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 second 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 #2

THE ROLE OF A CLINICAL TRIAL SPONSOR AND THE TRIAL CENTRE

Issue: *The concept of 'controller' and 'processor' are crucial to the application of the GDPR. A controller is the person or entity that, 'alone or jointly with others, determines the purposes and means of the processing of personal data'. Where two or more controllers jointly determine the purposes and means of processing, they are deemed 'joint controllers' and must, under Article 26, 'in a transparent manner determine their respective responsibilities for compliance with the obligations under [the GDPR] . . . by means of an arrangement between them'. In contrast, a processor processes personal data on behalf of the controller. Processing by a processor must be governed by a contract or other legal act that meets criteria specified in Article 28. This paper explores the application of the concepts of 'controller' and 'processor' to a clinical trial, focusing on the appropriate characterization of a clinical trial sponsor and trial centre.*

BACKGROUND

The trial centre plays an important and independent role in the conduct of an industry-sponsored clinical trial.

Clinical research with human subjects is carefully regulated by law and long-standing ethical practices to ensure the protection of study participants. One of the key aspects of the clinical research process is the use of investigators at trial centres to administer and conduct the research trial. These investigators ensure the scientific validity of the study data, maintain the 'blinded' nature of the data to ensure that results are not unconsciously biased by knowledge of the study's progress, and use their independent medical judgement to look out for the best interests of participants. In addition, studies are conducted under the oversight of ethics committees, who are responsible for approving the study protocol, monitoring the study as it progresses, and providing oversight when unexpected or unusual issues arise. Although the study sponsor plays an important role in the design of the study, the selection of data collection methods, and the identification of study end-points, the investigator is responsible for the conduct of the clinical trial at a trial site. This ensures the scientific validity of the study by reducing the opportunity for bias. The data collected by the trial centre is reported back to the trial sponsor using 'case report forms' (or 'CRFs'), which summarize the information related to the study. The trial centre assigns a code to each study participant and information is reported on the CRFs using the assigned codes. The decoding information that links the assigned codes to study participant identities is maintained confidentially by each trial centre.

For purposes of compliance with data protection requirements, it is important to characterize whether a party with access to personal data is acting as a 'controller' or a 'processor'. For example, with respect to transparency requirements, the GDPR mandates that a data protection notice is provided to data subjects that includes 'the identity and contact details of the controller' and 'the recipients or categories of recipients of the personal data'. The Article 29 Working Party has opined that 'other data controllers, joint controllers and processors to whom

data is transferred or disclosed are covered by the term "recipient" and information on such recipients should be provided in addition to information on third party recipients.'[1]

There appears to be broad agreement that when a health care provider processes personal data concerning health for purposes of providing care unrelated to a clinical trial, the health care provider acts as a controller in relation to that data processing. There also is broad agreement that a sponsor acts as a controller in relation to the data that it receives from clinical trial sites and that it then processes for its research purposes. Where there is some uncertainty is around the characterization of the trial site concerning its processing of personal data in relation to the study. Interpretations have ranged over time from describing the relationship of sponsor and site for purposes of this processing as one of separate, independent controllers[2] (based on the notion that the parties are each processing data independently, in a chain), to describing the parties as joint controllers[3] (based on the view that the parties share certain decision-making), to describing them as controller and processor[4] (based on the notion that the sponsor develops the study protocol and engages each site).

THE CASE FOR INDEPENDENT CONTROLLERS

Personal data is processed at clinical trial sites for purposes of health care delivery. This data is then shared, in a key-coded form, with the clinical trial sponsor, who uses the data for its research purposes.

Clinical trial sponsors engage research sites to operate trials of investigational products. The sponsor designs the trial, including development of the protocol. This protocol is approved by an ethics committee, and clinical investigators at each site must follow this protocol, except where deviations are necessary to eliminate an immediate hazard to trial participants. As clinicians, investigators have independent legal and ethical responsibilities to safeguard the well-being of each patient. Personal data is processed at research sites for delivery of health care. The data is then put into an agreed, key-coded format (in accordance with data minimization principles) and transferred to the research sponsor. The sponsor analyzes this key-coded data in accordance with its research objectives. The sponsor also engages monitors to oversee the progress of the trial at each site and ensure that each site conducts the trial in accordance with the protocol, Good Clinical Practice, and applicable regulatory requirements.

Those who view clinical trial sites and sponsors as independent controllers argue that each processes personal data for its own purposes. The site processes personal data for purposes of health care delivery. The sponsor processes personal data for purposes of analysis in accordance with its research objectives, as well as for oversight of the conduct of the trial.

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[1] See Article 29 Working Party, *Guidelines on Transparency Under Regulation 2016/679* (11 April 2018) at 37.

[2] For example, in *Guidelines for Data Processing within the Framework of Clinical Drug Trials* published by the Italian data protection authority (the "Garante") in July 2008, the Garante wrote that "[I]t appears that the responsibilities vested in the individual trial centres and sponsors are different as regards clinical trials – accordingly, they should be regarded as either separate data controllers or joint data controllers." See https://www.garanteprivacy.it/web/guest/home/docweb/-/docweb-display/docweb/1671330#5 at Section 5.

[3] For example, this appears to be the position taken by the Dutch Central Committee on Research Involving Human Subjects. *See* http://www.ccmo.nl/en/algemene-verordening-gegevensbescherming.

[4] For example, this appears to be the position taken by the Health Research Authority (HRA) at the UK's National Health Service. *See infra* n. 3 and accompanying discussion. It also appears to be the position taken by the French data protection authority (the "CNIL"). See Reference Methodology MR-001 (Decision 2018-153) in the Context of Health Research with Consent, at Section 1.1, available at https://www.cnil.fr/fr/declaration/mr-001-recherches-dans-le-domaine-de-la-sante-avec-recueil-du-consentement.

