines for the use of data in the healthcare field.

Appendix 1

Overview of the findings of the Study Group on Ethical Review Systems in Medical Research and Medical Treatment

Issues

- 1. Overabundance of accredited ethical review boards
    - There are a large number of accredited boards, which has hindered consolidation. In addition, accreditation is no more than a formality, and there is no way to prevent "ethics board shopping" where reviewees flock to review boards that conduct lax investigations.
    - Is the accreditation system not fulfilling its expected function of consolidation and quality assurance? (Tashiro, 2018(a))
- 2. Insufficient discussion of privacy issues
    - In both medical research and genome guidelines, personal identification codes and personal information requiring special consideration as defined in the revised Act on the Protection of Personal Information are handled in an ad hoc way, and discussion of this has been insufficient.
- 3. Ambiguity of privacy-related values
    - There is ambiguous treatment of values (such as social value of research) that are not directly connected to the protection of subjects that ethical review boards are responsible for ensuring (Tashiro, 2018(b)).
- 4. Unspecialized functionality
    - There are two ethical review boards (IRB and HEC) handling research ethics and clinical trial ethics, two fields that are in principle independent, and the boards themselves are unspecialized. It is suggested that this has resulted in boards not fulfilling their function of resolving ethical issues that arise in the field of medicine (the role of HEC) (Ikka, 2012).
- 5. Lack of personnel to conduct ethical reviews
    - 57.3% of research institutions do not train board members
    - 12.4% of boards have no external members
    - (The 8th Joint Meeting on the Review of Ethical Guidelines for Epidemiological and Clinical Research, Document 6. http://www.mhlw.go.jp/stf/shingi/0000031891.html)

Examination

- New challenges connected to Issue 2 above
    - The primary aims of the Next-Generation Medical Infrastructure Act (2018) and its AI medicine components are to facilitate the "big data" analysis of medical information that is collected from individuals, to develop diagnostic support software that harnesses artificial intelligence (AI), to provide optimal treatment regimens for each individual patient, and to make it easier to evaluate treatment results that integrate information from different medical institutions and different fields.
    - The ethical, legal, and social issues (ELSI) surrounding AI medicine are one of the most pressing problems in the fields of information ethics and bioethics.
    - The problems inherent to AI-IRB may be more serious than many people think.
        - Problems surrounding the use of AI itself
            - Algorithm biases, the blackbox nature of AI, potential for attacks

            - Issues with sharing responsibilities between humans and AI, training users to give them greater knowledge
        - Problems specific to medical treatment and research
            - Notification, informed consent, the physician-subject(patient) relationship
            - Equal access to medical care, the roles and abilities of medical care professionals
        - Problems in the review system
            - Consolidation, quality assurance
            - Securing the personnel needed to conduct reviews
- As in Issue 3, it is important to defend other values in addition to those surrounding subject protection.
    - The primary missions of the ethical review system are 1) to protect the subjects, but also 2) to ensure social value of research and keep it open to the public
    - However, this has not been subject to much discussion in deliberative bodies such as the Ministry of Health, Labor and Welfare.
    - The Clinical Trials Act lays out a legal obligation for specified clinical research regarding the usage of unapproved pharmaceutical drugs, as well as requiring companies to self-fund evaluations of their products.
    - "The purpose of this Act is to…promote the conduct of clinical trials through ensuring the confidence in clinical trials of citizens including clinical trial subjects in order to contribute to the improvement of public health and hygiene." (Article 1)

Primary literature cited

- Ikka, Tsunakai. Reconsideration of hospital ethics committee for its revision. *Bioethics*. 2012; 23(1).
- Tashiro, Shimon. Trends in Reform of the Ethics Review Board System in Japan. *Journal of Health Care and Society*. 2018; 28(1): 79-91. [2018(a) above]
- Tashiro, Shimon. Rethinking the Role of Ethical Review Boards: From Subject Protection to Social Trust. *The Annals of Legal Philosophy*. 2018 [2018(b) above]

Appendix 2

Interim Report on the Ethical Review System in the Healthcare Sector,
The PeOPLe Co-Creation and Utilization Consortium Task Force on Healthcare Data and Ethics – Executive Summary (Proposal)

Issue Awareness

Societal expectations regarding the use of data gathered in the healthcare field have been rising in respect to people's well-being, super-aging societies, and other factors. Simultaneously, a number of issues tied to the handling of such data have arisen, including legal, ethical, and social considerations regarding privacy, equality, and other values, and obstacles to proper data utilization due to a lack of real discipline in handling that data. It is therefore necessary to implement appropriate rules that will govern data utilization in the healthcare field.

