In preparation for the IPMPC-MedTech Europe Workshop with Data Protection Authorities on Data Protection in Health Research *we are issuing a series of Briefing Papers. This is the first in the series. Please visit https://www.surveymonkey.com/r/SBBCJG9 to register for the 27 November Workshop in Brussels, Belgium.*

IPMPC
International Pharmaceutical & Medical Device Privacy Consortium

IPMPC Briefing Paper #1

THE LAWFUL BASIS FOR PROCESSING PERSONAL DATA IN CLINICAL RESEARCH

Issue: *Article 6 of the GDPR requires that all processing of personal data have a lawful basis. Lawful bases include, for example, where "the data subject has given consent to the processing of his or her personal data for one or more specific purposes" and where "processing is 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." Further, Article 9 of the GDPR prohibits the processing of personal data concerning health unless a derogation applies. Possible derogations include, for example, "processing [that] is necessary for . . . scientific . . . research purposes . . . in accordance with Article 89(1) based on Union or Member State law which shall 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." This paper explores the appropriate legal bases for processing of personal data collected in the course of clinical research.*

THE HISTORICAL IMPORTANCE OF CONSENT IN CLINICAL RESEARCH

Ethical codes and laws governing clinical research have traditionally required the consent of the patient to participate in research.

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.

The practice of obtaining informed consent to participate in medical research involving human experimentation can be traced back to the Nuremberg Code of 1947.[1] Since then, this practice has become a bedrock principle of modern medical ethics, incorporated into the World Medical Association's Declaration of Helsinki, and adopted by

[1] "The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment."

governments throughout the world.[2] Obtaining consent for participation in clinical trials ensures that patients are informed of potential risks and safeguards each patient's rights to autonomy, self-determination, and inviolability.

In addition to addressing issues concerning a person's autonomy with respect to his or her body, the information provided to the patient in the informed consent form or supplementary materials also addresses the collection, storage, and use of identifiable information, and the measures adopted to protect the confidentiality of such information.[3] Good Clinical Practice (GCP) guidelines developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) require that written information be provided to prospective clinical trial participants that explains, *inter alia*, the purpose of the trial, the reasonably foreseeable risks, who will have access to a participant's original medical records and clinical trial data, and how records identifying the participant will be kept confidential. Each individual's informed consent to participate must be documented. These guidelines have been incorporated into Article 47 of the EU Clinical Trials Regulation (EU No. 536/2014).

Historically, one of the issues addressed in the written information provided to prospective participants in the course of obtaining informed consent for participation in a clinical trial has been data protection. In some cases, data protection language has been incorporated into the informed consent form (ICF) directly, while in others, data protection information has been provided in supplementary materials. Participants are typically informed of their right to withdraw from participation in the trial at any point for any reason. They are also informed that should they withdraw from a study, data already collected will continue to be stored and analyzed because continued processing of data already collected is necessary to preserve scientific integrity. This discussion stems from Article 28 of the Clinical Trials Regulation (and similar, prior legislation), which provides that: "Without prejudice to Directive 95/46/EC, the withdrawal of the informed consent shall not affect the activities already carried out and the use of data obtained based on informed consent before its withdrawal." Similarly, ICH GCP requires in Section 5.5.3 that the sponsor ensure that "there is no deletion of entered data (i.e., maintain an audit trail, data trail, edit trail)." Recital 76 of the Clinical Trials Regulation further emphasizes this: "With a view to respecting [personal data protection] rights, while safeguarding the robustness and reliability of data from clinical trials used for scientific purposes and the safety of subjects participating in clinical trials, it is appropriate to provide that, without prejudice to Directive 95/46/EC, the withdrawal of informed consent should not affect the results of activities already carried out, such as the storage and use of data obtained on the basis of informed consent before withdrawal."

The GDPR defers to these existing informed consent requirements with respect to participation in clinical trials. Recital 161 of the GDPR provides that "For the purpose of consenting to the participation in scientific research activities in clinical trials, the relevant provisions of Regulation (EU) No 536/2014 of the European Parliament and of the Council should apply."

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[2] See, e.g., International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice (E6), which has been adopted by medicines authorities in the European Union, United States, and Japan. See also Article 7 of the United Nations International Covenant on Civil and Political Rights (ICCPR).

[3] "It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects." World Medical Association, Declaration of Helsinki (last amended October 2013), at ¶ 9. "Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information." Id. at ¶ 24. "For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee." Id. at ¶ 32.

APPLICATION OF GDPR CONSENT REQUIREMENTS TO CLINICAL RESEARCH

Interpretation of GDPR consent requirements has led to uncertainty about the appropriate lawful basis to rely upon for processing clinical trial data.

