MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

January 18, 2019

Via email to EDPB@edpb.europa.eu

Ms. Andrea Jelinek
Chair, European Data Protection Board

Re: Comments on the Guidelines on the territorial scope of the GDPR (Article 3): Recommendations of The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard

Dear Chair Jelinek:

We write to you in your capacity as Chair of the European Data Protection Board (the "**EDPB**") on behalf of the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (the "**MRCT Center**").

Founded in 2009, the MRCT Center has three primary goals: (1) to improve the design, conduct, and oversight of multi-regional, transnational clinical trials; (2) to simplify research through the use of best practices; and (3) to foster respect for research participants, efficacy, safety and fairness in transnational, trans-cultural human subjects research. Consequently, the MRCT Center often comments on regulatory developments around the world that affect multi-national clinical trials.

The MRCT Center commends the EDPB for issuing guidance regarding the extra-territorial applicability of the European Union's General Data Protection Regulation (the "**GDPR**"). Because clinical trials and other scientific research often involves the cross-border transfer and processing of clinical research data, clear guidance on this topic is of utmost importance to researchers in the European Economic Area (**"EEA"**) and elsewhere.

We believe that the EDPB's Guidelines on the territorial scope of the GDPR (Article 3) (the "**Guidelines**") contain a number of clarifications that are of great value to the research community. That said, the Guidelines do not address certain aspects of the GDPR that arise frequently when evaluating the applicability of the GDPR to entities participating in multi-national clinical trials and other types of research. This has led to confusion amongst the research community and resulted in the delay of several important research projects that involve collaboration between EEA and ex-EEA researchers. The MRCT Center is submitting comments to bring to your attention certain elements of the Guidelines that we believe could benefit from substantive clarifications, changes or revisions prior to the Guidelines being finalized.

Comments and Recommendations:

1. **The Guidelines Could Provide Further Clarity Regarding Situations Involving Multiple Controllers**

The Guidelines speak to the need to examine separately the application of the GDPR's jurisdictional reach to processors and controllers. *See* Guidelines, Section 1(d), pages 9-12. It would be beneficial to clarify that this same analysis must be undertaken in the case in which there are multiple controllers, a situation which occurs frequently in multi-national research. One common example of this is when a United States (**"U.S."**) university or hospital participates in a multi-site clinical trial sponsored by an EEA-based research sponsor, for example an EEA-based pharmaceutical company. In such a scenario, the data subjects whose data are collected for the trial are patients located in the U.S. The Guidelines should make clear that in this scenario, the analysis of the application of the GDPR to the U.S. university and the EEA-based pharmaceutical company must be analyzed with respect to each entity independently. Such guidance would make clear that the GDPR does not apply to a U.S. university or hospital solely by virtue of the U.S. entity's participation as a clinical trial site sponsored by an EEA-based company, because the U.S. site in such a case would not be established in the EEA, offering goods or services to data subjects located in the EEA, or monitoring the behavior of data subjects located in the EEA.

The lack of explicit guidance addressing the situation of multiple controllers has led some EEA-based clinical trial sponsors to take the position that all sites in their sponsored clinical trials must comply fully with the GDPR merely by virtue of participating as a site in the trial. This is an untenable position for most U.S.-based universities and hospitals, and the advancement of this position by EEA-based pharmaceutical companies has led to protracted negotiations between U.S. sites and the EEA-based companies, leading to a delay in the initiation of several clinical trials of important treatments. Because data collected at U.S. clinical trial sites are often used in support of submissions to the European Medicines Agency for approval of pharmaceutical products, this delay negatively impacts patients in the EEA as well as in the U.S. and other jurisdictions.

