IPMPC
International Pharmaceutical &
Medical Device Privacy Consortium

17 April 2020

Mr. Wojciech Wiewiórowski
European Data Protection Supervisor
Rue Wiertz 60, B-1047 Brussels

By Email to: edps@edps.europa.eu

Cc: European Data Protection Board *(by email to edpb@edpb.europa.eu)*

Re: EDPS Preliminary Opinion on data protection and scientific research

Dear Mr. Wiewiórowski,

The International Pharmaceutical & Medical Device Privacy Consortium ("IPMPC") welcomes the opportunity to provide comments on the EDPS's Preliminary Opinion on data protection and scientific research. The IPMPC is comprised of chief privacy officers and other data privacy and security professionals from a number of research-based, global pharmaceutical companies and medical device manufacturers. The IPMPC strives to be a leading voice in the global pharmaceutical and medical device industries to advance innovative privacy solutions to protect patients, enhance healthcare, and support business enablement.[1]

The current COVID-19 global pandemic is a reminder of the importance of fostering an environment that allows for the rapid development and deployment of new drugs and medical technologies to address public health needs. Researchers at pharmaceutical and medical device companies need access to patient health data to study disease progression and the effectiveness of potential therapies. Numerous safeguards exist to protect the confidentiality of data and ensure respect for the privacy of patients in the context of clinical trial conduct and other research activities. Please find attached to these comments an IPMPC Briefing Paper on Personal Data in Healthcare. We hope that the Paper helps inform the EDPS of the types of biomedical research

[1] More information about IPMPC is available at www.ipmpc.org. This filing reflects the position of the IPMPC as an organization and should not be construed to reflect the positions of any individual member.

pharmaceutical and medical device companies undertake, the importance of personal data to that research, and our views on how the GDPR applies to it.

Our comments on the Preliminary Opinion focus on the Supervisor's suggested criteria for the GDPR's special regime for scientific research to apply. (§ 3.5.) In particular, our comments focus on the following criteria:

- 'Relevant sectoral standards of methodology and ethics apply, including the notion of informed consent, accountability and oversight'; and
- 'The research is carried out with the aim of growing society's collective knowledge and wellbeing, as opposed to serving primarily one or several private interests'.

A. The Preliminary Opinion fails to adequately consider the full range of biomedical research that could be impacted by a narrow definition of 'scientific research'.

While the Preliminary Opinion includes a discussion of clinical trials, there is little discussion of other types of biomedical research. This could lead one to under-appreciate the different types of research that pharmaceutical and medical device companies perform and how each of these types of research could be impacted by the proposed 'scientific research' criteria. In particular, the Preliminary Opinion suggests that 'only scientific research performed within an established ethical framework' should qualify for the GDPR's special data protection regime. Further, the Opinion suggests that 'the notion of informed consent, accountability and oversight' must apply, but there is little elaboration of the application of these concepts to different types of biomedical research. Thus it is not clear whether it is the EDPS's view that informed consent and Ethics Committee oversight are prerequisites for application of the 'scientific research' derogation. In practice, in some types of biomedical research, obtaining the informed consent of patients is impractical. (This can be due to the number of patients involved, the lack of current contact information, the response rate challenge and response bias, and many other factors.) Instead, researchers rely on alternative, viable safeguards to protect patients' rights and interests, such as pseudonymisation of data and Ethics Committee approval. In other types of research, obtaining a broad consent at the point of data collection to future biomedical research is common, but Ethics Committee review occurs only at the point of data collection, not at each subsequent research use of the pseudonymised data.[2]

Example: Real-World Data

Real-world data refers to data collected outside of randomized controlled trials. In a randomized controlled trial, participants are randomly allocated to either a group receiving the drug, device, or other treatment under investigation or a group receiving standard treatment or a placebo treatment as the control, and data is pseudonymised prior to any data analysis being performed. While randomized controlled trials are generally considered the 'gold standard' for demonstrating safety and efficacy, there are inherent limitations. For example, some experimental questions do not allow for random allocation of treatments due to ethical concerns. Moreover, the population as a whole tends to be more heterogeneous than the population of individuals who participate in clinical trials. The behavior of patients and clinicians is also more variable in the real world than in controlled, experimental settings. As a result, an 'efficacy-effectiveness gap' can occur – i.e., a

