Feedback to the EDPB Guidelines 1/2026 on processing of personal data for scientific research purposes

Fondazione per la Ricerca Farmacologica Gianni Benzi – ETS welcomes the EDPB Guidelines 1/2026 on the processing of personal data for scientific research purposes. As highlighted in the introduction of the Guidelines, the processing of personal data in the context of scientific research is both diverse and complex, making dedicated guidance particularly valuable.

Fondazione Benzi highly appreciates the inclusion of specific examples related to rare disease populations and minors, as these examples acknowledge the crucial role of scientific research for vulnerable groups and the need for appropriate additional safeguards. On the other hand, we consider it is important to provide further guidance on the challenges arising when participants enrolled in research as minors reach the age of legal competence. In fact, researchers could benefit from specific advice on how to deal with the subjects achieving the age of consent, since the consent obtained by guardians/legal representatives to process personal data of children can be confirmed, adjusted or pulled back by the data subject.[1]

For this reason, additional clarifications on this transition, including the role of consent and the continued participation of individuals in research projects, would be beneficial.

The use of key indicators to assess whether an activity qualifies as "scientific research" under GDPR represents a practical and useful approach. The discussion of the available legal bases is comprehensive and clear, while the Guidelines appropriately emphasise the importance of transparency and the right of data subjects to be informed. We also welcome the inclusion of different strategies for situations in which reaching individual data subjects may prove particularly difficult. Furthermore, the clarifications regarding the allocation of GDPR roles and responsibilities in the context of clinical studies are highly appreciated.

Specific comments are set out in the table below.

Paragraph	Section number	Comment and rationale	Proposed changes / recommendation
1		The aim of this document is missing and should specify that it is applicable to scientific research performed both in an academic and in an industrial setting.	
2	6	Formatting error for reference n. 8 - apex	

[1] Giannuzzi V, Landi A, Bartoloni F, Ceci A. A Review on Impact of General Data Protection Regulation on Clinical Studies and Informed Consent. J Clin Res Bioeth 2018; 9:3. doi: 10.4172/2155-9627.1000327

2.1	i. Methodical and systematic approach	Who is responsible for evaluating and confirming that research is conducted in a methodical and systematic way? Who determines, for example, whether a research plan is comprehensive? Furthermore, in the case of clinical studies, is the research plan aligned with/the same of the study protocol? I would suggest clarifying this point further.	The research activities, including formulation and testing of a hypothesis[13], are conducted following a methodical and systematic approach of the relevant research field, for example in accordance with a comprehensive research plan / clinical study protocol. If the research is exploratory or in a preliminary stage, it may have a stated objective as opposed to a hypothesis. The controller should detail this information in the research plan/protocol.
2.1	ii. Adherence to ethical standards	The description of ethical standards is valuable but may be insufficiently nuanced for specific research contexts involving for example vulnerable populations. Research involving paediatric and other vulnerable populations presents specific ethical complexities that are not fully captured by the current text. Additional clarification would better reflect established ethical practice in clinical research.	The meaning of *"adherence to ethical standards"* could be further elaborate by recognising that ethical safeguards should be proportionate to the characteristics of the research population and the context of the research. In particular, additional clarification could be provided for research involving paediatric and other vulnerable populations, where ethical standards commonly require enhanced safeguards, including age-appropriate information, parental permission, assent of minors when appropriate, minimisation of risk, and mechanisms for re-consent where participants reach legal adulthood.
2.1	iii. Verifiability and transparency	The current wording refers to "*protection of intellectual property and trade secrets"* as examples of legitimate limitations to access but does not explicitly prioritise the protection of research participants and personal data. Consideration	

