

GDPR-related Challenges for Cross-border Research Science Europe's Proposed Solutions

Context: Cross-border Research and Data Sharing

Research is often conducted and funded in cross-border collaboration, within the European Economic Area (EEA) and beyond. These international collaborations are key to push the frontiers of knowledge and innovation, maximise economic and societal impact, and strengthen the attractiveness of Europe as a research and innovation hub.

Data are one of the major building blocks of research processes. Researchers collect, generate, share, and (re-)use data, including personal data, to gain important insights in their fields and to advance their projects. Data are also essential in setting up and running international research collaborations. In addition, researchers' personal data are necessary for administrative reasons, for instance, when a researcher applies for funding, receives funding, or submits a scientific paper to be reviewed.

The EU General Data Protection Regulation ([GDPR](#)) has a strong influence on how research is conducted and how research projects are managed. Public Research Funding and Research Performing Organisations (hereafter jointly referred to as public research organisations) strive to be GDPR-compliant in their work, but currently encounter challenges and have numerous open questions. While the challenges these organisations encounter can sometimes differ depending on the type of organisation and activity, and might weigh stronger for one type of organisation than for the other, there are some that apply to both organisations.

Science Europe Member Organisations have identified four key issues that need clarification to ensure an efficient implementation of and compliance with the GDPR. These issues are summarised below and illustrated with examples.

Research Derogations and their Implementation at National Level

National rules need to be coherent so that researchers from different countries can work together on research projects.

Scientific research is subject to derogations from the GDPR general provisions: researchers can, provided that the necessary safeguards are in place, process personal data while being exempt from certain obligations (data subjects' right of access, right to rectification, right to restriction of processing, and right to object).

However, these derogations can be introduced either in EU or national legislation. Many Member States introduced their own rules, causing a fragmented legal landscape. For public research organisations that

collaborate internationally, the current situation causes uncertainties and confusion. This is especially the case when researchers use personal data in their projects as EU legislation and different national rules on data protection need to be considered.

Science Europe recommendations:

- Member States should work towards harmonised rules for the research sector. Harmonisation and compatibility between national rules are essential to facilitate cross-border research. The European Commission should encourage and support Member States to develop a harmonised approach.
- The European Commission should issue clear guidance for the research sector. It should detail which rules are applicable in which cases, and how research organisations should deal with different national rules.

Science Europe has always advocated for including research derogations in the GDPR to facilitate the use of data for research purposes. Back in 2013, during the legislative procedure leading to the adoption of the GDPR, Science Europe stressed how crucial harmonised data protection rules at EU level are for cross-border research collaborations.¹ In 2016, Science Europe and many other organisations called on Member States to, where possible, collaborate and facilitate cross-border research by promoting harmonisation and compatibility of national rules.² Today Science Europe would like to, once again, insist on the need for a harmonised implementation of research derogations across Europe.

This issue, and the fact that little guidance is currently provided on the application of data protection rules to research, has also been identified in the Preliminary Opinion on data protection and research of the European Data Protection Supervisor (EDPS).³

Joint Controlling vs. Separate Controlling

GDPR provisions on joint and separate controlling need to be clear and should not leave room for interpretation. Forms of legitimate written agreements, that can be used to set the roles and responsibilities of all partners in a GDPR-compliant way, should be well defined.

The provisions governing data controlling and processing are ambiguous and are interpreted differently by different organisations. This leads to difficulties for organisations to agree on the kind of controlling and agreements that are needed.

When the GDPR applies, research organisations need to specify each partners' roles and responsibilities for all kinds of data processing in their collaboration agreements. This involves defining for each case whether the data controlling is done jointly or separately. Several aspects need to be considered in order to establish the appropriate agreement (joint controller agreement or data sharing agreement in case of separate controlling), including the nature of the data that is shared with the partners, the appropriate legal base, the respective data flows, and the different roles the various partners fulfil.