[2] In all cases, researchers evaluate whether anonymised data would be sufficient to fulfil their research purposes. This often depends on whether the data needs to be traceable to its source in order to demonstrate the integrity of the data to competent authorities.

gap between the 'efficacy' of a test article as measured in randomized controlled trial settings and the 'effectiveness' as measured in real-world, clinical practice.

Collection and analysis of real-world data serves a number of important research purposes. First, it enables a more robust assessment of the safety and effectiveness of a health care product in clinical practice. This includes the identification of populations for whom the product is more, or less, safe/effective. This information, in turn, informs clinical decision-making and, in some cases, can even lead to a change in product labelling (e.g., new indications, contraindications, possible side effects). Second, it enables the evaluation of the relative effectiveness of a new product as compared with other, existing products in clinical practice. This also informs clinical decision-making and can influence reimbursement decisions.

Real-world data can be obtained by conducting new studies or by utilizing existing data sources. If the researcher desires to collect or use new data, experimental studies with methodologies that deviate from typical randomized controlled trials can be designed, or observational studies without any experimental interventions can be conducted in accordance with guidelines for good epidemiological practice. In many cases, however, existing data sources, such as electronic health records (EHRs) or health claims databases, may meet a researcher's needs. When utilizing existing data sources, obtaining informed consent of data subjects is often impractical due to the time, cost, and effort involved.

Example: Secondary Research Using Clinical Trial Data

Scientific research is often an iterative process in which the results of one study are used to design future studies. In the course of a clinical trial, researchers may notice results that were unexpected and require further investigation. They may wish to analyze the data collected in ways that were not originally envisioned in the clinical trial protocol. More generally, as scientific understanding evolves, researchers' questions may evolve as well. Analysis of existing clinical trial data sets may enable researchers to answer these new questions without having to design and run entirely new clinical trials. This is important not only for purposes of efficiency but also to avoid exposing research participants to unnecessary risks when existing data sources could answer the scientific question.

When individuals enroll in a clinical trial, they may be informed that the data collected about them may be used in future research projects, such as research relating to the same test article or research relating to the same disease or condition in question, or more broadly to research relating to disease mechanisms generally. Such 'future research' usually cannot be described with the same level of specificity as the information in the clinical trial protocol itself because the details of the future research are unknown at the time of data collection and could be further informed by the results of the of the trial itself.

The GDPR recognizes the importance of being able to analyze clinical trial data sets for purposes that may not have been described with as much detail as the original clinical trial protocol. GDPR Recital 33 states that 'It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose.'[3] This informed consent form is reviewed by

[3] Recital 33 provides important interpretive guidance by European lawmakers as to what degree of detail is sufficient to meet the requirements of GDPR Art. 4(11) and Art. 7 for a valid consent. Lawmakers were asked to provide guidance on what level of detail in the context of scientific research would be sufficient for consent to be viewed as 'specific', and in

an Ethics Committee prior to data collection, although subsequent research analyses of the pseudonymised data have not historically been viewed as requiring Ethics Committee review provided they are consistent with the consent that was obtained.[4]

B. The Preliminary Opinion creates new criteria for the 'scientific research' derogation that have no basis in the legislative text.

Recital 159 of the GDPR states that 'For the purposes of this Regulation, the processing of personal data for scientific research purposes should be interpreted in a broad manner [as] including[,] for example[,] technological development and demonstration, fundamental research, applied research and privately funded research.' The Preliminary Opinion, in contrast, suggests that the scientific research derogation should be limited to 'research [that] is carried out with the aim of growing society's collective knowledge and wellbeing, as opposed to [research] serving primarily one or several private interests'. This new criterion creates considerable uncertainty as to how it would be interpreted or who would have appropriate authority to decide whether a particular research project sufficiently benefits society's collective knowledge and wellbeing versus benefiting a private interest. The IPMPC disagrees with the Preliminary Opinion's framing of private interests as largely in competition with the public interest.