2. **The Guidelines Should Further Clarify the Meaning of Monitoring Behavior**

   a. **The Guidelines Should Provide Additional Clarity in the Targeting Discussion**

The Guidelines contain a helpful discussion of offering goods and services to data subjects located in the EEA and monitoring the behavior of data subjects located in the EEA within the meaning of GDPR Article 3(2). *See* Guidelines, Section 2, pages 12-18. The discussion of offering goods and services makes clear that there must be an intent on the part of the controller or processor to target the good or service to persons located in the EEA; the mere fact that some persons located in the EEA may choose to avail themselves of the good or service does not in and of itself lead to application of the GDPR. *See* Guidelines, Example 14, page 17. The discussion of monitoring behavior, however, is less clear regarding whether the intent to target persons located in the EEA is a relevant consideration, or whether all online monitoring for behavioral analysis or profiling means is subject to the GDPR if applied to persons located in the EEA. The Guidelines would benefit from further clarity on this point. For

example, Example 9 in the Guidelines notes that when a U.S. citizen downloads a mobile application directed exclusively to the U.S. market while on holiday in the EEA, the collection of the U.S. tourist's personal data via the app is not subject to the GDPR. This example makes clear that because the application is targeted only to the U.S. market, the availability of the app to a U.S. tourist located in the EEA does not constitute offering a good or service to persons located in the EEA. However, it is not clear in this example whether the application also performs activities that would be considered "monitoring behavior" and thus whether the fact that the application is targeted only to U.S. persons renders such monitoring outside of the GDPR jurisdiction even when performed on persons located in the EEA.

Clarification on this point is relevant to the research community because increasingly research is conducted by enrolling subjects online or through a mobile application and collecting data on such subjects over a lengthy period of time, such as through the administration of periodic online surveys. The research community is at present unclear as to whether these types of research studies, when conducted by entities such as U.S. universities not established in the EEA, would be subject to the GDPR. The Guidelines should clarify that if the researchers have no intent to target persons located in the EEA, the GDPR should not apply, even if the study does not explicitly exclude persons located in the EEA from participation in the research such that EEA residents may visit the applicable website or download the mobile application in question and enroll in the research study.

b. The Guidelines Should Provide Clarity Regarding the Application of "Monitoring" to Multi-Year Research Studies

The Guidelines discussion of the meaning of "monitoring" for purposes of the GDPR leaves unclear whether "monitoring" for purposes of GDPR Article 3(2)(b) would apply to longitudinal research studies that collect data on data subjects on an ongoing basis without the use of an app or a smart device (*e.g.*, by obtaining data from a data subject's clinician) and that do not attempt to build a profile of such individuals for marketing or other commercial purposes. For example, much important bioemedical research takes place in the context of biobanks that receive biological samples and accompanying medical data in pseudonymised form from health care providers on an ongoing basis pursuant to patient consent. The samples and accompanying pseudonymised data stored in these biobanks are often used for research purposes, with no attempt to contact the data subject from whom the samples and accompanying data originated. The examples provided by the Guidelines as written are unclear regarding whether the GDPR would apply to a biobank that is not established in the EEA but that receives medical data concerning patients on a regular basis for research purposes from a health care provider located in the EEA. This lack of clarity has hindered multi-national biobanking activity and with it important research.

3. **The Guidelines Should Provide Clarity Regarding the Meaning of Activities Conducted in the Context of an "Establishment" Under GDPR Article 3(1)**

The Guidelines include helpful context regarding when activities of a company would be considered to be "in the context of the activities" of an establishment located in the EEA. Specifically, Example 5 of the Guidelines provides that a pharmaceutical company with headquarters in the EEA that locates its clinical trial data processing activities at a branch that is not a legally distinct entity and is

located outside of the EEA must apply the GDPR to the processing activities in the ex-EEA branch because such activities are carried out in the "context" of the EEA headquarters. Additional clarity would be useful, however, regarding the more common situation in which the ex-EEA entity is a legally separate entity, incorporated under the local laws of the jurisdiction in which it is located, such as a subsidiary or affiliate. For example, it is unclear whether all activities of the U.S. subsidiary of an EEA-based pharmaceutical company would be considered conducted in the "context" of the EEA headquarters and thus subject to GDPR requirements. It would be beneficial if the Guidelines could clarify that such activities would be deemed not to be in the context of an EEA "establishment," reducing the compliance obligations for such entities in relation to ex-EEA-based data subjects. *See* Guidelines, Section 1(c), page 8.

