LUXEMBOURG NATIONAL DATA SERVICE

Enabling Value Creation from Secondary Use of Data

Response to the EDPB on the Guidelines 1/2026 on processing of personal data for scientific research purposes – published April 2026

1. Summary

The EDPB Guidelines 1/2026 address an important sector that needs more clarification of how scientific research and related activities can be pursued in a legally compliant way.

The LNDS invites the EDPB to

- Consider the responsibility it has towards an entire sector that may rely on the recommendations given,
- Be ready to accept that current practice in the research sector may not always follow data protection by design and default but that could benefit from embracing such concepts for the benefit of data subjects participating in the research as well as for the quality of scientific research,
- Revise the Guidelines, in particular the framing of scientific research purposes and the discussion of possible legal bases, based on a thorough legal analysis of all the relevant GDPR articles and other acts of EU law, as well as relevant case law by the Court of Justice of the European Union (CJEU).
- Consider for this revision
    - the separation of different purposes as required for compliance with Art. 5.1 GDPR in the context of scientific research,
    - the differentiation between processing necessary for a scientific research project and for related activities and
    - the interpretation of Recital 33 of the GDPR in view of the substantive requirements of consent to be specific, informed and freely given and the obligation that the controller must demonstrate that consent was given to the processing.
- Improve the examples to illustrate with more clarity and in realistic settings for scientific research scenarios how data protection by default could be pursued.

2. Introduction

The LNDS welcomes that the European Data Protection Board (EDPB) has dedicated one of their guidelines to the important field of scientific research. Scientific research is a complex field that is characterised by a multitude of purposes related to each

research question and complex processing chains that cover not only the processing for the actual analysis of personal data, in the following just referred to as 'data', but also all the processing that makes research scientific, such as the publication of results. On the other hand, there are processing operations in the context of scientific research projects that are merely closely related, which further increases complexity.

There are many diverging views in the scientific community on the requirements originating from the GDPR and how research activities or related activities should be treated in accordance with the law. Not all current practices pursued by the research sector are currently meeting the high level of protection of natural persons that was envisaged by the legislator as set out in Recital 10 GDPR. The EDPB has a high responsibility when advising an entire sector on what may constitute compliant personal data processing. While it is understandable that the EDPB does not want to cause a major disruption of ongoing research and current practice, it is nevertheless pivotal that all recommendations are made based on solid evidence by the GDPR or relevant case law, even if this comes at the expense of acknowledging that not all current customs are GPR compliant. It will not help the scientific community if an endorsement for current practices would be able to hold in Court. Therefore, at minimum, all recommendations must be discussed in relation to the relevant GDPR articles and available case law like it was done in an exemplary way in the EDPB *Guidelines 07/2020 on the concepts of controller and processor in the GDPR*. Providing clear and specific guidance for the research sector is an important step towards an improved compliance and a higher legal security for stakeholders in the field of scientific research including research infrastructures. Through advocating a thorough planning of all processing operations related to a research project as required for purpose determination, the EDPB would also support the rules of good scientific practice that lead to a better reproducibility of research.

The Guidelines could also serve as a strong message towards the legislator to provide a better legal framework for scientific research that makes full and reasonable use of the opening clauses foreseen in the GDPR for scientific research and reconciles the fundamental rights of natural persons under the Charter of Fundamental Rights in the EU (CFREU) with the freedom of and public interest in scientific research in accordance with Art. 52.1 CFREU.

It is in the view that the feedback is given by LNDS to the proposed EDPB Guidelines 1/2026 on processing of personal data for scientific research purposes, in the following referred to as the Guidelines. The feedback provided is meant to provide background from a legal point of view where the legal discussions are in the Guidelines are currently scarce. It should also offer some insights from scientific research experience and practice. The focus of this feedback document is directed towards the essential compliance elements of purpose definition and legal basis. Any GDPR compliance is based on the appropriate definition of the purpose as can be derived from Art. 5.1[1] as well as, e.g., the definition of a controller under Art. 4.7. This is in line with the statement of the EDPB that, for identifying the lawful basis for the processing, the

[1] References to articles or recitals without indicating a specific legal act are referring to the GDPR.

'*starting point is to identify the purpose for the processing*'.[2] The framing of scientific research purposes is therefore seen as an important element in these guidelines that should be given more attention.

Subsequently, the legal basis depends on both the purpose as well as the nature and the mandate of the controller. The recently published GDPR Enforcement Tracker Report 2026[3] found once again that an insufficient legal basis is among the most frequent reasons for significant fines. The focus analysis is limited to consent as a legal basis due to a widespread misconception that consent would provide the best or a mandatory legal basis for scientific research under the GDPR, but further comments on other legal bases also can be found in the annexes.

Two annexes are provided in addition to the focus feedback with a point-by-point commenting of the Guidelines in more detail, including other relevant aspects, expressing concerns and/or giving recommendations.

3. What constitutes processing for scientific research purposes?

3.1. Necessity to better frame the purpose determination

The Guidelines should provide more concrete input into what constitutes a specific purpose, how to determine the purpose and guide researchers into understanding the necessity of a precise research and data processing planning also from a data protection point of view.

The Guidelines often refer to 'scientific research activities' or even 'activities motivated by scientific research purposes' rather than directly to scientific research purposes. This bears a certain danger as researchers[4] may not understand the difference of activities in a wider research context to a purpose under the GDPR and its relevance for compliance work with the GDPR. The EDPB Guidelines 2/2019 specify: '*The purpose of the collection must be clearly and specifically identified: it must be detailed enough to determine what kind of processing is and is not included within the specified purpose, and to allow that compliance with the law can be assessed and data protection safeguards applied*.' Such guidance, in particular with suitable examples that demonstrate how detailed such a purpose definition may become to fulfil the requirements, can help researchers to understand that the purpose must be carefully phrased and cannot be too generic in its research questions.[5]

While the Guidelines mention, not under the introduction of the concept of processing for scientific research purposes but under consent, that the delimitation of the purpose should enable controllers to determine what personal data are necessary to process,

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[2] The European Data Protection Board, *Guidelines 2/2019 on the Processing of Personal Data under Article 6(1)(b) GDPR in the Context of the Provision of Online Services to Data Subjects (Version 2.0)*, Oct. 8, 2019.

[3] CMS Data Protection Group, GDPR Enforcement Tracker Report 2026 - In-depth analytical review of data protection enforcement trends across sectors and jurisdictions.

[4] 'Researchers' in this document always refers also to organisations pursuing research.

[5] More on the determination of scientific research purposes can be found in Regina Becker and others, 'Purpose Definition as a Crucial Step for Determining the Legal Basis under the GDPR: Implications for Scientific Research' (2024) 11 Journal of Law and the Biosciences lsae001.

this framing of the purpose is subsequently followed by the claim that the delimitation of a purpose could be to a certain field of research such as medical research in oncology. There is the danger that this claim will mislead the readers because the mere 'medical research in oncology' does not allow to determine the necessary data. Research questions can range from biomarkers to treatment to survival rates to underlying molecular mechanisms, from diagnostics to possible treatments to prediction of survival, they can be on environmental or genetic influences – every different research question comes with a different scope of data needed.

To properly frame the purpose, the necessity requirement should be more emphasised as well: 'could the result also be achieved without this processing?' is an important question to be answered. The systematic application of this question on all processing operations is an important compliance instrument. It may also lead to different conclusions than the ones indicated by the Guidelines:

- Example 5
  The example suggests that the processing of contact information is ancillary to a scientific research purpose rather than part of it. However, the question if the research could take place without the processing necessary to recruit patients would be answered with 'no', therefore suggesting that the processing of the contacting of data subjects is not ancillary but part of the scientific research purpose.

  This is also reflected by the fact that the recruitment of research participants is an important step in a research project that needs to comply with methodological requirements – not only the definition of inclusion criteria but also the way the recruitment takes place can lead to a selection bias and may jeopardise the generalisability of research results. Recruiting subjects for a research project is an intrinsic part of the project unless a mere data project is pursued and recruitment is not necessary. However, in that case, relevant data must be sourced, which can involve data processing as well, such as querying already collected data for their suitability for the new research project.
- Para 158 on pseudonymisation

  This paragraph suggests that the legal basis for the scientific research project applies equally to the processing for pseudonymisation. As the Guidelines clarify in Para 21, purpose compatibility does not replace the need to establish a valid legal basis and the legal basis for an initial purpose does not necessarily apply also to a compatible purpose. The conclusion about the same legal basis seems therefore to suggest that pseudonymisation is part of the processing for the research purpose. Yet, the question whether the answer to the research question could be achieved without the processing for pseudonymisation has to be answered with 'yes'. And potentially even better because pseudonymisation lowers the value of the data. This analysis indicates that pseudonymisation pursues a different purpose than the research project and therefore requires the establishment of an independent legal basis. Indeed, the motivation and therefore the legal basis for pseudonymisation can be found in the GDPR rather than in the research project.

The EDPB introduced in Para 43 of the Guidelines 07/2020 the notion of achievements on a micro-level when processing for a (macro-level) purpose. This is another element that could provide practical guidance to the scientific community – how to make sure that a micro-level achievement is not mistaken as the purpose for the processing? This approach could be used to illustrate that stages of a research project like the recruitment or the establishment of a research cohort is part of the processing of the research purpose but not an end, a purpose in itself. Even the answering of the research question by itself is insufficient without the related publication, as also indicated in the key-indicative factors for scientific research of Para 11 in the Guidelines 01/2026.

A discussion of the framing of scientific research purposes in view of these requirements would be useful, also for the conclusions reached by the EDPB on scientific research or examples provided, which may require some adaptation to avoid readers drawing wrong conclusions.

3.2. Key-indicative factors for scientific research

The Guidelines should build their key-indicative on or reconcile them with relevant definitions and concepts for research that are underlying existing EU law.

