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Patient Rights Regulations (Health Data Research Use), 2019 in the Face of the Coronavirus Pandemic

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1. As public health becomes at the center of public attention due to the Coronavirus (COVID-19) pandemic, the need for medical and health data for purposes of medical research becomes more crucial than ever. The richer the medical and health data is, the better the treatment governments and private sector can provide to support public health.

2. This publication discusses novel Israeli draft regulations, named "Patient Rights Regulations (Health Data Research Use), 2019" (the "**Draft Regulations**"). While these Draft Regulations present a tremendous step forward in the advancement of medical research and health care in Israel, in their current form they pose various material obstacles to industry players inclined to utilize Israeli medical and health data.

A. Introduction: What is the background of the Draft Regulations?

3. The use of health data for research purposes, in particular the so-called “big data” and use of machine learning and artificial intelligence techniques for its analysis and processing, presents tremendous potential for advancing medicine across the board. Some of the potential benefits of the use and analysis of such health data include the promotion of early diagnosis and preventive medicine; supportive systems enabling more accurate and efficient disease diagnosis than that of human physicians; and increasingly personalized medicine.

4. Israel is uniquely positioned in light of the scale of its repository of computerized medical data. Its long in place centralized health system and its early-day use of computing have created a unique pool of medical data, highly uncommon for other countries. **This data has tremendous value for data-based industry and research**.

However, medical and health data is simultaneously one of the most sensitive categories of data imaginable. Accordingly, its use raises dramatic questions and dilemmas, such as: Can such data be sold or licensed? If so, which segments? To whom? In what way? How can a patient's privacy rights be protected? What are the ethical implications of such activity?

5. The Draft Regulations, recently published for public consultation by the Israeli Ministry of Health, seek to update the existing framework for health data regulation and establish new rules for the field. The publication of the Draft Regulations has sparked a vibrant public debate within Israel concerning both the issue of a patient's right to privacy and medical confidentiality, as well as the separate question of ownership of these extremely sensitive data sets.

B. <u>What is the existing regime? What do the Draft Regulations aim to change</u>?

6. Despite the many advantages of the use of medical data for research purposes, there are also many practical obstacles and barriers – one key barrier is government regulation. In Israel, the vague and ambiguousness nature of the current regulatory regime, leads to overall uncertainty and confusion regarding the applicable limitations, ultimately resulting in limited availability of data to those that might be able to effectively utilize it.

7. Under the regime currently applicable in Israel, use of health data for research purposes is made under the approval of a special sub-committee of the *Helsinki* committee that regularly examines requests for conducting medical experiments in human beings (the "***Helsinki* Sub-Committee**"). The rationale of the approvals granted by the *Helsinki* Sub-Committee is that use of health data for research purposes is less intrusive than medical experiments in human beings. Therefore, obtaining approvals for the use of health data for research purposes is generally easier than obtaining approvals for medical experiments in humans. <u>However</u>, the existing regime suffers from ambiguousness, and does not fully address the privacy risks which could occur as a result of the use of new technologies.

8. The Draft Regulations propose a new framework for the use of health data for research purposes. Compared to the existing regime, the Draft Regulations strengthen privacy protection requirements and require the consideration of privacy risks as a condition for approval. In other words, the Draft Regulations are aimed at balancing an overall desire to promote research and collaboration in the medical and health fields, against the priority of protecting the privacy and confidentiality of individual patients' medical and health data. The ultimate goal is to improve the medical care system in Israel and promote medical research and human knowledge about health.

9. One of the most significant requirements added by the Draft Regulations is the "**approval mechanism**" – which provides for review by an internal professional committee ("**Organizational Committee**") appointed by a "health organization" (or group thereof), defined in the Draft Regulations to include hospitals of a specific size and Health Maintenance Organizations. The Organizational Committee examines the intended use of health data for research purposes, including to ensure the adoption of data protection measures in accordance with the level of data sensitivity – also known as a "privacy protection model". In particular, the Organizational Committee must prepare a *Privacy Risk Assessment* (a concept borrowed from the GDPR) which considers the privacy risks to patients in light of the specific purposes and circumstances of the proposed used of patient data. The privacy protection model is comprised of provisions and duties (assigned to health organizations and to health data receivers) as well as technological and procedural measures intended to reduce privacy risks and provide patients with more and better control of their data.