		could be given to explicitly recognising the protection of data subjects and research participants as the primary limitation, particularly in research involving sensitive personal data, genetic data, health data, paediatric populations, or vulnerable groups. This clarification would better reflect the GDPR risk-based and rights-based approaches, as well as the established ethical standards in scientific research, where participant protection constitutes a primary consideration.	
2.1	iv. Autonomy and independence	The statement "*The researchers processing the personal data have academic (e.g. a PhD title) or scientific qualifications (e.g. proven experience or recognition)" in the relevant field of research*" may unintentionally create an exclusionary threshold. Many scientifically valid research projects are conducted by multidisciplinary teams involving statisticians, engineers, clinicians, patient experts, data scientists, and industry professionals without traditional academic titles.	The reference to academic qualifications such as a "PhD title" may benefit from further clarification to avoid the perception that formal academic credentials are a prerequisite for conducting scientific research under the GDPR. The Guidelines could explicitly recognise equivalent scientific expertise, including for example demonstrated professional experience, sector-specific expertise, and interdisciplinary qualifications.
2.1	v. Objectives of the research	The requirement that research contributes to "*society's general knowledge and wellbeing*" could be interpreted ambiguously. Many research activities do not lead to immediate social benefits but still create useful knowledge that helps future research and development.	The text could further acknowledge and explain that contribution to scientific knowledge may also occur indirectly. Scientific value is not limited to studies generating immediate advances in knowledge, but may also arise through activities such as validation studies, feasibility studies, exploratory analyses, methodological research, and technology

			assessments, which contribute to strengthening the scientific evidence base and supporting future research objectives.
2.2	13	It could be worth to mention in this paragraph the role of the Data Access Committees in evaluating data access requests (as additional safeguard measure)	
2.2	13	The Guidelines acknowledge research infrastructures but do not sufficiently address cross-border infrastructures which are indeed important into European research, particularly in rare diseases and precision medicine.	Additional clarifications could be provided regarding research data infrastructures operating across countries. Further guidance on governance arrangements, attribution of controllership, secure access environments, and interoperability with the European Health Data Space framework would be highly valuable.
2.2	13	It is not entirely clear how the process described in this section would operate in practice. In particular, further clarification would be helpful regarding the roles and responsibilities of the different actors involved in data governance and access.	
3.2	27	Formatting error - apostrophe 41	
3.2	28	This section would require more clarifications since it may be in contrast with the storage limitation principle.	
4	32	Formatting error - apostrophe 48-49-50	
4.1		In this section, it would be worth to include reference to the granularity of consent as detailed in the EDPB guidelines on consent 5/2020.	
4.1	36	Formatting error - the sentence is missing the final period	
4.1.2	40	Formatting error - 57, and 58	

4.1.2.1	44	Formatting error - the sentence is missing the final period after 62-63-64	
4.1.2.1	45	Formatting error - the sentence is missing the final period after 66	
4.1.2.1	46	Formatting error - the sentence is missing the final period after 68	
4.1.2.1	48	Formatting error - the sentence is missing the final period after 69-70	
4.1.2.1	49	Formatting error - the sentence is missing the final period after 72	
4.1.2.1	50	Fully agree in addressing the challenge of digital divide because the accessibility access is a key issue in biomedical research.	
4.1.2.2	51	The section does not explicitly address dynamic consent in paediatric research settings. Longitudinal paediatric studies frequently involve participants who reach legal adulthood during the research, thus requiring specific ethical and governance considerations.	An example addressing paediatric research where participants reach the age of legal competence during a study could be added. Additional clarification regarding re-consent procedures and participant autonomy in such circumstances would reflect established ethical practice in paediatric research.
4.1.3		An example focused on a clinical study could be added, as this represents the typical scenario of "*scientific research pursuant to ethical or legal requirements not stemming from the GDPR*"	
4.1.3	53	Formatting error - the sentence is missing the final period after 76-77-78	
4.1.3	54	Formatting error - the sentence is missing the final period after 79	
4.1.3	55	Formatting error - the sentence is missing the final period after 82	
4.2	56	Formatting error - the sentence is missing the final period after 84	
4.2	57	Formatting error - apostrophe 86	
4.2	58	Formatting error - the sentence is missing the final period after 87	
4.3	61	Formatting error - the sentence is missing the final period after 92	