The EDPB rightly quotes the CJEU that a term that has no specific definition in a legal act of the Union should be given an autonomous and uniform interpretation in EU law. It is in this light that it is suggested that the key-indicative factors should be aligned with EU law. While it is true that there is no overarching and consistent definition of scientific research in EU law itself, it should be noted that the Horizon Europe Regulation[6] states that the concept of research should be used in accordance with the Frascati Manual developed by the Organisation for Economic Co-operation and Development (OECD).[7] Instead, the Guidelines seem to build largely on statements of the European Code of Conduct for Research Integrity (ECCRI), which is equally referenced by the preamble of the Horizon Europe Regulation, but merely for the ethical context, not for the understanding of what constitutes research. Aligning with the Frascati Manual is of pivotal importance for a coherent interpretation of scientific research considering that the Frascati Manual is the underlying interpretation of what constitutes research under the main EU research funding programme but also underlying the European statistics on research and development.[8] While some elements introduced by the OECD in the Frascati Manual are missing in the Guidelines, others, such as the contribution to society's well-being, have been added without any motivation on how either the qualification of 'research' or the qualification of 'scientific' is related to the growth of

[6] Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013, Recital 31.

[7] OECD (2015), *Frascati Manual 2015: Guidelines for Collecting and Reporting Data on Research and Experimental Development*, The Measurement of Scientific, Technological and Innovation Activities, OECD Publishing, Paris.

[8] Also, other sectors rely on the Frascati Manual such as the main concepts and definitions used for the production of R&D statistics by Eurostat. Source: https://ec.europa.eu/eurostat/web/science-technology-innovation/methodology

society's well-being (criterion v). Such deviations risk leading to major inconsistency with regard to the interpretation of scientific research in the EU. It is strongly suggested that the key-indicative factors are revised under consideration of the interpretation in EU law and EU practice based on the Frascati Manual and any deviations are substantiated by evidence from existing EU legislation or relevant case law.

3.3. Research support activities – 'processing of personal data motivated by scientific research purposes'

The Guidelines should rely on terms and concepts established by the GDPR or used by the CJEU and not introduce own terms that bear no clear relation to the existing framework. Activities related to scientific research must be differentiated from research purposes in accordance with the GDPR principles and existing practices for related activities in EU law. Research support is merely related to research purposes.

The Guidelines introduce '*processing of personal data motivated by scientific research purposes*' to assess if processing activities would fall under scientific research purposes or not. This approach is at odds with the GDPR where the processing must be necessary for a purpose to be covered by its legal basis.[9] Processing that is merely motivated by a purpose will likely be only a related or closely related activity but constitute a different, separate purpose.[10] This is very pertinent in the Example 4 of the Guidelines where it is claimed that the disclosure of data by a research repository would constitute a research purpose. Yet, the disclosure is only motivated by a research purpose – all the criteria that signify according to Para 11 of the Guidelines scientific research only apply to the recipient's research project, not the disclosure itself. Example 22 of the Guidelines rightly establishes that the disclosure of data to an independent recipient user is a controller-to-controller transfer, therefore taking place for independent (albeit closely related) purposes. The Frascati Manual states explicitly that the operation of databases and repositories should not be included in research and development activities.[11] This interpretation is also reflected in EU law that differentiates between research infrastructures and organisations pursuing research.[12]

Suggesting to the research community that the operation of a research infrastructure such as a data repository would fall under research purposes can lead to wrong assumptions regarding available legal bases because the research mission will normally not stretch to the operation of a data repository for independent data users, yet, based on the Guidelines, researchers may come to the conclusion that their research legal basis would hold.

The distinction of what does or does not constitute scientific research is therefore relevant not only for the valid legal basis that must be established under the GDPR but

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[9] See for example C-252/21 *Meta Platforms and Others (General terms of use of a social network), Paras 98-109.*

[10] See for example OECD (2015), *Frascati Manual 2015, Para 8.27.*

[11] OECD (2015), *Frascati Manual 2015, Para 8.28.*

[12] See for example Commission Regulation (EU) No 651/2014 of 17 June 2014 declaring certain categories of aid compatible with the internal market in application of arts 107 and 108 of the Treaty Text with EEA relevance, OJ L 187, 26.6.2014., Articles 2(83) and 2(91).

also to prevent an organisation operating *ultra vires* because it wrongly assumes that a mandate as a research organisation would comprise the provision of research services that are not related and ancillary to its own research.

For more information on differentiating research support from the pursuit of scientific research, see the publication '*The EU GDPR and secondary use of health and genetic data for research support purposes*'.[13]

4. Consent as a legal basis for scientific research

4.1. Consent as a legal basis: no provision of legal evidence

A large part of the Guidelines is dedicated to the subject of consent as a legal basis. Yet, it is striking that these sections are virtually free of any reference to relevant case law on consent. Nor are the articles of the GDPR (Art. 4.11; Art. 6.1.a; Art. 7.1; Art. 9.1.a) and the Recitals (Rec 32, 42) quoted or referenced with their wording, much less discussed with their consequences for consent to scientific research purposes. This is an indication that the statements in the Guidelines are not based on the provisions of the GDPR but are built on an independent framework seemingly conceived to justify current practice in some Member States. Indeed, the above mentioned articles and recitals state that consent is specific by definition(!) (Art. 4.11), that consent has to be given to specific (Art. 6.1.a) and specified (Art. 9.1.a) purposes, that in case of several purposes, consent has to be given to each of them (Rec. 32), that the controller must be able to demonstrate that consent was given to the processing and that for consent to be informed, the controller must be known (Rec. 42). The Guidelines on the other hand claim that a consent can be broad (Para 43), that a single consent can be given if purposes are interrelated (Para 38), that consent can be given to unknown downstream controllers (Example 8), and that neither the possibility to specify the precise purpose at a later stage in case of broad consent nor a change of a project in an unanticipated direction require reconsenting as long as research remains in an area of research, thus leaving the data subjects in the dark on the actual processing that is performed with their data and merely presuming their continued consent to the changed processing. The claimed autonomy of data subjects (Para 46) that a broad consent is alluded to respond to is at odds with the quoted EDPB Guidelines 4/2019 that '*data subject should be granted the highest degree of autonomy as possible with respect to control over personal data within the frames of the legal basis*' because data subjects do not have a choice between a specific and a broad consent, assuming that something like a broad consent were possible under the GDPR.[14]

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[13] Regina Becker, Edward S Dove, The EU GDPR and secondary use of health and genetic data for research support purposes, *International Data Privacy Law*, Volume 16, Issue 2, June 2026, ipag001

[14] To allow for data subjects' autonomy, those data subjects who do not want to be obliged to give an affirmative action for every new research project the possibility of an IT-supported, automated feedback could be offered if research projects fall under certain criteria. Such automated feedback could be granular according to the data subjects' wishes, be chosen by the data subject on the level that they deem being sufficiently informed and could be revoked by the data subject at any time. It would not change that all relevant information must be provided by the data controller in advance to any affirmative

Sadly, even Recital 33 is not quoted with the requirement that it is '*not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection*'. Neither the 'not possible' nor the 'fully' are considered in the Guidelines where it is suggested that any future projects can be covered by a single consent to as long as they are within certain areas of scientific research.[15] These considerations leave out entirely that Rec. 33 must build on an underlying necessity – that there is no other alternative than consenting to a not yet fully identified purpose because the consent must cover the commencement of the project, which is the data collection. A mere convenience, that a consent to processing operations for a future project starting later may be cumbersome, is not enough to justify a deviation from core elements of the GDPR as suggested in Para 43. Even in case of a specific project, the Guidelines could be understood that it is acceptable to start a collection of data for a scientific research project without having a research plan: 'when the precise processing purposes are clearly determined at a later stage, for example when a research plan that details the processing of personal data is drafted or finalised.' It would have been important to emphasise that a collection of data always requires a research plan that justifies the choice of data to be collected as well as their initial processing, and that has defined criteria when and how later stages of the project will be further determined because it is not possible to do this at the time of collection. Such an impossibility must be built on methodological reasons (such as in a birth cohort). The Guidelines, however, seem to suggest that the specific consent to the specific and specified purpose could be deviated from without necessity.

4.2. Broad consent vs. dynamic consent: interpretation of Rec. 33

Using Rec. 33 to interpret the provisions of the GDPR, in particular Art. 7.1, rather than derogating from the provisions, leads to the conclusion that the conditions for a dynamic rather than a broad consent are framed in the Recital.

The notion of broad consent suggested in the Guidelines is derived from Rec. 33. As stated by the CJEU in Case C-162/97 *Nilsson and Others*, '*the preamble to a Community act has no binding legal force and cannot be relied on as a ground for derogating from the actual provisions of the act in question.*' Advocate General Szpunar explains in Opinion in Case C-673/17 *Planet49* under reference to the Case *Nilsson and Others* regarding recitals: '*I feel compelled to recall that they obviously do not have any independent legal value, but that the Court frequently resorts to them in interpreting provisions of an EU legal act. In the EU legal order they are descriptive and not prescriptive in nature. Indeed, the question of their legal value does not normally arise for the simple reason that, typically, the recitals are reflected in the legal provisions of a directive. Good legislative practice by the political institutions of the EU tends to aim at*

indication by the data subject and would allow the controller to demonstrate that consent was given to the processing.

[15] A legal analysis of these terms can be found in the section '**Recital 33 as a potential gateway to broad consent?**' of Legal bases for effective secondary use of health and genetic data in the EU: time for new legislative solutions to better harmonize data for cross-border sharing?, *International Data Privacy Law*, Volume 14, Issue 3, August 2024, Pages 223–246

a situation in which the recitals provide a useful background to the provisions of a legal text.'