Extent of Healthcare Data and Related Issues

The term "healthcare data" as used in this interim report includes weight, body fat percentage, steps taken, amount of exercise, body temperature, pulse, blood pressure, blood glucose levels, heart rate, respiratory rate, sleep records, dietary records, facial images (for recognition of expressions), and other information. In a broad sense, it includes all such data intended to be acquired, collected, and analyzed by healthy adults in their daily lives for the purpose of promoting better health and well-being.

By definition, this type of healthcare data is not directly invasive, and does not directly correspond to the type of personal information requiring more considerate handling under the Act on the Protection of Personal Information. However, when such data is continuously acquired, collected, and analyzed, and under other potential conditions, at a certain point of time, such sensitive data could be used by others to learn private information about the state of an individual's illness or predict its future course. (For example, sleep and dietary records could be used to infer that an individual is in a state of depression.)

In handling such healthcare data, the first approach may be to understand the possibility that the information could become sensitive, and therefore consider it as personal information requiring careful protection from the outset. However, while that information will now be carefully protected, one concern is that such an approach would make it more difficult to search for pre-symptomatic illnesses. A second risk-based approach could allow for a more flexible response. This task force is examining the latter approach, and there are major ethical concerns in the field of healthcare data due to the fact that there is some validity to previously noted concerns in the medical field about information asymmetry, the irreversibility and importance of physical health, etc. For that reason, the issue lies in how to create a form of data governance that can be to some extent flexible, while at the same time ensuring that data is handled in an ethical way and compliance is maintained.

Three Research Theories – Testing and Analysis

These three theories were designed to consider three perspectives – problems, rules, and structure – and they were tested and analyzed after consultation with businesses working in the field. This resulted in the following suggestions being received.

- **Theory A** (Problems): It is not yet clear the extent of the legal, ethical, and social considerations that must be taken in handling healthcare data, and this may be hindering healthy business growth[19].

[19] This provisional model builds on the issues raised by the Personal Data +α Research Group in "Proposal regarding

- Chilling effect: Healthcare data tends to be as carefully handled and applied as if it were personal information requiring protection, but as there are no concrete rules in place, there has been a chilling effect on businesses that are considering potential risks to their reputation.
- Stakeholders: Important stakeholders include not only businesses using healthcare data, but also platforms distributing smartphone apps, and government bodies.

● **Theory B** (Rules)
It may be possible to support the growth of healthcare data businesses by giving direction to ethical guidelines and codes of conduct from a third-part expert perspective. This may help to prevent inappropriate business practices. [20].

- Ethical guidelines and codes of conduct can help manage risk to reputation to a certain extent, but they are even more useful when a concrete code of conduct is in place. For example, there is a certain need for the use of employee healthcare data.
- Unlike with promoting better health in individuals, where standards have been clarified to some extent, further review into the social value of impartiality and data use is necessary. Here, not only do the acquisition and use of data need to be reviewed, but the use of consumer-retention prizes and advertising in dubious healthcare apps with no scientific foundation also merits review.

● **Theory C** (Structure): Implementation may be made easier not only by presenting guidelines and standards, but also by presenting a healthcare data governance structure (e.g. system of review, procedures).

- There is room to re-build the structure to govern healthcare data as it lies outside of the area of focus of medical ethics review boards.
- When more extensive review is required, it could be entrusted to or conducted in cooperation with an organization able to guarantee that personal information will be handled appropriately (e.g. the Personal Information Protection Commission.)
- More decentralized reviews will require experience and knowledge sharing, and feedback, to ensure that each review committee is able to ensure high quality reviews.
- Consideration must be given to smoothness of operation and system speed. The best current example is a method by which any formal decisions can be kept separate from substantive ethical analyses.