4.3	62	Formatting error - the sentence is missing the final period after 96	
4.3	63	The Guidelines well-recognise the importance of "*appropriate safeguards*" when relying on legitimate interests. However, the examples provided remain relatively generic.	A non-exhaustive list of safeguard measures that may strengthen this point could be added (e.g., pseudonymisation, controlled access procedures, transparency measures, secure processing environments, etc). Such examples would promote harmonised implementation.
4.3	63	Formatting error - the sentence is missing the final period after 97	
4.4	64	Formatting error - the sentence is missing the final period after 101-102	
4.4	65	Formatting error - the sentence is missing the final period after 103	
4.4.2	68-72	Personal data manifestly made public by the data subject (Article 9(2)(e) GDPR) does not explicitly address the specific challenges associated with paediatric populations. Information concerning children may be made publicly available by parents, legal guardians, or family members, particularly in the context of rare diseases, fundraising campaigns, or awareness initiatives. In such circumstances, the child may not have exercised any meaningful control over the disclosure of the information.	It should be clarified the application of Article 9(2)(e) GDPR in situations where health-related information concerning minors have been made publicly available by parents, guardians, or other third parties. Additional guidance would be valuable to ensure that the best interests of the child and the specific protections afforded to minors are appropriately taken into account when assessing whether such data may subsequently be processed for scientific research purposes.
4.4.2	69	Formatting error - the sentence is missing the final period after 109-110	
4.4.2	70	Formatting error - the sentence is missing the final period after 111	

4.4.2	71	Formatting error - the sentence is missing the final period after 112-113	
4.4.2	72	Formatting error - the sentence is missing the final period after 114	
4.4.3	73	Formatting error - the sentence is missing the final period after 116	
4.4.3	74	Formatting error - the sentence is missing the final period after 118	
4.4.3	75	Formatting error - the sentence is missing the final period after 119	
4.4.3	119	It could be worth to include the specific reference to article 53(1)(e) of the EHDS regulation in the footnotes or in the text	
5.1	80	Formatting error - the sentence is missing the final period after 123-124	
5.1	81	Should the DPO act as contact point for the data subjects that would like to exercise their rights?	
Example 12		Formatting error - apostrophe 128	
5.2	83	Formatting error - the sentence is missing the final period after 130	
5.3	88	Formatting error - the sentence is missing the final period after 137-138	
5.3	89	Formatting error - the sentence is missing the final period after 140	
5.3	89	How determines the "*disproportionate effort*"? More clarifications should be added on this point	
5.4.1	94	Formatting error - the sentence is missing the final period after 144	
5.4.2	96	Formatting error - the sentence is missing the final period after 146	
5.4.2.2	99	Formatting error - the sentence is missing the final period after 147	
5.4.2.6	105	Formatting error - the sentence is missing the final period after 155-156	
6.2	113	Formatting error - the sentence is missing the final period after 169	
6.2.2	119	Formatting error - the sentence is missing the final period after 174	

6.2.2	121	Formatting error - the sentence is missing the final period after 176	
6.2.3	125	Formatting error - the sentence is missing the final period after 179	
6.2.3	126	Formatting error - the sentence is missing the final period after 180-182-183	
6.2.3	127	Formatting error - the sentence is missing the final period after 184	
6.2.3	128	Formatting error - the sentence is missing the final period after 186-187	
7.1	136	Formatting error reference n. 201 - apex	
7.1	137	Formatting error reference n. 204 - apex	
7.3	140	Formatting error reference n. 211 - apex	
7.3	141	Formatting error - the sentence is missing the final period after 215	
7.3	143	Formatting error - the sentence is missing the final period after 216	
7.3	144	Formatting error - the sentence is missing the final period after 217-219-220	
7.3	145	Formatting error - the sentence is missing the final period after 222	
8.2	151	Formatting error - apex	
8.2	151	Formatting error - the sentence is missing the final period after 230	
8.2	153	Formatting error - the sentence is missing the final period after 232	
8.3	155	Formatting error - the sentence is missing the final period after 233	
8.3	161	Formatting error - the sentence is missing the final period after 239	
8.3	171	Formatting error - "and"	