It is in this view that Rec. 33 must be read – it must reflect the legal provisions of the GDPR. In view of consent being defined as specific and to be given to specific purposes, the conclusion that it indicated a deviation of the substance of consent is not justifiable. However, Rec. 33 could be considered as providing background to Art. 7.1. While both Art. 6.1.a and 9.2.a require that consent must be given to purposes, Art. 7.1 demands, as conditions for consent, the controller to be able to demonstrate that consent was given to the processing. (emphasis added) This deviation from Art. 6.1.a / 9.2.a seems to anticipate that it may not always be possible to fully identify the purpose at the time of collection. In such a case, consent could be possible where it covers only the processing to the extent that purpose can be framed at the time of the collection. Rec. 33 would illustrate that, in case of scientific research, the consent could be given to the initial processing steps if and only if the scoping of areas of research envisaged and that were determining the collection are explained to the data subject. At no point does Rec. 33 mention that a later consent to the next processing steps and the precise purposes, once these can be identified, would not be necessary. Nor could this be possible in view of Art. 7.1, which imposes a clear accountability obligation on the controller: that a '*specific, informed and unambiguous indication of the data subject's wishes*' was given '*by a statement or by a clear affirmative action*' can be demonstrated.[16] The GDPR provides neither for a derogation of Art. 7.1 nor does it offer any compromise on the specificity regarding affirmative action. This precisely defined accountability cannot be replaced by '*the reasonable expectation of the data subject*' as suggested in the Guidelines in Para 46. The Guidelines even admit that a broad consent goes along with a '*lack of purpose specification*' (Para 48). The suggested measure to enable data subjects to receive information on the processing of their personal data such as through newsletters and the possibility to withdraw consent would not meet the accountability obligations set out in Art. 7.1GDPR, as can also be derived by association from the CJEU in *Planet 49*. The Court found that it is not 'unambiguous' if a passive behaviour of a data subject is interpreted as an agreement.[17] The 'lack of purpose specification' conceded by the Guidelines make it clear that, at the time of consent, the purpose was not yet specified and any later specification that may or may not reach the data subject cannot be presumed as consented to without a renewed affirmative action. Consequently, a controller would always have to re-obtain consent as soon as the purpose can be further framed to cover the next stage of the processing operations.

Based on the above considerations, Rec. 33 cannot justify a broad consent but rather frames what the Guidelines describe as dynamic consent.

[16] GDPR, Art. 4.11 – definition of consent.

[17] Case C-673/17 *Planet49*, Para 54: In particular, Article 7(a) of Directive 95/46 provides that the data subject's consent may make such processing lawful provided that the data subject has given his or her consent 'unambiguously'. Only active behaviour on the part of the data subject with a view to giving his or her consent may fulfil that requirement.

4.3. Information requirement for a valid consent as set out by the CJEU

All information required under Art. 13 must be given to the data subjects in accordance with Art. 12 for a consent to be valid. This includes the controller, the data types and all the circumstances around the processing.

The Guidelines have not dedicated a specific section to when a consent is deemed informed. Nevertheless, the Guidelines claim that, for scientific research, it would be sufficient information to obtain consent to future research projects if '*the purpose for the processing can be delimited to a certain field of research*' or is '*delimited in view of expected outcomes of the research, for example conducting genetic research to find better medical treatment methods*' (Para 45). Needless to say, none of these delimitations allows to foresee the processing related to these research projects, the full scope of data types used and the risk that may be associated with each project.

The claim that a valid informed consent could be obtained on the level of unspecific information (NB: Para 48 /49 of the Guidelines: offset the lack of purpose specification) is in contradiction with existing CJEU case law. The Court stated in Case C-757/22 *Meta Platforms Ireland (Representative action)*, Para 60: '*The validity of the consent given by the data subject depends, inter alia, on whether that person has previously obtained the information in the light of all the circumstances surrounding the processing of the data in question to which he or she was entitled, under Article 12 and 13 of the GDPR, and which allow him or her to give consent in full knowledge of the facts.*' (Emphasis added). Similar requirements were made in other cases, such as Case C-61/19 *Orange România* SA, where the Court specified in Para 40 that, before giving consent, the data subjects must be aware, inter alia, of the identity of the controller, the type of data, the period and procedure of that processing to which consent is given and that the data subject must be able to determine easily all the consequences that they may give.

The scope of content and the level of specificity proposed by the Guidelines cannot fulfil these requirements. None of the examples given would, e.g., allow to justify the types of data to be collected in accordance with data minimisation and to derive an initial design of the collection and processing.

In view of the ample case law, it is also not clear how the Guidelines came to the conclusion that several controllers could rely on the same broad consent

when it has not yet been decided how to use the data in individual research projects at the time of collection (Para 43), thus implying that not all controllers have been specified.

Each individual research project will have different risks – these may stem from the recipients, such as involving third country transfers, from the type or amount of data processed or the methodologies used such as training algorithms. Data subjects are not able to determine all the consequences of a broad consent based on the level of information suggested and are therefore not able to give their consent in full knowledge of the facts. The consent proposed in the Guidelines are therefore not valid according to the statements of the CJEU.

4.4. Freely given consent: dependencies must be discussed

The Guidelines should discuss, in more detail and ideally with criteria, dependencies of data subjects that may lead to an imbalance between the data subject and the controller.

The Guidelines take up the question of when a consent is not freely given and refer to situations when the data subject is in a vulnerable or disadvantaged position. This is subsequently only illustrated with examples. It would have been useful to also give criteria for vulnerabilities, such as by quoting the previous Guidelines / Opinions that there may be a strong presumption this is the case when a data subject is a situation of a dependency on the data controller.[18] This criterion is important and seems in contradiction to the suggestion in the Guidelines '*that the fact that a patient is receiving treatment does not in itself affect the data subject's capacity to freely provide consent*' unless '*the data subject is severely affected by a mental or physical medical condition*'. Not only the mental or physical medical condition needs to be considered but also the level of dependency, for example, if the consent is obtained from a patient by the treating healthcare professional. This can also be derived from the quoted EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research: rather than supporting the statement that the mental or physical medical condition would be the decisive factor as the footnote seems to suggest, it is stated that '*it needs to be established that no imbalance of power between data subjects and researchers exists*' and that '*this requires a careful assessment on a case by case basis*'.

4.5. Possibility to withdraw consent: a challenge for reproducibility

The Guidelines should discuss the potential consequences of the right to withdrawal of consent, including that it may make consent an unsuitable legal basis for scientific research, e.g., if publication and research integrity requirements demand a stable data set for reproducibility.

The Guidelines rightly state, albeit in a footnote, that in case of consent withdrawal '*the controller must stop the concerned processing operations and if there is no other lawful basis justifying continued processing of the personal data (e.g. further storage), then the data must be deleted or anonymised by the controller*'. The Guidelines fail to discuss though whether the controller can afford the withdrawal of consent at any stage of the processing for the research purpose. This consideration is particularly relevant in view of publishing and archiving data for reproducibility because publications are an intrinsic part of the scientific research purpose due to the aim of research to generate new knowledge based on reproducible results. Also rules for research integrity require the data used for the generation of results to be archived to permit demonstration of reproducibility. Withdrawal of consent could jeopardise reproducibility. There are also research projects for which a withdrawal of datasets may lead to considerable or

[18] Guidelines 05/2020 on consent under Regulation 2016/679, Opinion 15/2011 on the definition of consent.

unacceptable efforts or make the entire research impossible as also described in the Guidelines in Para 120.

The Guidelines should therefore point out that consent is not a suitable legal basis if the withdrawal of consent cannot be complied with at all stages of processing for the scientific research purpose.

5. Annex I: Point by Point feedback on the Guidelines: concerns and needs for clarification

Para	Guidelines	Remarks
9	*While the concept of scientific research should be interpreted in a broad manner, it "may not be stretched beyond its common meaning". Therefore, the EDPB has previously stated that: "'scientific research' [...] means a research project set up in accordance with relevant sector-related methodological and ethical standards, in conformity with good practice"10. In other words, the concept of scientific research purposes in the GDPR covers processing of personal data in research activities that are* ***genuinely scientific****.*	It is important that 'a research project' does not remain abstract. The Guidelines should describe what forms a research project – from the processing related to the design, the collection including all processing necessary to do the collection, data pre-processing, data analysis, verification of results, publication including peer-review and / or IP related measures, as well as archiving in accordance with good scientific practice. Also, other sources should be referenced here such as the Frascati Manual by the OECD, on which Horizon Europe builds (see Rec 31 Horizon Europe) as well as many other EU laws and institutions, and that looks in detail into what is covered by different types of research. The understanding of what constitutes processing necessary for a research project, what differentiates micro-level purposes from the actual purpose and what may be only related or closely related activities to scientific research should be clarified as early as possible in the Guidelines.
11	Entire paragraph, but in particular: *v. Objectives of the research* *The research activities are carried out with the aim of contributing to the growth of society's general knowledge and wellbeing*[21].	The key indicative factors set out in this paragraph must be aligned with the Frascati Manual to ensure compatibility with the acts on EU law that build for the interpretation of the concept of research on the Frascati Manual.[19] In particular, the requirement that research activities should be carried out with the aim of society's wellbeing may be relevant for research that is in the public interest, but it is not an intrinsic element of research nor of science. As an example, the CIOMS

[19] Apart from Horizon Europe referring to the Frascati Manual in the preamble, laws like the *Commission Regulation (EU) No 651/2014 of 17 June 2014 declaring certain categories of aid compatible with the internal market in application of arts 107 and 108 of the Treaty Text with EEA relevance* derive their definitions on the Frascati Manual.