4. **Reduced Obligations in the Context of the Activities of a Processor Subject to the GDPR that Performs Services for a Controller Not Subject to the GDPR Would be Beneficial for Research**

The Guidelines helpfully make clear that in the case of a controller-processor relationship, the jurisdictional scope of the GDPR must be analyzed separately for each entity. Thus, the Guidelines make clear that a U.S.-based entity operating as a controller does not become subject to the GDPR solely by virtue of using a processor located in the EEA. However, the Guidelines provide that the processor remains subject to the GDPR by virtue of the processor's establishment in the EEA and, consequently, the processor must comply with the GDPR's provisions applicable to processors, including restrictions on cross-border transfers of personal data. Given the lack of processor-controller standard contractual clauses, this position makes it difficult for non-EEA based controllers to receive personal data from EEA-based processors. *See* Guidelines, Section 1(d)(ii), Example 7, page 11. This situation arises frequently in the case of clinical trials, because U.S.-based researchers that are not subject to the GDPR often wish to use the services of vendors located in the EEA, such as clinical laboratories or data analysis companies, to process data generated in the U.S. during the course of a clinical trial. In such a case, the laboratory or data analysis company acts as a "processor" of the U.S.-based researcher. However, there is not a clear basis to legitimize the transfer of personal data from the EEA-based processor back to the U.S.-based researcher. This state of affairs has complicated research relationships and caused some U.S.-based researchers to avoid the use of processors located in the EEA, which has a detrimental effect on multinational research given the scientific expertise found amongst EEA-based companies, research institutes, and universities.

It would be beneficial to both EEA processors and ex-EEA controllers if the cross-border transfer requirements were relaxed when solely the processor is subject to the GDPR. In such a case, the data subjects do not receive most of their rights under the GDPR (which apply only against controllers), and thus it is not clear from a policy perspective why the personal data of such individuals should be subject to the cross-border transfer restrictions given that in many cases the data will merely be transferred by the processor back to the data subject's home jurisdiction.

5. The Guidelines Should Eliminate the Need for a Cross-Border Transfer Mechanism under Chapter V of the GDPR when a Transfer is Made to an ex-EEA Company that Complies with the GDPR as a Controller

The EDPB should consider allowing ex-EEA companies that are complying with the GDPR as a controller to receive personal data from the EEA without the necessity of a legal basis to legitimize the transfer under Chapter V of the GDPR. GDPR Recital 101 describes the intent of the cross-border transfer requirements as ensuring that "when personal data are transferred from the Union to controllers, processors or other recipients in third countries or to international organisations, the level of protection of natural persons ensured in the Union by this Regulation should not be undermined . . . ." Similarly, GDPR Recital 108 notes that the purpose of the cross-border transfer mechanisms is to "ensure compliance with data protection requirements and the rights of data subjects appropriate to processing within the Union, including the availability of data subject rights and of effective legal remedies, including to obtain effective administrative or judicial redress and to claim compensation, in the Union or the third country." If a controller is subject to the GDPR under GDPR Article 3(2), however, such controller is already required to comply with the data protection requirements of the GDPR, including with respect to the rights of data subjects and security of data. Moreover, supervisory authorities and data subjects have available remedies under the GDPR due to the ability to pursue an EU representative for liability of the U.S.-based controller. Requiring a separate basis to legitimize the cross-border data transfer in such cases does not meaningfully increase data protection but instead introduces barriers to the cross-border sharing of research data that slows the research enterprise and introduces additional administrative expenses that could be better spent on advancing scientific knowledge.

6. Regarding the Meaning of "Large Scale" Processing, the Guidelines Should Provide Further Clarity

The Guidelines currently do not adequately clarify the meaning of "large scale" processing. The Guidelines refer to the Article 29 Working Party guidelines regarding data protection officers, which state that processing of personal data by an entire hospital would be considered large scale, while the processing of personal data by a single physician practice would not be considered large scale. *See* Article 29 Working Party guidelines on data protections officers (DPOs), adopted on 13th December 2016, as last revised on 5th April 2017, WP 243 rev.01, page 8. These examples do not provide much clarity for the research space, however, because a given study will often fit somewhere between these two extremes. Because activities in the clinical research space typically involve special categories of data (*e.g.*, health data), whether an activity is "large scale" is the determinative factor for whether appointment of an EU representative and a data protection officer is required, as well as whether a data protection impact assessment must be conducted for a given processing operation. The clinical research community would benefit from receiving additional clarity on these points in the final Guidelines.

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We at the MRCT Center are grateful for this opportunity to provide comments, and we thank the EDPB for its attention to this submission.

Respectfully Submitted,

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On behalf of:

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