Suggestions Received
The key findings of the consultations are summarized below.

- **Include diverse business strategies**

profiling," pp 64-85, New Business Law Volume 1137 (2018), published by Shojihomu Co., Ltd.
[20] Connected in a practical way to the previously mentioned "Proposal regarding profiling." In addition, an example of this in practice can be found in the People Analytics and HR Technology Association article, "Request to distribute *Personnel Data Utilization Principles 1st Ed.* and the *Explanatory Video*," posted on 19 March 2020, https://peopleanalytics.or.jp/news/2025/

The lack of clear and concrete standards regarding the handling of healthcare data poses a potential reputational risk for companies that want to maintain a clean brand image and societal approval, and therefore that lack of clarity can have a chilling effect on business growth. However, there is great variety in business strategies, and each company makes its own decisions on whether to thoroughly comply with current law, or to proactively engage in rule-making. Any review must ensure that rules appropriately respect the judgement of each company.

・The role of platform operators

Platform operators such as Apple and Google can function as gatekeepers by reviewing healthcare data apps to determine rule compliance.

・The role of the public sector

It is necessary to assume that government bodies and other public sector organizations will play major roles in this effort. From the perspective of monetizing data and business growth, there is a tendency among companies managing and using personal information linked to diagnoses and other data to carefully protect it, and there have been no issues related to healthcare data in practice. On the other hand, from a medical economics perspective, there is demand for the acquisition, collection, and analysis of healthcare data from healthy subjects (not only for data that begins to be gathered after the discovery of an illness), although it is possible that business operators may not voluntarily proceed forward with formulating their own rules. For that reason, there is some merit to having healthcare data regulations be formulated by the public sector.

・Regulating objectives and risks

Different forms of governance are required during ordinary times, when health maintenance and improvement is the objective, and during emergencies, when life-saving becomes the priority. Moreover, it is possible to further divide data management during non-emergencies into what is required for medical treatment and what is required for detecting illness, and when neither of those apply, what is required for the management of everyday health. Additionally, when it comes to business growth, there are also concerns about what must be kept in mind when the data utilization objective changes after the fact. Ethical guidelines and codes of conduct should be designed in accordance with the objective of the use of healthcare data, and any potential risks, by considering specific use cases.

・Use of employee healthcare data

There is demand for the use of employee healthcare data, for example, by obtaining data from those working remotely in order to maintain physical and mental health, and to prevent employee turnover. Data related to mental health may require special consideration and handling due to the potential of it being used to discriminate on the basis of marital status or occupation. Here, business growth can be promoted by providing a code of conduct on connecting company personnel data with healthcare data.

・Rules regarding display content and advertisements

Issues have arisen regarding consumers harmed through the use of dubious, non-scientific healthcare apps, and regarding subsequent over-regulation. In response to this problem, it may be possible to consider adding new app categories to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, in a way that corresponds to the current food categories that allow for regulation of “foods with functional claims" and "foods for specified health use." In addition, it can be assumed that regulations of prize display and advertising will also be considered in order to protect consumers.

・Invasiveness, privacy, and other value-based issues

The use of healthcare data is generally not considered to be very invasive and it lies outside the scope of medicine and the purview of ethics review boards in the medical fields, so there is the risk that such bodies will not sufficiently consider privacy protections. For that reason, in order to maintain such protections, consideration should be given to outsourcing such work to or collaborating with organizations with experience in the appropriate handling of personal information like the Personal Information Protection Commission or organizations certified in the protection of personal information. Of course, there has been little progress in the formulation of laws or the practical operation of systems for non-privacy-related values (e.g. impartiality and the social value of data use). For example, there are still open questions regarding how to manage bias hidden in data and algorithms, and how to conduct evaluations from a medical economics perspective.

・Reviewing bodies and feedback

It was suggested that there are uncertainties regarding who will conduct ethical reviews of healthcare data utilization and that quality cannot be assured. It will also be necessary to prevent so-called “forum shopping.” Certain guidelines may need to be implemented in order to prevent this sort of situation. In addition, it will be difficult to gather knowledge if a decentralized review system is adopted, and there will be a problem with inconsistent standards. It will therefore likely be necessary to gather information about the experiences and knowledge of each review board, and generate feedback to be provided in return. Any economic incentives for the reviewing body should also be considered, e.g. in the case of a platform operator reviewing applications for apps to be sold on its platform.