		Guidelines illustrate the difference between the scientific and the social value of research.[20] Even the requirement of being in keeping with ethical standards may be questioned (see below).
12	***Example 1: Processing of personal data for scientific research purposes*** *A pharmaceutical company is developing a new pharmaceutical intended to combat a rare disease. To explore the potential side effects, the pharmaceutical company initiates a clinical trial. While the pharmaceutical is developed by a commercial company, the purpose of the clinical trial is also to further the scientific knowledge of the rare disease in question and improve the quality of life of patient suffering from the disease. To this end, the research activities carried out within the scope of the clinical trial correspond to factor v (objectives of the research).*	This Example is confusing – according to the description of the clinical trial provided in the Example, at least 3 distinct purposes are pursued, the pursuit of which would require the collection of, at least partly, different data. In addition, the purposes specified remain rather vague: further the scientific knowledge' does not allow to understand what questions would be envisaged and what data are necessary for this – would this be molecular mechanisms? Separation from other diseases? How is the quality of life to be improved? By the drug? Does that mean efficacy is to be tested already? By not separating these purposes and specifying them to a level that illustrates that a purpose definition must allow data minimisation, definition of an end point of the processing and to understand the processing that will happen, severe misunderstandings can be fostered in the scientific community that there is no need to be specific on purposes and that there is no need to deal with each purpose separately.[21]
13	[...] *The processing of personal data within the scope of a research infrastructure may be motivated by scientific research purposes, within the meaning of the GDPR.* [...] ***Example 4: Processing of personal data for scientific research purposes in a research infrastructure***	These statements are not in line with EU law that makes a difference between the operations of a research infrastructure and the pursuit of research.[22] The Frascati Manual explicitly states that Processing motivated by (scientific research) purposes is not a concept that is present in the GDPR. Rather, we find in EU law the distinction between the pursuit of a purpose / objective and closely related activities or related activities.[23]

[20] Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), International Ethical Guidelines for Health-related Research Involving Humans, Guidelines 1: Scientific and social value and respect for rights.

[21] This can also be derived from the Case C-757/22 *Meta Platforms Ireland* (Representative action), Para 54, where 'respectively' indicates that purposes cannot be aggregated and that information has to be provided per purpose.

[22] See among others: Horizon Europe, Article 2(1) '*research infrastructures' means facilities that provide resources and services for the research communities to conduct research and foster innovation in their fields, including* [...] *knowledge-related facilities such as collections, archives or scientific data infrastructures*; [...]

[23] See, e.g., Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax (VAT), Art. 132.1.b on hospital and medical care and closely related activities, as well as relevant case law exploring what constitutes closely related activities (e.g., Case C-366/12 *Finanzamt Dortmund-West v Klinikum Dortmund gGmbH*).

	[…] *Considering that the conditions for accessing the database trigger several of the factors listed above, the processing of personal data related to the management and provision of research data can be deemed to be conducted for scientific research purposes, in the meaning of the GDPR*.	It is in the very nature of research infrastructures that they are motivated by scientific research purposes – that is why they were created in the first place. The conclusion that the use of these facilities for scientific research projects renders the services provision of the facility, in this case the disclosure of data, a scientific research purpose in itself is, however, not justifiable in view of the EU legal framework. The disclosure, and therefore the purpose of the research infrastructure in Example 4, is achieved before the use by the researcher begins (see also Example 22 of these Guidelines, which state that there is a controller to controller transfer taking place in case of data use from a data repository). Last not least – the processing of the research infrastructure does not meet the key factors set out in the Guidelines under Para 11 – only the processing by the user does. The user's purpose is, however, distinct from the purpose of the research infrastructure's processing operations (controller to controller transfer).
14	Not only processing operations undertaken within the scope of research projects or research infrastructures may be motivated by scientific research purposes, but also other processing operations that are ancillary to scientific research projects. Ancillary processing operations can be processing operations in the preparatory step of research, for example processing contact details of individuals in order to identify potential research subjects (e.g. patients, pupils, persons receiving social welfare etc.). Other potential ancillary processing operations relate to the management of the research data as such and include (but are not limited to) identification of relevant data, data extraction, filtering, grouping, curation and categorisation of personal data[27]. Anonymisation or pseudonymisation of personal data prior to the processing of personal data in individual research projects may also be motivated by scientific research purposes[28].	Along the same lines as before, '*motivated by scientific research purposes*' is not helpful for researchers who must frame which processing belongs to which purpose. It is strongly recommended to focus on the GDPR approach only. This means the controller must identify for each processing operation for which purpose it is necessary. What is called here 'ancillary' is actually an essential part of a research project and needs to be carefully designed before the first data processing is commenced to avoid any recruitment or selection bias (including through the messages given when reaching out to data subjects) or wrong results if the data are not carefully pre-processed before the start of the analysis. The question whether the research question could be answered without these processing steps would be 'no'. They are part of the methodological standards that a scientific research project must comply with if new knowledge is to be generated. The same considerations apply to Example 3 of the Guidelines. Anonymisation or pseudonymisation are closely related to the scientific research purpose. However, the research question could be answered without anonymising or pseudonymising the data. This processing takes place as a legal obligation to protect

		as much as possible data subjects in the respective scientific research project. This renders anonymisation/pseudonymisation an activity related to that project but not part of it or even ancillary to it. Such analyses demonstrate that the newly introduced qualification of 'motivated by scientific research purposes', which lacks a counterpart in the GDPR, may rather be misleading.
22	[…] *It is, however, not always possible to rely on the same legal basis when further processing personal data for scientific research purposes. This applies in particular if the initial legal basis for the primary processing is consent or a legal obligation*[35]. **Footnote 35**: *A change of purpose could be contradictory to the specificity of consent or the scope of the legal obligation. For example, if further processing of personal data for scientific research purposes would exceed the boundaries of an initial consent obtained from a data subject, then the controller would need to obtain consent for the further processing, or determine another legal basis that it can rely on. In this regard, it should be noted that controllers may, provided that additional safeguards are adopted, obtain consent for processing of personal data that covers an area of scientific research. Such consent may include several processing operations in different research projects by several controllers. See further in section 4.1.2.1.*	The footnote rightly points out that a consent is obtained for specific processing (here, a reference also to Art. 6.1.a and Art. 7 would be useful) and further processing for another purpose cannot be covered by that consent. However, subsequently the footnote suggests that the very principle of a specific consent could be deviated from, merely if safeguards are proposed. It seems to suggest to the scientific community: if you want to further process your data for several research projects, you should go for broad consent. Such a message gives the impression that fundamental principles and rights guaranteed by EU law can be bypassed without being based on a legal provision and without necessity. While this message was likely not the intention when conceiving the Guidelines, it is important that they are not misinterpreted in such a way.
32	*The main legal bases that are relevant for the processing of personal data for scientific research purposes are consent (Article 6(1)(a)* [49]*), legal obligation (Article 6(1)(c)), public interest (Article 6(1)(e)) and legitimate interest (Article 6(1)(f))* [50]. Footnote 49	The Guidelines suggest in Para 32 that 'legal obligation', Art. 6.1.c, could be a legal basis for research purposes. However, considering that each new research question and related project constitutes a new purpose, it is not clear how a legal obligation to research can be established because the purpose of the processing must be determined in that legal basis.[24] Indeed, no explanation is given in the

[24] GDPR Art. 6.3.

	*As further clarified in sections 4.1.2.1 and 4.1.2.2, personal data processed for scientific research purposes on the basis of consent, pursuant to Article 6(1)(a) GDPR, may be collected using either **broad** or **dynamic** consent.*	Guidelines how / why research might be performed as a legal obligation. NB: the legal obligations under the Clinical Trial Regulation are not to answer the actual research question of the clinical trial but related, e.g., to safety as also clarified in the EDPB Opinion 03/2019. The Footnote 49 suggests that controllers could freely choose between a broad and a dynamic consent. As already mentioned above, a broad consent on mere convenience and practicability arguments, which cannot make any claim towards intrinsic necessity and that cannot build on any legal provisions, is unlikely to be compatible with EU primary and secondary law.[25]
Footnote 50	*Processing that is necessary for the protection of vital interests of the data subject or of another natural person, pursuant to Article 6(1)(d) GDPR, may also be a viable legal basis when processing personal data for scientific research purposes cannot be manifestly based on another legal basis (see Recital 46). However, as this would only occur in rare circumstances, Article 6(1)(d) GDPR is not elaborated upon in the present Guidelines.*	The choice of the suitable legal basis depends on the purpose pursued, in particular, when relying on Art. 6.1.d GDPR. In this case it is supposed to be about life and death of a data subject or another natural person. The aim of a scientific research project is to contribute to general and/or generalisable knowledge. Research is by default never directed towards an effect on individuals but build on significant statistics. While individuals may benefit from scientific research, such as in a clinical trial, this is not the purpose for which the research is pursued but merely a side effect. On the other hand, activities like experimental treatment do not meet the criteria of scientific research. It is suggested that the footnote is deleted to avoid researchers relying on that legal basis.
37	*If personal data is processed in the field of medical research involving patients, such as clinical trials, then the controller should consider the mental or physical condition of the patient. If a patient's capacity to provide consent is severely affected by his or her mental or physical medical condition, then the controller should refrain from relying on consent for the processing of personal data[54]. Conversely, the fact that a data subject is a patient receiving health care does not in itself affect the data subject's capacity to freely provide consent, in so far as the data*	The last sentence of Para 37 could be interpreted that the only limitation on consent to be feely given by patients is originating from their mental or physical medical condition. This does not sufficiently reflect the potential dependency between patients and their treating healthcare professionals that can lead to an imbalance as set out in paragraph 27 of the Declaration of Helsinki.[26] The Declaration requires that consent must be sought by an appropriately qualified individual who is independent of this relationship. The EDPB Guidelines 03/2020 seem to reflect this requirement in Para 20/21. The situation of an institutional or hierarchical dependency is also expressed in the EDPB Opinion 03/2019 in the context

[25] Art. 52.1 CFREU, GDPR Articles 6.1.a, 7, 9.2.a.

