



EDPS  
EUROPEAN DATA PROTECTION SUPERVISOR

# EDPS SUPERVISORY OPINION ON DRAFT INTERNAL RULES CONCERNING RESTRICTIONS OF CERTAIN RIGHTS OF DATA SUBJECTS IN RELATION TO PROCESSING OF PERSONAL DATA IN THE FRAMEWORK OF THE FUNCTIONING OF THE GLOBAL HEALTH EDCTP3 JOINT UNDERTAKING (Case 2023-0658)

## 1. INTRODUCTION

1. This Supervisory Opinion relates to the draft internal rules concerning restrictions of certain rights of data subjects in relation to processing of personal data in the framework of the functioning of the Global Health European and Developing Countries Clinical Trials Partnership 3 Joint Undertaking ('EDCTP3') of 12 June 2023 ('draft IR').
2. The EDPS issues this Supervisory Opinion in accordance with Article 41(2) of Regulation (EU) 2018/1725<sup>1</sup>, ('the Regulation').

## 2. FACTS

3. The EDCTP3 formally consulted the EDPS on the draft IR on 12 June 2023.

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<sup>1</sup> Regulation (EU) 2018/1725 of the European Parliament and the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ, L 295, 21.11.2018, pp. 39-98.

## 3. LEGAL ANALYSIS AND RECOMMENDATIONS

### 3.1. General comments

4. The EDPS welcomes the fact that the EDCTP3 consults the EDPS on its draft IR and relatively shortly after the appointment of its DPO.
5. The EDPS further welcomes that the EDCTP3 has partially made use of the draft internal rules provided as Annex II to the [EDPS Guidance on Article 25 of the Regulation 2018/1725 and internal rules restricting data subjects rights](#) ('EDPS model internal rules').

### 3.2. EDPS recommendations

6. We note that the “Whereas” provisions 3) and 7) of the draft IR in the light of its “Whereas” provision 2) seem to overlap to a great extent and should be merged or omitted in the light of the similar wording of Article 1(2).
7. We further note that the “Whereas” provisions (unlike the EDPS model internal rules) do not refer to the following:
  - potential breaches of security rules for European Union classified information ('EUCI');
  - external audits;
  - cooperation with other Union institutions, bodies, offices and agencies in the context of administrative inquiries, audits and investigations;
  - involvement in cases before the Court of Justice of the European Union;
  - The consultation of the DPO in due time on any restrictions that may be applied and the possibility for the DPO to verify their compliance with the internal rules in order to guarantee utmost protection of the rights and freedoms of data subjects and in accordance with Article 44(1) of the Regulation.

We recommend that EDCTP3 include these “Whereas” provisions.

8. In addition, whilst the “Whereas” provision 10) states that EDCTP3 “is bound to respect... the fundamental rights of the data subjects”, it qualifies this by stating “to the maximum extent possible. This wording seems to not reflect legal obligations adequately. EDCTP3 is bound to *respect* the fundamental rights of the data subjects without such limitations. It may, however, have to *restrict* certain data subject rights in situations outlined in the internal rules. The EDPS recommends omitting the words “to the maximum extent possible” from the “Whereas” provision 10).

9. Article 3 of the draft IR specifies safeguards aimed at preventing abuse or unlawful access or transfer of personal data. Given this objective, which goes beyond the scope of the draft IR (restrictions of certain rights of data subjects in relation to processing of personal data), the EDCTP3 should details such technical and organisational measures as necessary in EDCTP3 internal decisions, procedures and implementing rules (see Article 4 of the EDPS model internal rules).
10. Regarding the “Restrictions” set out in Article 4 of the draft IR, the reasons to apply restrictions listed there should further specify the EDCTP3 specific processing operations referred to in Article 1(2) of the draft IR and preferably be moved there (see e.g. Article 2(1) of the EDPS model internal rules).
11. Article 5(1) of the draft IR reiterates which data subject rights might be restricted. In view of Article 1(1) of the draft IR, this seems redundant and should be omitted.
12. Regarding Article 5(2) of the draft IR, the processing operations listed there should complement Article 1(2) of the draft IR and preferably be moved there. They should further underlie the revision of the “Restrictions” set out in Article 4 of the draft IR (see above point 10).