・Regular and substantive reviews

Consideration must be given to smooth, rapid processing of reviews. For example, reviews related to genome analysis have application numbers in the tens of thousands, so the acquisition of consent and conditions of use based on that consent are processed regularly and automatically matched. Consent and conditions of use must be regularly confirmed for healthcare data as well, but a type of dual system can be considered for when future risk is uncertain, or when review is conducted based on more flexible interests of the reviewee. Once conditions of use are decided, it would be beneficial to determine which parts will be determined automatically, and which will undergo substantive ethical review.

・Internal audits and external audits

As mentioned previously, ethical guidelines and codes of conduct should be designed in accordance with the objectives of healthcare data use and any potential risks. Subsequently, that makes it possible to have a selection of auditing frameworks available, including internal

and external audits, and audits conducted by third-party committees. At the same time, attention should be paid to maintaining diversity among auditing personnel, to securing the personnel needed to conduct audits, and to securing administrative functions. In addition to the forming of ethics committees to regulate data usage, it is also conceivable to have data use promotion committees that advocate for the societal value of data utilization. Other ideas received include the establishment of numerous expert sub-committees, and structuring the main committee such that it provides summaries of all projects being undertaken. The methods by which votes are placed, whether through unanimous decision, supermajority, etc., can also have a major effect on actual operations.

・Other considerations

Other factors that are serving as hindrances to the healthcare data business include issues surrounding standardization and data interoperability. Interoperability may need to be achieved under the guidance of the public sector. Also, technical standards that incorporate Privacy by Design and other ethical aspects are being formulated. We would like to discuss this point in cooperation with JIS and other working groups in the future. Other obstacles include the difficulties in coordinating data sharing between national governments, local governments, and the private sector. However, this issue is being addressed through the 2021 Amendments to the Act on the Protection of Personal Information, which aims to unify data usage rules that adapt to the characteristics of different data handling organizations. These trends should be watched.

Towards the Future

For this interim report, theories on the ideal ethical review system for the field of healthcare were proposed; consultations were undertaken to obtain the opinions of businesses actually working in the field; and the results were reviewed and analyzed.

The plan for the future is to create questionnaires (check sheets) for use in self-evaluation and third-party evaluation, and to organize a data handling framework for rules and systems that account for healthcare data usage and ethical concerns in consideration of concrete use cases.

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(Honorifics omitted; includes positions and affiliations at time of publication)

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Appendix 3

Overview of comments received from overseas experts regarding the summary of the interim report

1. (USA) Supheakmungkol Sarin
Head of Data and AI Ecosystems, World Economic Forum

Overall comments:

- Definition of healthcare data: The text defines "healthcare data" as information gathered by healthy adults in their daily lives for promoting better health and well-being. However, healthcare data can also include information collected by healthcare professionals or derived from medical tests and examinations, as well as data related to individuals with chronic illnesses or those seeking medical care. Is it better to use another term?

- Invasiveness: The text states that healthcare data is "not directly invasive." However, the invasiveness of healthcare data depends on the context in which it is collected, used, and disclosed. If used improperly, healthcare data can be invasive and violate an individual's privacy.

- Personal information protection: The text suggests that healthcare data does not require "more considerate handling" under personal information protection laws. This statement is not accurate, as many jurisdictions have strict regulations in place for handling healthcare data or sensitive personal information, such as GDPR in the European Union or HIPAA in the United States.

- Sensitive data: The text acknowledges that sensitive data could be used to infer private information about a person's health. However, it's worth noting that even without continuous data collection or under specific conditions, individual data points (like sleep and dietary records) can still be sensitive and reveal information about a person's health or well-being.

Individual comments: Nine remarks (omitted here) made about content of the document

2. (South Korea) Son Hyeungseob
Professor, Kyungsung University

Question 1: In South Korea, are there any special rules (e.g. privacy laws or laxer guidelines) regarding the handling of everyday “healthcare data,” i.e. that data which differs from the medical information handled by hospitals?