[26] WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Participants, Version October 2024.

	subject is not severely affected by a mental or physical medical condition[55].	of clinical trials.[27] The footnote 55 in the Guidelines references the Response to the Commission document[28] as evidence for the (too) limited statements. However, the respective document explicitly refers to the potential imbalance between the controller and the data subject, not the inability of the data subject to give consent. The considerations of this power imbalance must be reflected in the Guidelines as potential dependencies of patient and treating healthcare professionals, even if only a perceived ones, cannot be neglected and, as pointed out in the Response document, a case by case analysis is always needed.[29]
38	*A controller can obtain a single consent for clinical research that involves the processing of personal data which are necessary both for the purposes of providing healthcare and conducting scientific research, since those purposes are interrelated.*	This statement seems to conflict with Rec. 32. which clarifies that, '*when the processing has multiple purposes, consent should be given for all of them*'. There is nothing in the GDPR provisions or the preamble that suggests that this interpretation of the specificity of consent would not apply in case of interrelated purposes. Evidence has to be provided for the proposed statement in its current form if it is to be kept and the interaction with Rec. 32 as well as Art. 6.1.a is to be discussed. The Guidelines contradict themselves subsequently where they state in Para 39 that the consent to research cannot be a condition for providing healthcare. Yet, a consent that unifies both purposes would have this effect. This is also reflected in Rec. 43: '*Consent is presumed not to be freely given if it does not allow separate consent to be given to different personal data processing operations despite it being appropriate in the individual case* [...]'.
40, 43	*40. In the field of scientific research, it is possible for controllers to rely on the consent of a data subject to collect and process personal data in a certain area of scientific research when the purposes of research are not fully known at the time of collection of the data.* *43. A controller can obtain broad consent from data subjects when collecting and storing personal data for processing in*	The phrasing of Rec. 33 should be discussed here. This covers in particular the impossibility to specify the full purpose at a time when consent is obtained for the data collection and therefore the commencement of the processing for that purpose. It also needs to be emphasised that Rec. 33 does not state that the initial consent obtained would be sufficient for the downstream processing. In view of Art. 7.1, the controller must be able to demonstrate that consent was given to the processing, the assumption must be that this initial consent in view of

[27] EDPB Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR), Para 19.

[28] EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research.

[29] Ibid, Para 10.

	future research projects within certain areas of scientific research. In certain cases, several controllers can rely on the same broad consent[61]*. This is possible when it has not yet been decided how to use the data in individual research projects at the time of collection and when the precise processing purposes are clearly determined at a later stage, for example when a research plan that details the processing of personal data is drafted or finalised.*	the areas of scientific research can only be given to the extent that the areas of research provide a justification for the initial processing, data minimisation and that another consent is obtained once purposes can be framed more specifically. In no way consent can be obtained for a data collection for projects in the future that have not yet commenced and that cannot be specified yet. This is scenario not covered by Rec. 33. Collecting consent for a processing that is not yet decided at all does not meet the necessity requirement. Future research projects that have not yet commenced may be pursued as further processing. In this case, there is no necessity to obtain consent at the time of collection.
45	*The purpose for processing can be delimited to a certain field of research, for example medical research in the field of oncology, or sociological research in the field of criminology.*	Rec. 33 refers to purposes that cannot be fully identified at the time of collection. This collection, however, must be justified by the 'areas of research' referenced in the Recital. The suggested level of specification would not allow designing the collection and cannot be the basis to obtain the consent to a related processing because the scope envisaged here is too broad. The controller will not be able to demonstrate that the data subjects have consented to the processing as required under Art. 7. The approach is also in contradiction with Convention 108, which states that '*specified "purposes" indicates that it is not permitted to process data for undefined, imprecise or vague purposes.*'[30]
46, 47	*46. When doing so, controllers should evaluate if the processing of personal data correlates with the reasonable expectations of the data subjects, in line with the principle of fairness and the autonomy of data subjects*[67]*.*	While the processing must be fair, fairness does not replace the requirement of lawfulness. The reasonable expectation by the data subject is, same as autonomy, part of the fairness principle,[31] which needs to be fulfilled in a cumulative way.[32] Therefore, the reasonable expectation of the data subject regarding how their data are used does not substitute the transparency and the lawfulness principles. In

[30] Council of Europe, Convention 108 +Convention for the protection of individuals with regard to the processing of personal data, Para 48.

[31] EDPB Guidelines 04/2019, Para 69: '*Fairness is an overarching principle which requires that personal data should not be processed in a way that is unjustifiably detrimental, unlawfully discriminatory, unexpected or misleading to the data subject.*[...] *Key elements may include: autonomy; interaction, expectation, non-discrimination, non-exploitation, consumer choice, power balance, no risk transfer, no deception, respecting of rights, ethical, truthful, human intervention, fair algorithms*.'
Para 70: '*Key design and default fairness elements may include: Autonomy* [...]'.

[32] Case C-77/21 *Digi*, Para 47: '*However, first, as the Advocate General noted in point 24 of his Opinion, the principles relating to the processing of personal data set out in Article 5 of Regulation 2016/679 apply cumulatively.*'

	47. Broad consent can be relied on for the processing operations of – _inter alia – _collection, curation, storage and provision of data (e.g. by way of transmission or giving access through a secure processing environment), as well as subsequent processing operations in individual research projects or parts thereof, as long as the processing of personal data remains within the relevant research area and the reasonable expectations of the data subjects.	case of consent, it is in particular required that all the transparency information set out in Art. 13 was given to the data subject before the consenting.[33] A broad consent is therefore in direct contradiction to the Guidelines 04/2019 referenced in Footnote 67 of the Guidelines: '*The data subject should be granted the highest degree of autonomy as possible with respect to control over personal data within the frames of the legal basis*.' Broad consent is exclusively a choice by the controller where data subjects are faced with a 'take it or leave it' situation, i.e. to either accept broad consent or not participate, and any further information that data subjects would be entitled to would have to be actively searched by the data subject (e.g., from newsletters or webpages) rather than being provided to it. A consent is being presumed and therefore the data subject is put into a situation that it may be too late to prevent the processing of data if the information is not found in time or cannot be responded to in time. Autonomy of the data subject in case of consent would be the data subject choosing in which cases it may provide a specific or dynamic consent and in which cases it may consent based on a more overarching information.
46	*If a controller determines that the processing of personal data in an individual research project (or part thereof) would fall outside the scope of a broad consent, then it should ask the data subjects to consent to that individual research project (or stage thereof) – i.e. rely on dynamic consent[68].*	These statements bear no equivalent in the GDPR. This interpretation of Rec. 33 is not sustained by any article of the GDPR in the Guidelines as it should be.[34]
47	*Broad consent can also be relied on if a research project progresses towards a direction that was not anticipated or expected at the time when the personal data was collected, as long as it remains within the relevant research area.*	These statements bear no equivalent in the GDPR. This interpretation of Rec. 33 is not sustained by any article of the GDPR in the Guidelines as it should be.[35] Rather, it seems in direct contradiction with Art. 7.1.

[33] C-757/22 *Meta Platforms Ireland (Representative action)*, Para 60: '*The validity of the consent given by the data subject depends, inter alia, on whether that person has previously obtained the information in the light of all the circumstances surrounding the processing of the data in question to which he or she was entitled, under Article 12 and 13 of the GDPR, and which allow him or her to give consent in full knowledge of the facts.*'

[34] See, e.g. Case C-307/22 *FT v DW*, Para 44 and in particular Advocate General Szpunar in Case C-673/17 *Planet49*, Para 71.

[35] Ibid.

48/49	*48. If a controller asks for broad consent, then it should adopt specific safeguards that give data subjects sufficient control over the use of their personal data to offset for the lack of purpose specification[69]. [...]* *49. Controllers should also assess whether they should implement safeguards to compensate for the lack of purpose specification. Safeguards may include, among others, measures for use and access controls (such as an independent data trustee)[71], time-limited validity of consent or an independent oversight body[72]. An oversight body may include a representative of the research participants, experts in the respective scientific research field, experts in data protection, as well as the data protection officer (DPO) (when a DPO has been designated[73]).*	These Paragraphs make it particularly pertinent that the EDPB seems to pursue an approach of 'Derogation by Guidelines'. An entire framework for a consent different to the one set out in the GDPR is developed and is not sustained by any provision in the GDPR. In line with this approach, no provisions of the GDPR are quoted nor any relevant case law on consent as a legal basis. Such an approach aiming to establish derogations, even in relation suitable safegards, is in direct conflict with Art. 52.1 CFREU, which requires that '*any limitation on the exercise of the rights and freedoms recognised by this Charter must be provided for by law*'. Deviation from the basic principles of the specificity of consent, which make part of the definition of consent, cannot be based on Guidelines and compensated for by safeguards.
48	*In particular, controllers should make detailed information available to data subjects (for example on a webpage) on how their personal data are being processed, as the research progresses in individual research projects. This allows data subjects to consider whether or not they want to exercise their rights, e.g. the right to withdraw consent[70]. In addition, controllers should adopt measures that enable data subjects to receive information about the processing of their personal data, for example by subscribing to a newsletter. The modality for receiving information and its regularity should be determined in line with the wishes of the data subject, as well as legal requirements or ethical considerations for communication with participants in research projects.*	While the Guidelines require that the modalities for data subjects receiving information should be determined in line with the legal requirements, they disregard the legal requirements that information must be given in advance to the consent.[36] Furthermore, the notion that data subjects have to retrieve the information on the processing of their data by themselves (such as from a webpage, find it among other information from a newsletter) where it may not even be clear whether or not their data is included in a project is not compatible with the transparency and fairness principles of the GDPR. At the same time, the consent is presumed to be given to this processing based on a consent to generic information. This is not only in contradiction with the requirement that data subjects must be given all relevant information in advance to consenting, it also contradicts the affirmative act that must be demonstrated to fulfil the Art. 7.1 conditions for consent, as well as the qualification of consent under the definition in Art. 4.11 to be unambiguous. Here, the CJEU Case *Planet49* applies by analogy.[37] A pre-

[36] Art. 6.1.a and Art. 9.2.a; Case C-413/23 SRB, Para 106; C-61/19 *Orange România*, Para 40; C-673/17 – *Planet49*, Para 74; C-757/22 *Meta Platforms Ireland (Representative action)*, Para 60 and others.