In support of this new criterion, the Preliminary Opinion cites to an inapposite European Court of Justice case from 1985. The referenced case, ECJ Case 234/83 *Gesamthochschule Duisburg v Hauptzollamt München-Mitte,* relates to customs duties on educational, scientific and cultural materials under Regulation No 1798/75 (10 July 1975). That Regulation included an exemption for scientific instruments and apparatus imported exclusively for non-commercial purposes, and one of the questions in the case involved how to interpret the term 'scientific activities' as used in the definition of 'a scientific instrument or apparatus'. Because the tariff exemption in the Regulation was limited to scientific instruments and apparatus imported exclusively for non-commercial purposes, the ECJ Judgment concludes that in the context of Regulation No 1798/75, 'scientific activities' refers to scientific research carried out for non-commercial purposes. It is entirely unclear how this case is relevant to the interpretation of 'scientific research' under the GDPR or how it supports the newly proposed criterion.

Conclusion

The current COVID-19 pandemic highlights the importance of the development of harmonized, practical, and balanced guidance on the application of the GDPR to health research. While we applaud the EDPS for addressing the very important question of how the 'scientific research' derogation should be applied, the IPMPC believes that the Preliminary Opinion fails to fully appreciate the full scope of the types of health research impacted and the role of privately funded research in the development of products and services to meet important health needs. Personal data is critical to this research. In both the recitals and operative text, the

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Recital 33 they did so. It would be contrary to ordinary rules of legislative construction to treat Recital 33 as simply ancillary text not relevant to interpretation of the GDPR. In any event, the 'scientific research' derogation provides a separate means for meeting the requirements of GDPR Art. 9.

[4] To the extent consistent with the research purpose and the need for source data traceability, further de-identification of the pseudonymised data may occur prior to secondary analysis.

GDPR recognizes the importance of privately funded biomedical research and provides for appropriate flexibility in the application of data protection requirements.

We thank you for the opportunity to provide these comments.

Sincerely,

Peter A. Blenkinsop
IPMPC Secretariat

IPMPC
International Pharmaceutical & Medical Device Privacy Consortium

IPMPC BRIEFING PAPER

PERSONAL DATA IN HEALTHCARE

Synopsis: *Collection and further processing of personal data is crucial to the development of medical products and delivery of healthcare services. The GDPR recognises the importance of these activities and creates a flexible data protection framework that takes into account the data processing needs of health researchers.*

INTRODUCTION

Over the last century, medical science has transformed human health. At the start of the 20th Century, the average life expectancy in developed countries was slightly over 45 years. Today, life expectancy exceeds 75 years. The 20th Century witnessed the eradication of smallpox and considerable progress toward the eradication of polio and other infectious diseases that until such time killed by the millions. Immunizations and antibiotics greatly reduced diseases such as tuberculosis, whooping cough, diphtheria, and typhoid fever. In this golden era of medicines research, the structure and function of DNA was elucidated, leading to the mapping of the human genome. Numerous medicines from immunosuppresives to antidepressants to contraceptives were developed, improving and saving lives. Prosthetic limbs have been invented that closely mimic natural body motions for amputees; advances in medical imaging have enabled doctors to quickly and accurately identify injuries and diseases; and artificial organs have been engineered that can replace natural organs, allowing patients to return to a normal life.

The life-saving treatments available today were made possible by an environment that fostered health research and recognized that medical innovation benefits society. Medical discoveries rely on the ability to safely and effectively collect and analyze personal data concerning patient treatment and outcomes. Without personal data, scientists would lack insight into the causes of certain conditions and diseases, and development of curative and preventative measures would be impossible. In each of the steps in the scientific process – i.e., an observation leading to a hypothesis, followed by testing and then confirmation – the ability to effectively collect, analyze, and re-analyze patient information is crucial. The ability to sustain and expand on such scientific innovations depends upon the continued availability of patient information to meet researchers' needs.