Response 1: The Republic of Korea’s Ministry of Food and Drug Safety has guidelines governing the licensing and review of AI medical devices. In accordance with Article 2 of the Medical Device Act, those guidelines are applied to devices that provide disease diagnosis and management using medical data analysis, and to machine learning-enabled medical devices (MLMDs).

MLMDs are unlike medical software that is used to detect or diagnose issues through existing medical image analysis in that users or manufacturers can use training datasets to change the analysis algorithms in real time.

This provision to the law includes software that falls under the definition of “medical device”, and software that does not (e.g. exercise and leisure software, daily health management software, etc.) The Ministry of Food and Drug Safety can classify and administer a device as “medical” even when it originally falls under the “non-medical device” description if, when it analyzes both domestic and foreign documentation to determine applicability of the law, it discovers any risk in a product under development.

Question 2: Is the distinction between medical and non-medical devices stipulated in the Medical Device Act? Also, are there any differences between how the two types of device are evaluated?

Response 2: According to Article 2, Paragraph 1 of the Medical Device Act, “medical devices” refers to instruments, machines, devices, materials, software, and other similar products controlled by or used in conjunction with either human individuals or animals, and that fall under any of the following categorizations: 1) products used for the purpose of diagnosis, curing, alleviation of symptoms, treatment or prevention of disease; 2) products used for the purpose of diagnosis, healing, alleviation of symptoms or otherwise correcting an injury or disability; 3) products used for the purpose of examination, substitution, or transformation of body structure or functionality; and 4) products used to regulate pregnancy.

In the “Permit and inspection guidelines for medical devices to which big data and artificial intelligence (AI) technologies are applied” released in 2019 by public request, there is a distinction made between medical software categorized as “medical device” and medical software that is not. Examples of the latter include software that collects data on insurance claim to support the administrative work done by medical institutions, and software used for exercise and health management.

Question 3: Are there any particular penalties in place regarding the handling of non-medical devices in the Ministry of Food and Drug Safety guidelines governing the licensing of AI medical devices (Complainant Guide).

Response 3: Article 51 (Penalties) of the Medical Device Act requires that any individual or organization that obtains a manufacturing license (Article 6, Paragraphs 1 and 2), certification, or report from the Ministry of Food and Drug Safety through deception or other wrongful means be subject to a penalty that could include imprisonment of five years or less and a fine of no more than 50 million won. It is easy for forgery and other forms of deception to become apparent during the actual review process. In addition, the Ministry of Food and Drug safety has also introduced regulations (by notification) governing permissions, notifications, examinations, etc. of medical devices.

Question 4: When conducting clinical trials, do universities and other research institutions conduct ethical reviews even when the objective of the trial is not the development of pharmaceutical products or medical devices?

Response 4: At universities, ethical reviews of research are conducted by institutional bioethics committees. The relevant law is the Bioethics and Safety Act. This is the same as the United States. Article 10 of the Act requires that review boards examine the ethical and scientific validity of research proposals, and examine any measures in place to protect personal information.

The “Medical device manufacturing and quality control standards” require that good manufacturing practices (GMP) be implemented for high-level quality control of medical devices. This involves an initial review, additional reviews, reviews when changes are implemented and periodic checks as well. These reviews are conducted on-site in a joint effort by the head of the local Food and Drug Safety Agency and the head of the quality control inspection office.

We also have U-healthcare systems harnessing ICT (defined in the guidelines for licensing and examination of medical devices (released by public request)). Such systems fall under the definition of medical device.

Question 5: Is there currently any movement towards creating a framework for the governance of healthcare data (e.g. review systems and other procedures.) If not, would it be possible to implement the type of company-by-company ethical review proposed by this report in South Korea?