C. Why are the Draft Regulations important to you?

10. While the Draft Regulations are a tremendous step forward in the advancement of medical research and health care in Israel (without the need for amending primary legislation), in their current form, the Draft Regulations pose various material obstacles to industry players inclined to utilize Israeli medical and health data. In our view, these obstacles should be considered and remediated by the Israeli Ministry of Health in collaboration with industry representatives. **At this important inflection point, and in particular in the face of the Coronavirus pandemic, it is essential that the input of local and international industry actors be actively solicited, welcomed and considered in this regard.**

11. As an initial matter, we have identified the following matters for particular consideration:

a. *First*, the Draft Regulations require that health data may only be used for research purposes in anonymized form, and only with the narrowest scope of data required to achieve the desired research purpose (similar to the *data minimization* and *storage limitation* principles under the GDPR). The precise scope of data available for use for a particular project or effort will be determined by the relevant Organizational Committee. While these principles would indeed decrease privacy risks, we strongly advocate for their practical implementation in a manner that does not hinder R&D. Indeed, data anonymization poses significant obstacles to the ability to cross-reference data sets relating to a particular patient. In our view, in certain circumstances, it should be made possible to use identifiable data or at least pseudonymous data (instead of anonymized data), subject to imposing reasonable privacy-protection measures. A blanket rule demanding anonymized data across the board might be unnecessary in certain circumstances or under certain technological solutions, while limiting the innovation these rules are intended to help encourage.

b. *Secondly*, the Draft Regulations require that access to the anonymized data be granted to researchers only in a research room (physical or virtual), under the control of the relevant health organization. Further, transferring health data out of the health organization's premises is forbidden unless both the Organizational Committee and a national committee are convinced that exceptional circumstances justify such transfer and strict conditions are met, and in any event may only be transferred within Israel. Additionally, any researcher who is not part of the health organization must be a resident of Israel (or a corporation, including foreign corporation, registered in Israel).
In our opinion, these restrictions are detrimental to the research activity. Research has become a globalized enterprise, and many providers of key tools for R&D purposes can provide an adequate level of data protection. Further, there is an essential need for, and abundant benefits to, international data sharing and research collaboration – to take the most obvious example, among reputable universities and medical centers around the world. These restrictions are likely to prevent international bodies and institutions from studying Israeli medical data. The exclusion of Israeli medical data from international studies may reduce the relevance of results for Israeli patients, thus denying them the benefits of such research. It should also be noted that scientific journals are increasingly requiring the submission of raw data to support conclusions in studies for publication, as a check on reliability and accuracy. The restriction on transfer of data outside the project's research room will preclude satisfaction of this requirement, thereby hindering the publication of pioneering Israeli research.

c. *Third*, the Draft Regulations themselves do not address, and do not restrict, the payment that health organizations might demand for accessing health data in their possession. This raises questions regarding fair access to the data and ownership of such data.

d. *Fourth*, the mechanism of research-by-research approval by a multiparty committee – which addresses again and again ethical issues, the level of anonymization required, the fields of data to be given access to, and the level of data protection to be applied – will likely create excessive bureaucracy. Structuring and laying down regulatory green lines and guidelines for obtaining the approval are thus essential.

e. *Fifth* – the downside of a decentralized system with no appeals and no overarching authority who can overrule each of the separate Organizational Committees.

D. What can we do to help?

1. We encourage the industry to react to these Draft Regulations and express their concerns, if any. It is becoming increasingly common and customary for industry actors to take an active role in expressing concerns raised by proposed regulations and regulatory guidance, as illustrated, for example, by the European Data Protection Board (who encourages all kinds of stakeholders to comment on their draft guidelines). See their "public consultations" here.

2. If you are interested in sharing your own observations and any concerns raised by the Draft Regulations, we would be happy to discuss with you, including how we might help you contribute to the Ministry of Health's deliberations and final rule making process.

3. Meitar's robust regulatory and data protection practice group includes experts from jurisdictions across the globe. We regularly represent both local and multinational clients as they navigate the waters of the patchwork of data protection and privacy regulations applicable today, including through conducting data protection impact assessments and analyzing and addressing privacy risks. Accordingly, we are well positioned to advise on potential revisions to the Draft Regulations, implementation preparedness and ongoing compliance.

For an additional review of the Draft Regulations composed by the Israeli Tech Policy Institute, please see here.

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