Personal data is not only critical to the work of the biopharmaceutical and medical device industries; the ability to use personal data has healthcare ramifications for policy makers and government as well. Analysis of personal data is an important public health tool used to quickly identify and remedy adverse events in certain populations when they are first reported. Personal data also shapes healthcare policies which are based on information about the costs and benefits of interventions. In short, personal data has a profound and often understated impact on many aspects of healthcare.

THE IMPORTANCE OF PERSONAL DATA TO HEALTHCARE

As described above, the ability to use personal data is critical to medical innovation, public health, and healthcare efficiency. These uses are further summarized below:

- The development of new medical interventions demands extensive testing to ensure patient safety and effectiveness. Moreover, the European Medicines Agency and other health authorities are increasingly requiring the evaluation of the effectiveness of medicines and medical devices in real-life settings creating a need to collect 'real-world evidence' derived from patient medical records.

- Advances in life sciences are enabling far more targeted delivery of medicines to patients. Such 'personalized' medicine looks at the genetic and phenotypic characteristics of individual patients to determine which treatments will be most safe and effective.

- Financial pressures demand that healthcare resources are used efficiently. Data about healthcare resource use and health outcomes can help inform policy development to increase healthcare efficiency.

- With the adoption of electronic health records (EHRs) and platforms for sharing EHRs, new opportunities are arising for the study of patterns of disease development and progression, providing new insights into the causes and control of disease.

Biomedical Research

Research uses of personal data can be further broken down into the following categories:

- **Discovery and early-stage development** is the first stage in medical product R&D. In the development of new drugs, for example, this often involves the testing of human biological samples to validate or disprove a research hypothesis.

- **Clinical research** involves the evaluation of the safety and efficacy of medical interventions under controlled conditions in human subjects. Clinical research is highly regulated. Clinical research in the European Union is subject to requirements at the Union and Member State levels[5], as well as international standards, such as the good clinical practice guidelines issued by the International Council for Harmonisation.

- **Pharmacoepidemiology and Medical Device Epidemiology** is the study of the use and effects of drug therapies and medical devices in large numbers of people. As an example, in the field of cancer, pharmacoepidemiology examines the effects of medications on cancer risk, disease prevention, and

[5] Clinical research requirements vary from member state to member state. Clinical trials of medicinal products are currently subject to the EU Clinical Trials Directive and will be subject to the Clinical Trials Regulation once its full application goes into effect. Similarly, clinical investigations of medical devices are currently subject to the Medical Devices Directive and the In Vitro Diagnostic Directive will be subject to the Medical Devices Regulation and the In Vitro Diagnostic Regulation on their respective dates of application.

response to treatments, as well as any adverse and/or long-term effects of chemotherapeutic and other pharmacologic agents used to treat cancer.

- **Pharmacogenomics** focuses on understanding how variability in genes impacts drug response. Thus, pharmacogenomics seeks to correlate individual differences in adverse effects and treatment effectiveness with gene expression for drug-metabolizing enzymes, drug transporters, drug receptors, and proteins involved in pathway signaling.

- **Pharmacoeconomics and medical device health economics** evaluate the costs and benefits of a pharmaceutical or medical device product. Pharmacoeconomic and medical device health economic studies serve to guide optimal healthcare resource allocation.

- **Pharmacovigilance and medical device vigilance** encompass the science and activities relating to the detection, assessment, understanding, and prevention of adverse events or any other drug/device related adverse effects. Pharmaceutical and medical device companies have ethical and legal obligations to accurately collect, analyze, and report adverse events in a timely fashion both during clinical trials and after a drug/device is on the market. In the EU, pharmacovigilance and medical device vigilance are specifically regulated under the CTD/CTR, MDD/MDR, and IVDD/IVDR.

What Is Biomedical Research?