Response 5: The certification and review of medical devices is based on Article 26 of the Regulations on licensing, reporting and review of medical devices. That is based on Article 6 of the Medical Devices Act (which states that a manufacturing license must be obtained from the Ministry of Food and Drug Safety). There are specific provisions laid out for the licensing, reporting, and review of medical devices. It allows for B2B sales, in which a company licensed for medical devices provides its own corporate information to other companies, and B2C, which uses remote diagnosis to provide services to consumers. Genetic testing is conducted with permission of the Ministry of Food and Drug Safety. Users of personalized healthcare information, biotechnology associations, and remote diagnosis operations are revitalizing their marketing platform businesses using the MyData program. For healthcare ethical review, it would likely be a good idea to provide general guidelines on the use of healthcare data, then set up either voluntary or legislated review procedures. Medical data for patients that receive treatment is kept at each different hospital. Hospital data systems are designed to support hospital administrations in a comprehensive way by dealing with treatment, administration, finances, legal issues, services, and more. It is necessary to develop a set of ethical and reliable rules and guidelines in cases that a user visiting a hospital has cancelled their cloud computing contract and their healthcare data is to be uploaded to the cloud.

Question 6: Have you heard anything about businesses handling healthcare data (including public sector operations) not being able to grow? For example, are there any businesses that avoid moving into business areas where regulations are unclear because they want to avoid damaging their reputation and becoming the focus of criticism?

Response 6: IoT equipment and other devices connected to digital healthcare are growing in number, and the MyData platform is being actively used as a means of acquiring consent. Healthcare data includes a wide range of information about an individual’s illnesses and state of health, and that information can be separated into different categories, including medical treatment data, dielectric data, public sanitation data, and more. Digital therapeutics and remote diagnosis are currently being implemented (by more than 20 companies in a regulatory sandbox). Public data is provided by the government through the My Healthway program, and the plan is to commercialize this in the future (three years from now.) In South Korea, the 2020 revision to the Credit Information Use and Protection Act allows financial information to be used, and revisions to the Personal Information Protection Act recognize the right to transfer information, so we are preparing for being able to use medical data. There are still psychological barriers when it comes to medical data, but when using only specific data in analyses, it will be able to be used in many areas.

Question 7: Do you think it would be useful to provide ethical guidelines and codes of conduct based in specific use case examples to companies and other related stakeholders? One example would include the creation of a code of conduct for the use of employee healthcare data.

Response 7: Nurses and other medical staff in health promotion teams at large companies use health data internally to look after employee welfare. Mid-sized companies collect data by having employees exercise in gyms, checking their exercise amount, and then providing health advice. However, there are no guidelines in place, and no means of conducting review yet. Such data is expected to be used internally through the consent of individual employees. However, it is highly likely that people are unaware about whether or not such consent extends beyond in-company use (for the purposes of employee welfare) to research and commercial purposes, so it is necessary to implement concrete procedures to obtain such consent.

Question 8: Do you have any opinions about creating an ethical review system governing healthcare data usage at companies (including those not involved in medical research or advanced medical care), or about implementing a similar ethics review system for local or national government bodies that handle healthcare data?

Response 8: Review procedures are currently being implemented in South Korea to allow medical devices to receive approval of the Ministry of Food and Drug Safety, and smart health devices defined as “medical devices” are included. However, review procedures for non-medical healthcare devices are not being properly observed. With medical data, this becomes an issue in South Korea under the Personal Information Protection Act. There needs to be a standardized system of ethical review for companies using non-medical ICT devices as they come into more common use, even when they are being used internally. This is particularly true when it comes to healthcare devices with cognitive functionality – ethical guidelines and regulations for review need to be formulated. If such ethical regulations do not function well enough to prevent their use becoming a social issue, the laws themselves will have to be amended to include such types of ethical review. If safety standards for medical and non-medical ICT healthcare equipment can be implemented, local governments can then establish bodies that review the safety standards in light of the law just as the central government would do, rather than create ethical standards that differ by locality. If Japan is able to introduce ethical and review standards in both the private and public sectors governing healthcare products, artificial intelligence, and other issues, I expect that this will have a positive influence on similar efforts in South Korea and other neighboring countries.

3. (Malaysia) Chin Hai Teo
Senior Lecturer, Universiti Malaya

The publication of the Interim Summary of "Report on the Ethical Review System in the Healthcare Sector” by the PeOPLe Co-Creation and Utilization Consortium’s Task Force on Healthcare Data and Ethics is timely and commendable. Although data privacy and confidentiality is a well-known issue, there is a lack of official guideline that could guide healthcare institutions and companies in managing personal health data of the people particularly wellbeing data obtained on a daily basis. This halts the effort to untap the true potential of big data in health care. The effort led by the PeOPLe Task Force could potentially bring a solution to this persistent issue.

