

The Multi-Regional Clinical Trials Center of Brigham & Women’s Hospital and Harvard (“MRCT Center”)¹ submits this comment in support of the European Data Protection Board (“EDPB”) “Guidelines 04/2021 on codes of conduct as tools for transfers” (the “Guidelines”). By way of background, the MRCT Center is a research and policy center that addresses the ethics, conduct, oversight, and regulatory environment of international, multi-site clinical trials. It functions as a neutral convener to engage diverse stakeholders from academia, patients and patient advocacy groups, industry, non-profit organizations, global regulatory agencies, and others.

Many important research studies today involve researchers located in multiple countries across the globe and necessarily require the transfer of personal data across international borders in the conduct of the research. The MRCT Center has written extensively about the challenges posed by the European Union’s General Data Protection Regulation (“GDPR”) to cross-border research as a result of the GDPR’s restrictions on cross-border data flows. A Code of Conduct that is approved for cross-border data transfers would permit researchers in each of the countries participating in a research study to adhere to the same Code of Conduct, thereby facilitating cross-border transfer amongst the researchers. The Code of Conduct would be more flexible than Standard Contractual Clauses because it can be adapted to the specific use cases of scientific research.

Certain MRCT Center members have begun developing Codes of Conduct as a tool for transfer of research data. In presenting those Codes of Conduct for approval by the competent member state Supervisory Authority, however, our members have been told that the Supervisory Authority will not entertain Codes of Conduct for transfer until final guidance on this topic has issued by the EDPB. We thus strongly encourage the EDPB to finalize and adopt the Guidelines expeditiously so that Supervisory Authorities may begin to approve Codes of Conduct for transfer, thereby facilitating important cross-border research.

¹ The responsibility for the content of this document rests with the leadership of the MRCT Center, not with its collaborators, nor with the institutions affiliated with the authors including Brigham and Women’s Hospital, Ropes & Gray LLP, Harvard Medical School, Harvard University, and Yale Law School.