Research organisations also have doubts about which legal text forms can legitimately be used to fix such agreements. For example, it is not clear whether adding the data protection agreement or joint controller agreement as an annex to a collaboration contract or to a Memorandum of Understanding (MoU) is sufficient as these documents are not always legally binding. Clear formal advice on which legal

¹ Science Europe Medical Sciences Committee Opinion Paper on The Benefits of Personal Data Processing for Medical Sciences in the Context of Protection of Patient Privacy and Safety (May 2013): <http://scieur.org/med-data-proces>

² Joint Statement on Implementing the General Data Protection Regulation to Maintain a Competitive Environment for Research in Europe: Position of Research and Patient Organisations (September 2016): <http://scieur.org/joint-gdrp>

³ European Data Protection Supervisor: A Preliminary Opinion on data protection and scientific research, p.5 (January 2020): https://edps.europa.eu/sites/edp/files/publication/20-01-06_opinion_research_en.pdf

forms can legitimately be used is needed.

Science Europe recommendations:

- The European Commission should provide clear guidance on the definition and data sharing requirements of both joint and separate controlling to avoid different interpretations of the provisions of the GDPR.
- The European Commission should issue clear advice on which forms of written agreements can be used to ensure full compliance with the GDPR.

Ambiguity of GDPR provisions on joint or separate controlling is a problem that exists for all kinds of international research collaborations, such as ordinary programmes via calls for proposals, multilateral or bilateral research collaborations, and collaborations in the context of the European Framework Programmes (Horizon 2020, Horizon Europe). International collaboration can take place between organisations from different EU or EEA member states or with organisations from outside the EEA.

In international research projects, personal data is exchanged not only by researchers who conduct a study, but also by their home institutions and by funding organisations that sign Joint Controller Agreements. Research organisations process and exchange personal data for numerous reasons, for example when storing and assessing applications for funding, sharing applications with reviewers who select projects to be funded, and when processing the data of the researchers whose projects receive funding.

Applicability of Standard Contractual Clauses and Other Tools

Public research organisations need greater clarity on whether Standard Contractual Clauses (SCCs) are still compliant with the GDPR and which other tools are available and legally applicable.

In collaborations with partners from outside the EEA, where the GDPR does not apply directly, other solutions are needed. Adequacy decisions confirm that a country outside the EU offers a comparable level of data protection. However, these are currently only in place for 13 different countries and in the cases of Canada and Japan are not applicable to public research as they are limited to the commercial sector. The same problem occurs with the US Privacy Shield, which only provides a mechanism to comply with data protection requirements to companies in the US and the EU. This means that public research organisations can currently only benefit from adequacy decisions when collaborating with organisations from 10 different countries outside the EEA.

Several public research organisations have resorted to introducing SCCs in their international collaboration agreements. However, as the SCCs date from before the entry into force of the GDPR, some research organisations are reluctant to use SCCs. They fear that the SCCs might be outdated and not compliant with the GDPR. Although the general current understanding is that SCCs are still valid, there is need for official guidance to reassure those organisations that have doubts.

Science Europe recommendations:

- The European Commission should update its SCCs as soon as possible to ensure that they clearly are compliant with the GDPR and therefore a tool that is legally safe to use. Including scenarios of joint controlling in SCCs would go a step further in providing clarity for public research organisations.
- The European Commission should further develop its toolbox for agreements on data processing and controllership with regards to international data flows. This toolbox should comprise sufficient tools that can also legally be used by public research organisations. It should be clear for each tool which kinds of organisations (public/private) are legally allowed to use it.

Some of the other solutions provided by the European Commission through its toolbox for agreements on data processing and controllership with regards to international data flows, cannot be used by public

research organisations. For example, binding corporate rules, which can provide a good solution for the private sector, cannot legally be used by public research organisations.

Certifications and codes of conduct could be useful and convenient for the research sector, particularly considering that codes can be adapted to specific types of data and data transfers. However, codes of conduct need a 'code owner' and a monitoring body. So far, no codes of conduct have been developed for international data transfer. Administrative arrangements between public authorities are problematic as they are of technical nature and non-binding.

Convincing International Partners

Many organisations from outside the EEA are reluctant to sign agreements on data protection with their European partners.

Several public research organisations represented by Science Europe have encountered difficulties when negotiating collaboration agreements with their potential partners. Research organisations from outside the EEA often are either not aware of the necessary requirements or not willing to adapt their way of working to EU legislation which they feel is not applicable to them.

Science Europe recommendations:

- The European Commission should issue clear guidance on the legal provisions that apply also to organisations from non-EEA countries. This information should not be limited to commercial entities and should both be publicly available and easily findable on the European Commission website and as an official information leaflet that research organisations can share with their potential partners.

Science Europe would like to stress that it is ready to work together with the relevant EU Institutions and their services to explore ways forward to address the above concerns.