[37] C-673/17 –*Planet49*, Para 55: '*In that regard, it would appear impossible in practice to ascertain objectively whether a website user had actually given his or her consent to the processing of his or her personal data by not deselecting a pre-ticked checkbox nor, in any event, whether that consent had been informed. It is not inconceivable that a user would not have read the information accompanying the*

		ticked box is not dissimilar from a consent given to processing, which is only specified later – it cannot be derived from this consent whether the data subject agrees to the later data use. The possibility to withdraw consent, once the precise processing is known, rather than that the consent is given, once the precise processing is known, can hardly be justified in view of the provisions of the GDPR and all currently available case law on the subject.
Example 8	*Various university hospitals work together in a research network in order to make personal data from the treatment of patients available for scientific research through a federated database. The envisaged storage and further processing of pseudonymised personal data will be based on broad consent from each patient, as the specific research projects and the relevant purposes are not foreseeable at the time of medical treatment when consent is obtained.* […] *The personal data are collected by the university hospitals when treating data for a period of five years. During this time period, the personal data are collected and made available for scientific research purposes, as long as the data subject does not withdraw their consent. The collected personal data can be processed for scientific research purposes for a specified period of time, that spans beyond the time period for consent. However, no new personal data collected from the treatment of the data subjects are made available for scientific research after the five-year period has expired. If a data subject visits a university hospital after the five-year period has expired, they are asked again if they want to consent to making their personal data available for scientific research purposes for five more years.*	This Example illustrates that the Guidelines do not dissect the individual purposes of the processing chain, do not describe the processing related to them and do not look into their possible legal basis. The Example refers to '*consent being obtained*'. Yet, there are a number of different controller processing for different purposes and the conditions for these consents would be different. The Example refers to data made available for secondary use by third parties. This is similar to the establishment of a disease repository, which may be the most familiar type of scenario. There are 3 different steps that need to be differentiated. First, data subjects need to consent to their data being made available for secondary use through that repository in general. That may involve a change of controllership between the entity that collected the data and the entity/entities responsible for the disclosure to data users. In case of a disease repository, this is from the hospital to the repository operator. In the current example, this is from the university hospital to the group of university hospitals that agreed jointly that their data should be made available for secondary use according to a jointly agreed data governance. In any case, this is a specific consent – agreeing to the future availability for a defined are of use in principle. However, this covers only the transfer from the initial collector, the individual hospital, to the repository operators. The recipient controllers then pursue as joint controllers their own purposes, which is the contribution of data to the research projects of data users. The data users on the other hand pursue again their own purposes which is the pursuit of a scientific research project. The example seems to mix up these different purposes and related consents, which leads to the conclusion that processing may take place for a

preselected checkbox, or even would not have noticed that checkbox, before continuing with his or her activity on the website visited.'

		consent that has 'expired' rather than realising that the consent was given for a different purpose and therefore cannot be related to the processing by the data user.
51/52	51. […] *If a controller relied on broad consent when it collected the personal data, there* *are circumstances where it should rely on dynamic consent when further processing the personal data for scientific research purposes. This includes situations where the further processing of personal data for individual scientific research projects (or parts thereof) would fall outside the reasonable expectations of data subjects, or if those projects would not fall within the specific research area that a data subject has consented to.* 52. *Dynamic consent enables the controller to address changes in both the researchers' scientific needs and the data subjects' interests, when processing personal data for scientific research purposes over extended periods of time.* […]	Para 41 of the Guidelines specify that dynamic consent is the re-consenting to specific research projects once they become known. As such, it is not clear why dynamic consent is not discussed in the Guidelines as a GDPR compliant way of operating based on consent in case of purposes that cannot be fully identified at the time of collection for methodological reasons. Instead, dynamic consent seems to be suggested only when new purposes fall outside what is assumed to be a broad consent. It is not clear why this differentiation is made and, in the mindset of the existence of broad consent, the controller would not simply ask for another broad consent for new purposes. The different interpretations to respond to Rec. 33 seem to be dealt with in an inconsistent way. It is recommended that the idea of a dynamic consent is discussed in line with the provisions of the GDPR when relying on Rec. 33. Dynamic consent could well be the explanation of the aim of Rec. 33 – it can reconcile the requirement of consent to be given to specific and specified purposes for those cases where it is not possible to give the full purpose at the time of data collection. Building on Art.7.1, the initial processing, to the extent that it can be framed based on the areas of research that is driving the collection, can be consented to. The areas of research here serve as both – the driver of the design of the initial processing as well as an objective that the data subject may or may not agree to. Rec. 33 illustrates how Art. 7.1 covers for cases where the full purpose is not yet possible to be determined at the time of collection, as situation, which is by no means reserved to scientific research. There are also other areas in which there are interim decision points that influence the processing chain to take different directions. These must als be possible and are enabled by the conditions for consent under Art. 7.1. Rec. 33 is merely an illustration in the concrete field of scientific research. Sadly, the Guidelines fail to make this connection remain in the fiction of a broad consent that is not related to the any provisions of the GDPR.

75	*Finally, the EDPB notes that reliance on Article 6(1)(f) GDPR in the context of medical research (such as clinical trials) also requires the application of a derogation, pursuant to Article 9(2) GDPR. One example of a provision in Union law that provides for a derogation pursuant to Article 9(2) GDPR is Article 53(1)(e) in the European Health Data Space Regulation (EHDS). This provision can be relied upon for controllers intending to process health data for the purposes of conducting scientific research on the basis of Article 6(1)(f)*[119].	Art. 53.1.e EHDS is giving health data access bodies a legal basis to disclose electronic health data for secondary use purposes of health data users. This is not a research purpose in itself, nor is it directed at research actors. Therefore, it is no suitable example of a provision that researchers can rely on for processing special categories of data in a research context. Rather, the article in the EHDS that provides the Art. 9.2. permission for the health data user in case of research or other secondary use purposes is Art. 61.1 EHDS.
77	*When a controller intends to or anticipates that it will process personal data for scientific research purposes over longer periods of time, then it should give data subjects an opportunity to voluntarily provide contact details. This will make it possible for data subjects to get necessary updates on the processing of their personal data. Data subjects should get this opportunity, even if the purposes for processing personal data do not require the processing of contact details.*	This Para lacks clarity of what is meant with '*process personal data for scientific research purposes over long periods of time*'. This may refer to a single project that is pursued over a long timeframe. However, much more likely, the Guidelines are referring to processing for a succession of new research purposes not specified at the time of collection. Here, it would be important to highlight to the researchers that, if further processing for new research projects is envisaged, then the controller is obliged to inform the data subject about these new purposes. As such, the collection of contact details is not optional / voluntary if these data are to be included into future research projects. To that extent, it is important to give Art. 11.1 GDPR a closer examination.[38] The reference in that Article is made to purposes for which data are processed and that do not need an identification. This includes *inter alia* that the purposes for which data are processed will not change substantially and will therefore not require any new information. In particular, this Article does not refer to any future purposes. For those cases the provisions of Art. 13.3 and Art. 14.4 apply – the controller is under an obligation to inform the data subjects directly. Data protection by design and default requires that the controller must plan the processing in such a way that it is possible to fulfil these information requirements.[39] The Guidelines

[38] Art. 11.1 GDPR: '*If the purposes for which a controller processes personal data do not or do no longer require the identification of a data subject by the controller, the controller shall not be obliged to maintain, acquire or process additional information in order to identify the data subject for the sole purpose of complying with this Regulation*.'

[39] Article 29 Working Party – Guidelines on transparency under Regulation 2016/679 (Guidelines on transparency) (WP260 rev.01, endorsed by the EDPB on 25 May 2018), Para 43: '*Another relevant issue relating to transparency is data protection by design and by default (as required under Article 25). These*

		state in Para 87 that knowingly deleting contact details to subsequently not having to inform directly on further processing may lead to breach of transparency principle. The same considerations must apply to failing to collect the contact information when further processing is intended. As such an intention is almost the default in scientific research, this means that a way of recontacting the data subject must be considered at the outset of the collection. Neither cost nor risks associated with the handling of contact data can be brought forward as an argument not to pursue such a collection. A balancing exercise was performed on the level of the legislation with the conclusion that these arguments cannot outweigh the necessity to inform data subjects on the processing of their data and are therefore not listed as potential reasons for derogations. Indeed, the Court has stated in Case C-184/20 *Vyriausioji tarnybinės etikos komisija*, Para 89: '*However, it must be pointed out that a lack of resources allocated to the public authorities cannot in any event constitute a legitimate ground justifying interference with the fundamental rights guaranteed by the Charter.*' The derogation under Art. 14.5 GDPR related to the specific situation that the information is not possible due to the specific situation of data being not obtained from the data subjects directly.[40]
79	*Controllers should consider setting up a webpage or providing an application through which data subjects can stay informed on the processing of their personal data, if relevant using a layered approach, as detailed in the Guidelines on transparency[122]. If several controllers participate in the processing of personal*	It is not clear in the first sentence if 'webpage' means a general information webpage that does not constitute an active reaching out as required under Art. 13 GDPR and where data subjects need to actively scout for information. The last sentence of Para 79 seems to suggest that indeed only non-targeted information is being

principles require data controllers to build data protection considerations into their processing operations and systems from the ground up, rather than taking account of data protection as a last-minute compliance issue. Recital 78 refers to data controllers implementing measures that meet the requirements of data protection by design and by default including measures consisting of transparency with regard to the functions and processing of personal data.'
Para 60: '[...] *Given the requirements of data protection by design and by default,54 transparency mechanisms should be built into processing systems from the ground up so that all sources of personal data received into an organisation can be tracked and traced back to their source at any point in the data processing life cycle (see paragraph 43 above).'*