Since the GDPR came into effect, data protection authorities, health authorities, and medical research entities have adopted different interpretations of the appropriate legal basis that should be relied upon for data processing in clinical research. As noted, because of the importance of continuing to process data collected during a trial to ensure the scientific validity of the outcome, protect other study participants, and enable government agencies to accurately assess the risks and benefits of regulated medicines and devices, the deletion of data collected during a study is prohibited and its continued processing is required.[4] The requirement to continue processing a study subject's data has led some data protection authorities and research oversight entities to conclude that "consent" should not be the lawful basis for processing study subject data under Article 6 of the GDPR. For example, the Health Research Authority (HRA) at the UK's National Health Service has explained that "consent should not be used as the legal basis under GDPR if the subject's rights that follow from consent under the legislation cannot be applied[,] eg because it would limit the validity of the research." Consequently, "for the purposes of the GDPR, the legal basis for processing data for health and social care research should NOT be consent. This means that requirements in the GDPR relating to consent do NOT apply to health and care research."[5] The position of the HRA follows guidance issued by the Article 29 Working Party and UK Information Commissioner's Office (ICO). In its guideline on consent under the GDPR, the Article 29 Working Party wrote that "withdrawal of consent could undermine types [of] scientific research that require data that can be linked to individuals, however the GDPR is clear that consent can be withdrawn and controllers must act upon this – there is no exemption to this requirement for scientific research." The UK ICO has written that "If you would not be able to fully action a withdrawal of consent – for example because deleting data would undermine the research and full anonymisation is not possible – then you should not use consent as your lawful basis (or condition for processing special category data). Consent is only valid if the individual is able to withdraw it at any time."[6] Other data protection and health authorities have issued similar statements, suggesting that medical research should rely on the "public interest" or "legitimate interest" bases for processing in Article 6 of the GDPR, and not on the data subject's consent.[7]

In various other EU member states, however, formal and informal guidance from relevant stakeholders requires obtaining each participant's consent to their data processing, whether as part of the informed consent to participation in the clinical trial or as a separate document. For example, this is the case of the Central Committee on Research Involving Human Subjects in the Netherlands[8] and of many ethics committees in Germany.

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[4] *See* Art. 28 of the Clinical Trials Regulation. *See also* Arts. 16-17 of the GCP Directive (Directive 2005/28/EC). Article 17.3(d) of the GDPR states that the right of erasure does not apply to personal data necessary for scientific research in so far as erasure would render impossible or seriously impair the achievement of the objectives of the research.

[5] https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/what-law-says/consent-research/

[6] https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/consent/what-is-valid-consent/#what10

[7] For example, the position of the French data protection authority (CNIL) is summarized here: https://www.cnil.fr/fr/recherches-dans-le-domaine-de-la-sante-ce-qui-change-avec-les-nouvelles-methodologies-de-reference. The position of the Czech State Institute for Drug Control is summarized here: http://www.sukl.eu/medicines/kh-vs-gdpr-smernice-na-ochranu-osobnich-udaju.

[8] See http://www.ccmo.nl/en/algemene-verordening-gegevensbescherming.

ALTERNATIVES TO CONSENT FOR DATA PROCESSING IN CLINICAL RESEARCH

The GDPR permits reliance on other lawful bases for processing personal data in the context of scientific research, in addition to the data subject's consent.

Although the patient's consent to participation will always be required under existing clinical research laws and ethical requirements, if the data subject's consent cannot be relied upon in certain EU member states as the lawful basis for processing data in the clinical research context, then researchers will need to turn to other lawful bases to justify the processing of data. For privately sponsored research, a separate legal basis exists under Article 6 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.[9] 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.

An alternative to reliance on consent would also be required to satisfy the limits on processing special categories of personal data in Article 9, since clinical research involves the processing of health information. Under Article 9, processing of sensitive data may be done when 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." 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, to process data for registries under the derogation for processing that is necessary for scientific research, researchers must follow the rules and safeguards established by Member States for such research. Similarly, clinical trials of medicinal products in the EU will be subject to the Clinical Trials Regulation (CTR) and clinical investigations of medical devices will be subject to the Medical Device Regulation (MDR), both of which include 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 or MDR should be viewed as based on EU law.

While the combination of the legitimate interests legal basis (for purposes of GDPR Article 6) and the scientific research derogation (for purposes of Article 9) provide an alternative to reliance on consent, the data subject

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

nevertheless retains a limited right to object to the data processing. Article 21(6) provides that whenever personal data are processed for scientific research purposes pursuant to Article 89, a data subject can object to such processing "on grounds relating to his or her particular situation, . . . unless the processing is necessary for the performance of a task carried out for reasons of public interest."[10]

CONCLUSION

The post-GDPR interpretations of the role of consent to data processing in the clinical trial process have created uncertainty. Compliance with laws regulating clinical trials, which are designed to protect study subjects and future patients by ensuring the scientific validity of the trial, limits the ability of study sponsors to delete data or respond to specific data subject requests to limit processing. This has led some, but not all, authorities to suggest that "consent" should not be the basis for processing data collected in a clinical study. Uncertainty about the appropriate approach to data processing hinders clinical research and makes it difficult to provide data subjects across the EU with clear, uniform notices about the lawful bases that will be relied upon when processing their data.

[10] Member States are permitted to limit this right of objection pursuant to Article 89.2.