Biomedical research is a category of scientific research that involves the study of biological processes and diseases with the goal of developing effective treatments and cures. There are multiple ways to classify biomedical research, irrespective of whether the research is public or private. For example, basic research aims to advance fundamental knowledge about medical science whereas applied research focuses on the practical application of science to medicine. Another classification focuses on whether the research is clinical or epidemiological. Clinical research involves the investigation of medicines, medical devices, and diagnostic products to evaluate their safety and effectiveness. Epidemiological research examines the distribution and changes of the frequency of diseases in defined populations with the goal of identifying causes. A third possible classification focuses on the role of the investigator and whether the research is interventional versus observational. Interventional research (sometimes also referred to as 'experimental research') involves the administration of a test article or change to clinical practice or to research participants' usual behaviors. In contrast, in observational research, patients are allocated treatments based on clinical decisions and researchers simply observe how differences in clinical decisions result in different health outcomes. Yet another classification focuses on the temporal nature of the study design and looks at whether the research is prospective versus retrospective. Prospective studies are forward-looking whereas retrospective studies involve the analysis of historical data.

A clinical trial is a type of prospective, interventional clinical research. In a clinical trial, a test article is administered to research participants and data is collected concerning participants' health outcomes. In other types of clinical research, blood, tissue, and other biological samples may be collected and analyzed.

GDPR'S APPLICATION TO BIOMEDICAL RESEARCH

The General Data Protection Regulation (GDPR) provides special rules for the processing of personal data for scientific research purposes. These rules reflect a recognition that scientific research serves the public good

and seek to enable the use of personal data for research purposes as long as certain protections are implemented. The special recognition given to the processing of personal data for scientific research purposes is discussed in Recital 159 of the GDPR which declares that the Regulation 'should take into account the [European] Union's objective under Article 179(1) [of the Treaty on the Functioning of the EU (TFEU)] of achieving a European Research Area.' Article 179(1) of the TFEU states: 'The [EU] shall have the objective of strengthening its scientific and technological bases by achieving a European research area in which researchers, scientific knowledge and technology circulate freely . . . .' Article 13 of the Charter of Fundamental Rights of the European Union sets forth (in the same chapter as the right to protection of personal data (Art. 8)) that '*scientific research shall be free of constraint'.* Recital 159 of the GDPR also declares that 'For the purposes of this Regulation, the processing of personal data for scientific research purposes should be interpreted in a broad manner including for example technological development and demonstration, fundamental research, applied research and privately funded research.'

Under the GDPR, a number of rules apply to the processing of personal data. These include, first, that all processing of personal data must have a legal basis. Second, the processing of special categories of personal data, such as data concerning an individual's health, is prohibited unless one of several criteria is met. Third, personal data may only be collected for specified and explicit purposes, and they may not be further processed in a manner incompatible with those initial purposes. Fourth, data subjects have a number of rights with respect to their personal data, starting with a right to transparency of information processing by data controllers.

Legal Basis for Processing

Within a particular biomedical research project, aside from the overall objective of gaining scientific understanding, there may be several closely-related ancillary data processing needs. For example, in a clinical trial, some data processing is necessary to comply with applicable regulations governing clinical trials. One could potentially view the legal basis for these particular data processing activities as processing that is necessary to comply with a legal obligation to which the controller is subject. Some data processing activities could also rely on the consent of the data subject as the legal grounds for processing, provided that consent is freely given, specific, informed, and unambiguous.

As a potentially more broadly applicable legal basis for biomedical research activities, GDPR Article 6 allows for processing of personal data 'necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data.' The Article 29 Working Party has previously commented that the processing of personal data for research purposes is one of the most common contexts in which the issue of legitimate interests may arise.[6] Recital 47 of the GDPR elaborates on factors to be considered in conducting the required weighing of interests. Recital 47 suggests that particular weight should be given to whether data subjects would reasonably expect the processing in question.

[6] Working Party Opinion 06/2014, at 24-25.