[40] Case C 422/24 Storstockholms Lokaltrafik, Para 39: '[...] *By contrast, Article 14 of that regulation was adopted in order to respond to situations in which the controller is not in direct contact with the data subject, but collects the personal data from another source, with the result that the disclosure of the information referred to in that provision at the time when that information is obtained is, in practice, made difficult or even impossible. The indirect nature of such collection therefore justifies the latter provision providing for the possibility of deferring the controller's obligation to provide information.*'

	data in scientific research activities, the setting up of webpages or applications should be co-ordinated. In this regard, it should be noted that for certain types of research, or if the research project only concerns a limited number of participants, it might not be necessary to provide a webpage or application, as the controller *may have more direct ways of informing the data subjects, for example via calls, text messages, e-mail or regular mail.*	discussed here. This requires clarification as under the GDPR a direct information of data subjects is obligatory. Any deviation from that direct and targeted information must be justified by more than the suggested number of participants. It is also not clear why only 'certain types of research' may require direct information. In view of the current, wide-spread practice that no targeted information is provided to data subjects and the information provided on webpages is of limited scope and impact, a clarification of the transparency obligation of the GDPR that also applies to scientific research is important. A mere cost argument cannot be used to interfere with the transparency principle.[41]
104	*If, pursuant to Union or MS law, a controller must obtain or disclose personal data for scientific research purposes, and that law "imposes on the controller a sufficiently comprehensive and binding obligation to provide to the data subject information relating to obtaining or disclosure of personal data",[153] then there is no separate obligation to inform the data subjects about the processing, at the condition that the information provided to data subjects is at least equivalent to that required by Articles 14(1) to (4) GDPR[154].*	As already pointed out in relation to Para 32 of the Guidelines, a legal obligation requires the purpose for which the processing takes place to be determined in that legal basis. For that reason, it is not likely that the pursuit of research or the contribution of data to a scientific research project can be based on a legal obligation. As an illustration, the disclosure of data to a research project by a health data access body under the EHDS Regulation takes place under the legal basis of Art. 6.1.e. Only health data holders act under legal obligation where they transmit data to the health data access body following the health data access bodies request.[42] This data transmission is based on an approved health data access application or health data request, i.e. an administrative act. The data transmission by the health data holder is not related to the actual research project and the health data holder does not have to verify the suitability of its contribution to that specific research project. If the Guidelines want to make the point that it could be sufficient if the disclosing controller, e.g. a data repository operator, informs about the disclosure for the project and the recipient, then Case C-201/14 *Barra* might be more appropriate.[43]

[41] Case C-184/20 *Vyriausioji tarnybinės etikos komisija*, Para 89.

[42] EHDS Regulation, Rec. 52: '*For processing of electronic health data held by the health data holders, this Regulation creates the legal obligation within the meaning of Article 6(1), point (c), of Regulation (EU) 2016/679, [...]. This Regulation also assigns tasks in the public interest within the meaning of Article 6(1), point (e), of Regulation (EU) 2016/679 to the health data access bodies [...].*'

[43] Case C-201/14 *Barra*, Para 34: '*It follows that the requirement of fair processing of personal data laid down in Article 6 of Directive 95/46 requires a public administrative body to inform the data subjects of the transfer of those data to another public administrative body for the purpose of their processing by the latter in its capacity as recipient of those data.*'

126	*Necessity must be interpreted restrictively*[180]*. Accordingly, a controller must be able to show that the processing of the personal data involved is strictly necessary for performing a task carried out for reasons of public interest, entailing scientific research purposes, and that the task cannot be carried out, or not be carried out as efficiently*[181]*, unless that data is processed*[182]*.*	The very element of necessity is that the processing is essential to achieve the envisaged effect. For that reason is the Court referring in the cases listed under Footnote 181 of the Guidelines to '*the effective application*' or '*achieved just as effectively by other means*'. 'Efficiently' has a different meaning and does not meet the restrictive interpretation of necessity.
137	*[…] Exceptionally, there may be circumstances where researchers as natural persons are considered controllers for the processing of personal data in their own right. This may be the case when the research is carried out at a small healthcare facility or by a researcher that is conducting research in full independence with no affiliation to any research organisation.*	The EDPB Guidelines 07/2020 clarify under Para 19 that '*in principle, any processing of personal data by employees which takes place within the realm of activities of an organisation may be presumed to take place under that organisation's control'*. It is not clear from the definition of a controller under the GDPR why the size of the organisation would play any role in whether an employee is considered a controller as a natural person.
140	*[…] An essential criterion for joint controllership is that the processing of personal data would not be possible without the entities' concurrent involvement, meaning that the respective entities' processing is inextricably linked.*	The EDPB Guidelines 07/2020 differentiate in Para 55 for joint controllers between common decisions and converging decisions. Only for the latter, the processing must be inextricably linked. As an example, in a research consortium, the partners decide jointly on the purpose and the means for the processing. This may include for example clinical partners that help selecting the inclusion criteria for data subjects. However, these partners may not be involved in any processing at all, from which it follows that the processing is not inextricably linked for them. The 'inextricably linked' processing is referring to situations like the CJEU Case C-40/17 *Fashion ID* where the data collection on Fashion ID's webpage and therefore through Fashion ID via the Facebook Like-Button constitutes at the same time the transfer to and collection by Facebook.

Then in particular the related Opinion by Advocate General Bobek, Para 73 states: '*More specifically, it is up to the Member State to provide for the necessary measures so that the required information is communicated to the data subjects by one or other of the two institutions who are both responsible for the processing of the personal data at issue in the main proceedings, namely the ANAF under Article 10 of Directive 95/46 and the CNAS under Article 11 of that directive, unless, in the latter case, registration or disclosure of the data have been provided for by law.*' (emphasis added)

143	*If several parties carrying out the research are joint controllers, they can generally rely on the same legal basis. However, the GDPR does not preclude that different joint controllers rely on different legal bases, depending on their applicability to a given processing operation[216].*	It is not clear why several parties would be able to rely on the same legal basis merely because they are joint controllers. This cannot be derived from the GDPR and was not stated in the Guidelines 07/2020. Rather, the referenced Guidelines 07/2020 state in Footnote 73 merely that '*it is recommended to use, whenever possible, the same legal basis for a particular purpose'*. This statement does not offer any conclusions as to whether or when that is actually possible. As an example, a company will likely have to rely on Art. 6.1.f as the legal basis whereas a public body would have to use its legal mandate and operate under Art. 6.1.e. The same legal basis rather excluded under these circumstances (unless consent is chosen, which comes with its own pitfalls and might be excluded for those).
156, 158	*156. […] With regards to lawfulness, a controller may be able to rely on the same legal basis for the process of anonymisation and for the preceding processing operations, if those processing operations form part of a set of operations that are undertaken for the same scientific research purposes[235].* *158. If a controller processes personal data for scientific research purposes and applies pseudonymisation, then the legal basis for the processing of the personal data extends to all processing operations needed to apply the pseudonymising transformation[238].*	The legal basis must be assessed for each processing operation separately – why is this processing taking place? For which purpose is it pursued (necessary!)? The purpose of anonymisation and pseudonymisation in the context of a research project is the protection of data subjects, not the answering of a research question. The legal basis can therefore be derived from the GDPR rather than the legal basis of the research project.
169	*Genetic research on isolated population groups should be accompanied by information campaigns directed towards the community involved. Such information campaigns should, in addition to the mandatory information pursuant to Articles 12-14 GDPR, describe the nature and methods of the research, the objectives pursued and the expected risks or benefits for the population groups involved.*	The elements highlighted in the text should not form an 'addition' and a safeguard for high-risk processing as claimed but be a default part of the information provision on a scientific research project in accordance with the transparency principle as they are part of the purpose definition, which needs to frame the processing and the risks associated.