According to the [EDPS Guidance](#) (§42), in drafting internal rules, it is advised that the EUI identify which (categories of) processing operations need to be covered by the internal rules (see Article 2(1) of the EDPS model internal rules).

As further outlined in the [EDPS audit report](#) (remote audit on Article 25),

- in drafting the internal rules, each EUI needs “to specify which of the grounds provided for in Article 25(1) of the Regulation the EUI wants to rely on and/or in doing so, to refer only to the grounds from the exhaustive list set out therein” (p. 15);
- Furthermore, “The grounds for restrictions listed by EUIs should therefore be framed in the light of the specific processing operations they perform or reasonably expect to perform and each specific processing purpose should be linked with the applicable ground for restriction of data subjects' rights. Article 2(1) of the template IR contained in the EDPS Guidance contains an indicate overview of how this can be achieved.” (p. 16);
- The [EDPS Guidance](#) (§51) notes that “As far as possible, the internal rules should link the processing operation, the categories of personal data concerned, the scope of the restrictions and the rights that will be restricted. For example, possible restrictions of the right of access to data for alleged harassers in anti-harassment procedures, where this is necessary to protect other persons.” (see reference on p. 17 of the [EDPS audit report](#)).

We recommend merging Articles 1(2), 4 and 5(2) of the draft IR (see also above point 10) and align the respective wording of the provision to link each specific processing purpose with the applicable ground for restriction of data subjects' rights.

13. Unlike Article 2(4) of the EDPS model internal rules, Article 6(2) of the draft IR does not stipulate that the EDCTP3 prepare periodic reports on the application of Article 25 of the Regulation. For accountability purposes, we recommend including such reporting obligation in the internal rules.
14. Article 6(3), second and third sentence should not be separated by a period, but rather a comma.
15. Under Article 8(1) of the draft IR, the EDCTP3 shall *inform* the Data Protection Officer (DPO) without undue delay whenever the controller *restricts* the application of data subjects' rights or extends the restriction. Recommendation R6 of the [EDPS Guidance](#) clearly states the following: "*Consult* the DPO *before* and during the restriction" (emphasis added)" (see also pp. 8/9 of the [EDPS audit report](#)). As further explained in the [EDPS audit report](#) (p. 11): "This recommendation aims at making sure that the controller benefits from the DPO's input before any decision to restrict data subjects' rights is taken, e.g. when assessing the necessity and proportionality of the measure or to ensure consistency with precedents. For most cases, an independent, ex post factum review of the application of restrictions by the DPO will not be able to ensure compliance in the same way". We therefore recommend aligning the wording of Article 8(1) of the draft IR accordingly.
16. Unlike Article 5(1), second sentence of the EDPS model internal rules, Article 8(1), second sentence of the draft IR does not give the DPO access to any documents concerning the factual or legal context, but only to the record of the restriction. In view of guaranteeing utmost protection of the rights and freedoms of data subjects and in accordance with Article 44(1) of the Regulation, we recommend adding the words "and to any documents concerning the factual or legal context" to Article 8(1), second sentence of the draft IR.
17. Unlike Article 5(3) of the EDPS model internal rules, Article 8 of the draft IR does not stipulate the obligation to document the information that is shared with the DPO in the application of restrictions. As mentioned in the [EDPS audit report](#) (p. 11): "For accountability purposes, to facilitate dealing with precedents and to ensure a smooth transition in case a new DPO is designated, the involvement of the DPO should be documented in writing". For accountability reasons and to give effect to Article 44(1) of the Regulation, we consequently recommend complementing Article 8 of the draft IR accordingly.
18. Although Article 1(1) of the draft IR refers to Article 35 and 36 of the Regulation, the draft IR do not contain specific Articles covering such situations. We recommend introducing provisions in line with Article 7 and 8 of the EDPS model internal rules.

## 4. CONCLUSION

The EDPS has made several recommendations to ensure compliance of the processing with the Regulation.

In light of the accountability principle, the EDPS expects the EDCTP3 to implement the above recommendations accordingly and has decided to close the case.

Done at Brussels on 19 June 2023

*[e-signed]*