In addition, only the trial centre maintains a copy of the information that can be used to 'decode' the case report forms and identify the patient to whom they relate. When study participants have questions about their data, wish to exercise a right of access or amendment, or otherwise require assistance, the trial centre is the only party in a position to identify the appropriate records and resolve the inquiry.

THE CASE FOR JOINT CONTROL

The Article 29 Working Party opined in 2010 that clinical trial sponsors and trial centres are 'joint controllers'.

In 2010, the Article 29 Working Party issued an opinion on the concepts of 'controller' and 'processor' under the Data Protection Directive. In its Opinion, the Working Party provided the following guidance to aid organisations in assessing their data protection roles and responsibilities where there is an exchange of data among two or more parties:

- '[A]n exchange of data between two parties without sharing purposes or means in a common set of operations should be considered only as a transfer of data between separate controllers.'
- Nevertheless, 'when different actors would decide to set up a shared infrastructure to pursue their own individual purposes[,] . . . these actors determine the essential elements of the means to be used, they qualify as joint data controllers - in any case to that extent - even if they do not necessarily share the same purposes.'
- Moreover, '[i]n some cases, various actors process the same personal data in a sequence. In these cases, it is likely that at micro-level the different processing operations of the chain appear as disconnected, as each of them may have a different purpose. However, it is necessary to double check whether at macro-level these processing operations should not be considered as a 'set of operations' pursuing a joint purpose or using jointly defined means.'
- '[I]n the context of joint control the participation of the parties to the joint determination may take different forms and does not need to be equally shared. Indeed, in case of plurality of actors, they may have a very close relationship (sharing, for example, all purposes and means of a processing) or a more loose relationship (for example, sharing only purposes or means, or a part thereof).'

In its Opinion, the Working Party concluded that the role of the sponsor and site in a clinical trial should be characterized as that of joint controllers: '[B]oth trial centres and sponsors make important determinations with regard to the way personal data relating to clinical trials are processed. Accordingly, they may be regarded as joint data controllers.'[5]

Those who view clinical trial sites and sponsors as joint controllers usually argue that this joint control extends only to the processing of personal data at the trial site for purposes of the trial. They usually view the sponsor as an independent controller with respect to its processing of key-coded data received from trial sites. They note that sites are obligated to collect data in accordance with the study protocol but also have independent responsibilities. The patient's improvement or decline may cause the trial centre to make changes to the patient's care or make adjustments to the research protocol provided by the sponsor, including terminating certain data collection activities or altering the timing. Although the study sponsor still provides the case report form and has paid the trial centre to provide the information requested, the ultimate determination of what information gets recorded is left up to the trial centre and influenced by its own independent medical judgement about what is best for the patient in their care. In short, the site and investigator may process a research subject's personal data without

[5] Example No. 25, on p. 30, available at https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2010/wp169_en.pdf.

'documented instructions' from the study sponsor, and should not be expected to request or await such instructions when making treatment decisions to ensure each participant's health and safety.

THE CASE FOR A CONTROLLER-PROCESSOR RELATIONSHIP

Some regulatory authorities view sites as processors on behalf of trial sponsors when processing personal data for trial purposes.

Guidance issued by the UK NHS's Health Research Authority in Spring 2018 focuses on the distinction between the records of health treatment maintained by a care provider and the case report forms used to record the progress of the research. The NHS HRA views the entry of data into the case report forms and maintenance of research records as a separate and distinct data processing activity from the use of information in patient care. Thus, the HRA suggests that the 'care organisation' would be 'a processor acting in accordance with the instructions of the sponsor' when recording and transmitting this information, but would remain a 'controller' when 'processing the data for care purposes.'[6] In the HRA's view: 'In some cases, particularly interventional research, information will be collected from participants and recorded in both the medical records for care purposes and in the Case Report Form or equivalent for research purposes. In this situation the sponsor is obtaining the data directly from the data subject and is the controller for processing for research (with the care organisation being a processor acting in accordance with the instructions of the sponsor). The care organisation is also a controller for processing the data for care purposes.'

For those who view the site as acting as a processor on behalf of the trial sponsor with respect to certain data processing activities, it is important for data protection purposes to precisely define what records and activities come within the scope of the 'processor' relationship versus those records that are processed and activities conducted by a site as a 'controller'. This is critical for determination of responsibilities in the event of a data breach, for example.

CONCLUSION

There are different, reasonable views on the relationship of sites and sponsors for clinical trial purposes. However, the lack of harmonization of guidance means that in trials that span multiple EU member states, trial sponsors may be forced to adopt different positions by trial site. Because the characterization of the parties impacts the data protection agreements that are necessary between the parties and the data protection notices that are provided to trial participants, addressing divergent views may result in clinical trials being delayed. For example, if trial sites are deemed data processors on behalf of trial sponsors, then processing agreements must be put in place in accordance with Article 28 of the GDPR. Similarly, if sites and sponsors are deemed joint controllers with respect to data processed at a site, then a clear allocation of data protection responsibilities in accordance with GDPR Article 26 is required. In all cases, data protection notices must provide trial participants with a clear explanation of the roles and responsibilities of each party.

Trial sites, sponsors, and interested stakeholders should consider how best to address this issue. One option would be to explicitly recognize that there are different, reasonable views and allow sites and sponsors discretion to structure and determine their relationships for data protection purposes. An alternative option would be to issue pan-EU guidance to promote consistency across the EU.

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[6] https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/what-law-says/data-controllers-and-personal-data-health-and-care-research-context/