Pharmaceutical and medical device companies have a legitimate interest in research and development of new products to diagnose, treat, and prevent diseases and conditions. Moreover, these interests are compelling and beneficial to society at large. Subject to appropriate safeguards, biomedical researchers can rely on these legitimate interests to meet the requirement of the GDPR that all processing must have a legal basis.

It is important to understand that where processing is based on the legitimate interests of the controller or a third party, the data subject has the right to object to such processing at any time 'on grounds relating to his or her particular situation'. (Art. 21) If an objection is raised, the controller is obliged to cease processing the personal data unless it can demonstrate 'compelling legitimate grounds' that override the data subject's interests.

Prohibition on Processing of Special Categories of Personal Data

Article 9 of the GDPR sets forth the general rule that the processing of special categories of personal data is prohibited unless one or more criteria are met. The explicit consent of the data subject provides one means of overriding the prohibition, but there are several other grounds as well that could be applicable to biomedical research. These include:

- Processing that is necessary for reasons of 'substantial public interest', where such processing is 'on the basis of [European] Union or Member State law';
- Processing that is necessary for reasons of 'public interest in the area of public health, such as . . . ensuring high standards of quality and safety of health care and of medicinal products or medical devices', again where such processing is 'on the basis of [European] Union or Member State law'; and
- Processing that is necessary for scientific research purposes 'in accordance with Article 89(1),' and, again, where such processing is 'based on [European] Union or Member State law'.

In each case, the EU or Member State law in question 'must be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.' (*See also* Recital 52.) Recital 41 serves to clarify what can qualify as 'based on EU or Member State law'. Recital 41 indicates that references in the GDPR to a legal basis or a legislative measure do not necessarily require a legislative act adopted by a parliament but rather simply require a legal measure 'clear and precise' and foreseeable in its application by persons subject to it.

What Is 'Scientific Research'?

The *European Textbook on Ethics in Research* (commissioned by the European Commission in 2010) seeks to tackle the question of 'what is research'? The authors propose the following working definition: 'Research aims to generate (new) information, knowledge, understanding, or some other relevant cognitive good, and does so by means of a systematic investigation.'

The qualifier 'scientific', as used in the GDPR, may be aimed at distinguishing research concerning the structure and behaviour of the physical and natural world – including biomedical research – from other types of research (for example, from marketing research). In any event, as is made clear in Recital 159 of the GDPR, 'scientific research' can be publicly and/or privately funded.

As indicated, the derogation for processing that is necessary for scientific research purposes references Article 89(1). Article 89(1) states that processing of personal data for scientific research purposes must be subject to 'appropriate safeguards . . . for the rights and freedoms of the data subject'. In particular, Article 89(1) highlights the principle of data minimisation and suggests the use of pseudonymisation or anonymisation as techniques to protect data subjects' rights.

Interpretation of References in Article 9 to EU or Member State Law

The text of the GDPR does not indicate whether the repeated references in Article 9 to processing that is 'based on EU or Member State law' require some explicit act or statement indicating a legislative desire to establish a derogation to the prohibition on processing of special categories of personal data, or whether a more general law or regulation covering the type of research in question would qualify provided it addresses safeguards to protect data subjects' rights. The recitals to the GDPR strongly suggest the latter interpretation. For example, Recital 157 states:

> By coupling information from registries, researchers can obtain new knowledge of great value with regard to widespread medical conditions such as cardiovascular disease, cancer and depression. . . . Research results obtained through registries provide solid, high-quality knowledge which can provide the basis for the formulation and implementation of knowledge-based policy, improve the quality of life for a number of people and improve the efficiency of social services. In order to facilitate scientific research, personal data can be processed for scientific research purposes, subject to appropriate conditions and safeguards set out in Union or Member State law.