Many of lifestyle monitoring mobile apps offer rather good benefits to the users in monitoring their health, hence leading to consistent use of the apps by the users. However, the users often do not give much attention to how the app providers would use their data and how they keep the data safe. As witnessed in other countries particularly the developing countries, the public's awareness about data privacy is still low. The people often fail to give sufficient attention to data privacy, perhaps they are not aware about the potential risk of their information being abused. In most cases, people do not read the terms of use of apps that they install and accept the terms without much thought. Studies have also shown that the people have low e-literacy skills in appraising quality and trustworthiness of health apps. These could potentially put them at risk of their information being abused. Japan is a highly looked-up developed countries but there bound to be some population with lower literacy that may not be aware and do not take proactive precaution about their personal data. Knowing the public's needs and providing sufficient education to the public on data protection is also crucial besides enhancing data management from the healthcare providers' perspective.

That aside, this report looked at the management of wellbeing data such as diet, physical activity and pulse instead of disease-based data. This complies with the current norm or practice as disease-based information are considered sensitive and could potentially cause discrimination or bias in various aspects including finance, opportunity and social status. That being said, as technology matures particularly in this big data digital era, synergising wellbeing data with disease data could help make health prediction more accurate, so that doctors could provide more precise intervention or management to the patients (precision medicine), preventing patients' condition from deteriorating and improve their survivability. With sufficient data, strong prediction could be done even at prevention stage before someone developing diseases. Currently, the wellbeing data or so-called patient-generated health data are not well-integrated with the medical data in the hospital. This is perhaps due to the lack of guideline and uncertainties faced by health institutions to move this forward. There are still debates about who is the owner of the patient data in the hospital to date. Data are now scattered sporadically and not well consolidated. Only when 'all is one', a powerful potential could be unleashed. It would be great if the PeOPLe Task Force could somehow include this when discussing and proposing the way forward in managing health care data.

At one point in the report, it was mentioned that the governance of health data in 'ordinary times' should be different from 'emergency times', which is very much agreed upon. During the COVID-19 pandemic, many countries made it compulsory for personal data of the people such as COVID-19 status and locality to be submitted to a central application typically managed by the government. That has enabled effective surveillance to be done to control the outbreak of COVID-19. An all-in-one perhaps nationally integrated health data warehouse could be powerful in improving health care. To date, it has been a struggle to integrate health systems into one in many countries. A top-down approach by the government during COVID-19 pandemic has shown us a glimpse of the great potential of having an integrated health data system. However, this brings us back to the autonomy ethics principle where everyone has the rights to their own data and should not be forced to share the data with others. There is a need to strike a balance in creating policy on this matter so that the maximum potential of health care using big data could be unleashed while keeping in-tact the people's autonomy. Learning from successful countries such as Estonia in implementing an integrated health system would be advisable, to adopt their effective strategies and policies in health data governance considering multiple perspectives including the government, healthcare institutions and the people.

The PeOPLe Task Force's effort in getting views from the business leaders in healthcare is also praiseworthy. Nothing worth more than hearing first hand from the end users to identify the gaps and needs in health data management. The 11 suggestions from healthcare business leaders compiled by the task force will serve as a good base to start off towards the formation of a guideline on ethical use of healthcare data. They are very comprehensive views covering multiple perspectives. I am particularly fond of the idea of creating a check sheet which would be beneficial and practical in ensuring the important criteria in managing health data are met. Perhaps, the formation of the check sheet could benefit from the Delphi methods, by gathering consensus from a big group of stakeholders

of different roles such as policy makers, healthcare directors, health system technicians, lawyers, academicians and others to ensure that the check sheet is comprehensive and applicable to most. This mammoth task will only show fruit via a concerted effort by multiple parties, led by trustable, passionate and empathic leaders in Keio University. I sincerely hope my humble opinions could offer some use to the team and I look forward to the next interesting outcomes from the project!