23 January 2018

Chairwoman, Article 29 Working Party  
Office N° MO-59 02/013  
European Commission  
B-1049 Brussels  
Belgium

By email to: just-article29wp-sec@ec.europa.eu and presidencyg29@cnil.fr

Subject: Comments on Article 29 Working Party Guidelines on Transparency under the GDPR (WP260)

Dear Ms. Falque-Pierrotin:

The Association of Clinical Research Organizations (ACRO) represents the world’s leading, global clinical research organizations (CROs). Our member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices – from discovery, pre-clinical, proof of concept and first-in-man studies through post-approval and pharmacovigilance research. With more than 130,000 employees engaged in research activities around the world (including 57,000 in Europe), ACRO advances clinical outsourcing to improve the quality, efficiency and safety of biomedical research. Each year, ACRO member companies conduct more than 7,000 clinical trials involving 1.3 million research participants in over 100 countries. On average, each of our member companies works with more than 700 research sponsors annually.

ACRO welcomes this opportunity to comment on the Guideline relating to Transparency under the General Data Protection Regulation (GDPR) developed by the Article 29 Working Party and issued on 12 December 2017. We strongly support the Working Party’s efforts to provide guidance concerning the new standards of the GDPR; however, ACRO is concerned that certain parts of the guideline relating to transparency could have the effect of impeding biomedical research. For example, we agree that plain language disclosures are important to ensuring that individuals can understand how information about them is collected and used. But, we are concerned that discouraging conditional language, such as “might,” “often” and “possible” will, in fact, muddy the waters of understanding as many processing operations depend upon contingencies, such as adverse medical events, that are not foreseeable at the time of the initial consent and will depend upon later choices by the individual.

Following here, in table form, are our comments in regard to six issues:
<table>
<thead>
<tr>
<th>Issue (Reference in the draft Guidelines)</th>
<th>Comments</th>
<th>Recommended amendments to the text of the draft Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Use of the &quot;may&quot;, &quot;might&quot;, &quot;some&quot;, &quot;often&quot; and &quot;possible&quot; qualifiers</strong> (paragraph 12, p. 9)</td>
<td>In some circumstances, the use of the qualifiers may more accurately reflect the processing activities undertaken. For example, information may be disclosed to law enforcement authorities in some cases, but not in all cases (and it may not occur at all if such requests are not made), so it would be inaccurate to use “will” instead of “may”.</td>
<td>We suggest amending paragraph 12 as follows: 12. Language qualifiers such as “may”, “might”, “some”, “often” and “possible” should also be avoided where necessary.</td>
</tr>
<tr>
<td><strong>Compatibility analysis</strong> (paragraphs 39-40, p. 21)</td>
<td>Though the compatibility analysis is required to be undertaken under Article 6.4, and data controllers are required to inform data subjects of the purposes other than that for which the personal data were collected under Articles 13.3 and 14.4, we respectfully submit that providing the compatibility analysis is not a requirement under the GDPR. Regardless of whether the compatibility analysis is provided, data subjects will have the opportunity to object to or restrict processing when they are told about the other purposes for which their data will be processed, which can be communicated efficiently and succinctly without providing the compatibility analysis. Providing the compatibility analysis is not likely to provide additional safeguards for data subjects, who may not be in a position to easily understand the compatibility analysis which is likely to be technical and legalistic and contain business sensitive information. Explaining the compatibility analysis is also likely to be lengthy, and may cause information fatigue to the data subjects.</td>
<td>We suggest amending paragraphs 39 and 40 as follows: 39. […] However the default position is that all such Data controllers should consider providing the information set out in that sub-article should be provided to the data subject, if appropriate unless one or more categories of information does not exist or is not applicable. […] 40. […] data controllers should provide further information on the compatibility analysis carried out under Article 6.4.</td>
</tr>
<tr>
<td><strong>Poor practice example of exercise of data subjects’ rights</strong> (paragraph 48, p. 24)</td>
<td>The poor practice example provided of informing data subjects to contact the customer services department can be a practical solution where the customer services department has personnel trained to deal with requests from data subjects to exercise their rights. Paper forms, on the other hand, can be restrictive in that data subjects may have questions or comments that go beyond the paper form and that can be better dealt with on the phone. On this basis we suggest clarifying the poor practice example by stating why using customer services to</td>
<td>We suggest amending the poor practice example on p. 24 as follows: Poor Practice Example A health service provider has a statement on its website informing all data subjects to contact its customer services department to request access to personal data when the customer services department does not have the</td>
</tr>
</tbody>
</table>
| **Balancing test**  
(Schedule, p. 31)  
The draft guidelines state that as a matter of best practice, the data controller should provide the data subject with the information from the balancing test carried out to rely on legitimate interests as a lawful basis for processing. | Similar to the compatibility analysis (see item 2 above), the balancing test analysis is likely to be technical and legalistic, and may include confidential business information. Explaining the balancing test is also likely to be lengthy and/or confusing, and may cause information fatigue to the data subjects. Specifying the purposes and describing the legitimate interests clearly is likely to be sufficient for data subjects to understand why and on what basis their information is being processed. | We suggest amending the text in the Schedule as follows:  
As a matter of best practice, the data controller should also provide considering the data subject with the information from the balancing test. |
| **Article reference for transfers to third countries**  
(Schedule, p. 33)  
The draft guidelines state that the relevant GDPR article permitting the transfer should be specified. | Stating the GDPR article that permits the transfer is legalistic information of little value that data subjects may not be in a position to easily understand. We recommend removing this requirement in the interests of clarity and transparency. | We suggest amending the text in the Schedule as follows:  
The relevant GDPR article Information about the mechanism permitting the transfer to third countries and the corresponding mechanism (e.g. adequacy decision under Article 45 / binding corporate rules under Article 47/ standard data protection clauses under Article 46.2/ derogations and safeguards under Article 49 etc.) should be specified. |
| **Retention periods**  
(Schedule, p. 33-34)  
The draft guidelines state that where relevant, different storage periods should be stipulated for different categories of personal data and/or different processing purposes, including where appropriate, archiving periods. | There are many considerations for determining the retention periods of different types of data, such as the relationship with the data subject, statutory and legal requirements, regulators' expectations and any potential legal disputes. Comprehensive information about the retention policy for different categories of data and different processing purposes, including archiving periods, is likely to be lengthy and technical information that data subjects may not be in a position to easily understand. Data subjects are more likely to be interested in the criteria used to determine the retention period, so that they understand the reasons for the data being retained. On this basis, we suggest stressing the importance of providing the criteria to determine data retention periods rather than giving information on the actual retention periods. | We suggest amending the text in the Schedule as follows:  
It is not sufficient for the data controller to generically state that personal data will be kept as long as necessary for the legitimate purposes of the processing. The data controller should provide information about the period for which the personal data will be stored, or if that is not possible, the criteria used to determine the retention period. Where relevant, data controllers should consider stipulating the different storage periods should be stipulated for different categories of personal data and/or different processing purposes, including where appropriate, archiving periods. |
Please contact ACRO if we can provide additional information or answer any questions (knoonan@acrohealth.org).

Respectfully submitted,

Karen A. Noonan
Vice President, Global Regulatory Policy

**EU Transparency Register:**
ACRO’s public ID number in the Transparency Register is: 150920420956-26