Thus, it is lawful to process data for registries under the derogation for processing that is necessary for scientific research purposes provided that researchers follow the rules and safeguards established by Member States for such research. Similarly, clinical trials of medicinal products in the EU will soon be subject to the Clinical Trials Regulation (CTR), which includes extensive requirements to safeguard research participants' rights, including data protection rights. Thus the processing of personal data for a clinical trial conducted in accordance with the CTR (once in effect) should be viewed as based on EU law (or before the Clinical Trials Regulation goes into effect, such processing should be viewed as based on each member state's law implementing the Clinical Trials Directive).

As noted, GDPR Recital 41 serves to clarify what can qualify as 'based on EU or Member State law'. Recital 41 indicates that references in the GDPR to a legal basis or a legislative measure do not necessarily require a legislative act adopted by a parliament but rather simply require a legal measure 'clear and precise' and foreseeable in its application by persons subject to it. An approved code of conduct pursuant to GDPR Art. 40 provide one means to fulfil the requirement for a legal measure clear, precise, and foreseeable in its application.

Compatibility of Further Processing

Article 5 of the GDPR states that personal data may only be collected for 'specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes'. It goes on to state that 'further processing' for scientific research purposes shall 'not be considered to be incompatible with the initial purposes', in accordance with Article 89(1). Therefore, biomedical research using data that was originally collected for a different purpose is not inconsistent with the GDPR's 'purpose limitation' principle.

Recital 50 clarifies that where processing is 'compatible' with the initial purposes of data collection, then no separate legal basis is required to enable the further processing: 'The processing of personal data for purposes other than those for which the personal data were initially collected should be allowed only where the processing is compatible with the purposes for which the personal data were initially collected. In such a case, no legal basis

separate from that which allowed the collection of the personal data is required'. Moreover, Recital 50 states that 'Further processing for . . . scientific . . . research purposes . . . should be considered to be compatible lawful processing operations.' Recital 50 suggests that identification of a new legal basis under Article 6 for further processing of personal data for biomedical research purposes is unnecessary. In any event, as discussed above, biomedical research should ordinarily be viewed as having a legal basis under GDPR Art. 6(1)(f) – i.e., the legitimate interests of the controller or a third party, provided those interests are not overridden.

Right to Information

Pursuant to GDPR Articles 13 and 14, controllers must provide data subjects with certain information concerning the processing of personal data about them. Where the data is collected from someone other than the data subject, the information must be provided 'within a reasonable period after obtaining the personal data'. However, an exception to the requirement to provide this information is available where 'the provision of such information proves impossible or would involve a disproportionate effort, in particular for processing for . . . scientific . . . research purposes . . . , subject to the conditions and safeguards referred to in Article 89(1) or in so far as the obligation [to provide the information] is likely to render impossible or seriously impair the achievement of the objectives of that processing.' The exception goes on to require that '[i]n such cases the controller shall take appropriate measures to protect the data subject's rights and freedoms and legitimate interests, including making the information publicly available.' Recital 62 states that in evaluating whether providing notice involves disproportionate efforts, 'the number of data subjects, the age of the data and any appropriate safeguards adopted should be taken into consideration.'

When collecting personal data from patients as part of a clinical trial, the sponsor (through the clinical investigator) provides patients with information concerning potential secondary data analyses. The personal data that is reported by the clinical investigator to the sponsor is key-coded, and the sponsor has no means to identify or contact the participants without the assistance of the clinical investigator. In the context of research using real-world data, the researcher is again typically provided access only to pseudonymised data. GDPR Art. 11(1) states that '[i[f the purposes for which a controller processes personal data do not or do no longer require the identification of a data subject by the controller, the controller shall not be obliged to maintain, acquire or process additional information in order to identify the data subject for the sole purpose of complying with this Regulation.'

CONCLUSION

Collection and further processing of personal data is crucial to medical research. Recognizing the importance of research and development of new medical devices, diagnostics, and medicines, European legislators created a data protection legal framework that takes into account health researchers' needs. As further GDPR implementation guidance and measures are adopted, it is vital to consider all the different types of health research that public and private entities engage in and how data protection rules could impact such research if not implemented in the flexible manner allowed under the legislation.