6. Annex II: Point by Point feedback on the Guidelines: recommendations

Sections 3/4/5/6	**3. Data protection principles (Article 5 GDPR)** **4. Lawfulness (Articles 5(1)(a), 6(1) and 9 of the GDPR)** **5. Obligations to inform (Articles 12-14 GDPR)** **6. Data subjects' rights (Articles 15-21 GDPR)**	The title of Section 3 seems to suggest that the Guidelines lead one by one through the data protection principles, same as it was done in the Guidelines 04/2019 on Data Protection by Design and Default. Yet, subsequently, only purpose limitation and storage limitation are discussed. Lawfulness is addressed in a separate section, yet, the relevant articles are not discussed. Transparency is only partly dealt with in a separate section, leaving out the right of access. Fairness is not discussed but can be seen as part of Section 6 where once again the Section itself does not cover the full scope of data subjects' rights that is set out in the title. This may be confusing for the less adept researcher. A systematic analysis of the data protection principles together with the relevant articles in view of scientific research and, where foreseen in the GDPR, its privileges would be desirable.
17	*If a controller collects personal data to process it for a specific scientific research purpose, then the research purpose is considered to be the* ***primary*** *purpose of processing. If a controller subsequently wants to process that personal data for* ***another*** *scientific research purpose that is not covered by the primary purpose, such processing is considered to be* ***further processing for another purpose****. If a controller initially collects and processes personal data for* ***non-scientific purposes****, but later on decides to process the personal data for scientific research purposes, this is considered* ***further processing for scientific*** *research* ***purposes****.*	The term 'later on' can be misleading in this Paragraph. Any processing for scientific research purposes that was not the initial reason to collect the data and was not driving the collection will constitute further processing, irrespective of when it is decided upon and when the data subjects are informed. The scientific research purpose leading to further processing may already be known at the time of collection for the primary purpose. It would be useful to clarify that the purpose, which was leading to the design of the data collection, is the primary purpose, e.g. a healthcare episode is still healthcare driven, even if it is known that data will subsequently also be further processed for a research project. The data would not have been collected without the primary purpose to provide healthcare to that person.
21/24	*21.* [...] *In this regard, the EDPB has previously stated that under certain conditions, and provided that appropriate safeguards have been adopted pursuant to Article 89(1) GDPR, a controller may be able to rely on the legal basis for the initial processing operations when further*	It is appreciated that the Guidelines provide this clarification that originates from the unfortunate phrasing in Rec. 50. To emphasis this point, the Guidelines could also refer to the CJEU Case C-77/21 *Digi* where the Court clarifies in Para 47 that the principles of Art. 5.1 apply cumulatively. One cannot replace another.

	processing personal data for scientific research purposes[32]. *However, the EDPB and the EDPS have also stated that the question of compatibility of purposes should not be confused* *with principle of lawfulness*[33]*. Therefore, the possibility to rely on the legal basis that the initial processing was based on requires an assessment of lawfulness to determine that this legal basis is also suitable to rely on for the further processing of personal data for scientific research purposes.* *24. If a controller further processes special categories of personal data, pursuant to Article 9(1) GDPR, for scientific research purposes, it may also rely on the presumption of compatibility of purposes, pursuant to Article 5(1)(b).*	In view of this important message, the phrasing in Para 24 of the Guidelines is very unfortunate as it may be interpreted that there can be a relation between lawfulness and purpose compatibility. For that reason, it would be relevant to explicitly explain that the data protection principles need to be fulfilled cumulative and that they cannot replace one another. The prohibition of processing special categories of data and the exemption from that prohibition are independent of purpose compatibility. Rather, it would have been useful to point out that compatibility of purposes needs to take into account the nature of the data, in particular whether special categories of data are processed. While scientific research may rely on the presumption of compatibility, this will not automatically be the case for activities related to scientific research, such as the establishment of a data repository with a provision of data to third party users.
26	*When providing personal data to another controller for scientific research purposes, neither the providing (controller A) nor receiving controller (controller B) needs to undertake a compatibility assessment, pursuant to Article 6(4) GDPR*[40].	This statement is correct. It could help to remove misunderstandings about further processing if it is clarified that the receiving controller is not further processing the data but collecting the data and therefore still processing for a primary purpose.[44] However, a warning should be issued that, where the data are not shared as part of a research project pursued by the providing controller, the disclosure is not taking place for a scientific research purpose and would require a compatibility analysis.
73/74	*73. Controllers may rely on derogations to the prohibition of processing of special categories of data provided for by Union or MS law, pursuant to Article 9(2)(g), (i) and (j) of the GDPR, when processing personal data for scientific research purposes.115 Such laws must "respect the essence of the fundamental rights and observe the principle of proportionality"116. To fulfil the principle of proportionality, the laws must – inter alia – provide for suitable and specific measures, to safeguard the fundamental rights and interests of the data subject, to be adopted by the controller117.*	Article 9.2.j has a dedicated opening clause for national and EU law to provide for an exemption of the prohibition of Art. 9.1 for scientific research purposes. Such legislation must provide for suitable and specific measures to safeguard the rights and freedom of data subjects. Considering that the measures must be specific for scientific research, it is not obvious how and why scientific research purposes could be based on other subparagraphs of Art. 9.2. The situation is different for related processing activities such as the provision of data for research projects or the safety reporting in clinical trials. Also, research activities that may not fulfil the key factors of being

[44] See in this context: Case C-175/20 *Valsts ieņēmumu dienests*, Para 37.

	74. A controller that intends to rely on a derogation pursuant to Article 9(2)(g), (i) or (j) GDPR should consider and be able to demonstrate that the law in question applies to the intended processing for scientific research purposes.	scientific but that will contribute to public health, could be considered. However, if legislation does not provide safeguards that are specific for research, it is not clear how this could be a valid exemption covering scientific research purposes.[45] On the other hand, if the legal provisions set out safeguards that are specific for research, then it is not clear why these would fall under a different subparagraph than Art. 9.2.j.
Example 12	***Example 12: Information to data subjects whose personal data is directly collected from the data subject through interviews*** [...] *Therefore, the researchers inform the data subjects orally about the central elements of processing of personal data before the interview starts[128]. The researchers also inform that more detailed information can be found on the webpage of the university, or be obtained by calling the university's central number.*	The Example provides insufficient clarity if information is given orally only or if the oral information complements written materials. It needs to be noted that Art. 12 refers to oral information when requested by the data subject. Oral information comes with many disadvantages and should only be chosen as an exclusive way of information if there is a necessity to do so. If oral information is chosen, the controller must find ways to document the information that was given and the data subjects should have access to the recorded messages. All these elements are missing and may give a wrong idea of how information can be provided. In addition, the data subject must have time to understand and 'digest' the messages before the data collection starts. The initial information and the commencement of the project should not take place in the same phone call. While this requirement originates from research ethics[46] rather than from direct provisions in the GDPR, the situation of an oral interaction may hamper the understanding of the data subject of the processing and its aims and it may be perceived as an undue pressure, which would lead to unfair processing.
86	*It may be challenging for controllers to inform data subjects of further processing for scientific research purposes if they have not retained the contact details of the data subjects, for example due to pseudonymisation of the personal data where identifiers or a table of correspondence are not accessible for the*	It would make sense to also touch upon the question how data subjects can exercise their rights in such a situation. The WP29 Opinion 03/2017 on Processing personal data in the context of Cooperative Intelligent Transport Systems (C-ITS) states regarding Art. 11: '*This article should be interpreted as a way to enforce 'genuine' data minimization, without hindering the exercise of data*

[45] In Case C-34/21 *Hauptpersonalrat der Lehrerinnen und Lehrer*, the Court finds in Para 61 '*from the use of the words 'more specific' that the rules referred to in that provision must have a normative content specific to the area regulated, which is distinct from the general rules of that regulation*.' By analogy, it can be concluded that legislation that does not foresee safeguards that are specific for scientific research may not provide a valid exemption for scientific research purposes.

[46] International Ethical Guidelines for Health-related Research Involving Humans, Guidelines 9: Individuals capable of giving informed consent.

	controller. To that end, if the controller knows at the time of collection (or when contact details are deleted because they are not necessary to process) that the personal data will be processed for scientific purposes at a later stage, then the controller should make sure that data subjects can stay informed, in accordance with Articles 12 and 13 GDPR[136].	*subjects' rights. Exercise of these rights must be made possible with the help of 'additional information' provided by the data subject. By invoking art. 11 of the GDPR without specifying what additional data are necessary to enable identification of the data subjects, the exercise of data subjects' rights (access, rectification, portability, etc.) is de facto prevented. However, pseudonymised data are personal data by definition (see art. 4 GDPR), in that they are data relating to an identifiable individual (see, in particular, Recital 26 GDPR).* *Therefore, the Article 29 Working Party calls for proposals from the C-ITS WG on the concept of 'additional information' that can be provided in the context of this new service to make this provision effective, taking into account for instance specific vehicle data, or the highly identifiable nature of location data. The Working Party rejects any interpretation of Article 11 aiming at reducing the responsibility of the controller(s) for compliance with data protection obligations.'*
91	*New personal data generated in the course of a research project will fall within the scope of Article 14 of the GDPR and are not considered as collected directly from data subjects*[142].	The sentence can be misleading and should be improved: new data generated in the course of a research project can also be generated directly from the data subject, e.g. longitudinal studies.
93	*If personal data is provided by intermediaries for scientific research purposes, for example where a provider of a research database collects personal data from several controllers that is thereafter provided to researchers conducting individual research projects, the EDPB considers it a good practice for all involved parties to agree on how to comply collectively with their transparency obligations*[143].	It would be useful to define what is meant by 'intermediaries for scientific research purposes' and to separate them from the recently introduced 'health data intermediation entities' under the EHDS Regulation.
Example 16	***Individual information which is likely to render impossible or seriously impair the achievement of a research project*** *Researchers at a university faculty in the field of social sciences are carrying out research on public servants, such as medical staff, teachers and police officers, who report suspected parental child abuse to social services.* [...] *However, the provision of such information would*	This example is not the best choice to illustrate covert research. Under Art. 21.1 and 21.6, it would still be possible to overwrite the objection by the data subjects. Covert research is typically needed where the research question builds on behavioural studies. If people know that they are observed, they often behave differently. This is often dubbed as 'the observer changes the experiment'. A good example is the monitoring of people for security research

	inevitably lead to the persons being alleged of abuse to object to the processing of their personal data. This would in turn render the research impossible or at the very least seriously impair the research.	reasons. People act much more mindful if under scrutiny.
107	[...] *When determining whether it is necessary to inform data subjects about changes to processing operations, controllers should consider that a main objective of the principle of transparency is to ensure that the reasonable expectations of the data subjects are met. Conversely, there is no need to inform data subjects if they have already been sufficiently informed and if the changes would not go beyond the reasonable expectations of the data subjects*[159].	The EDPB Guidelines 01/2024, Para 53 state: '*Reasonable expectations do not necessarily depend on the information provided to data subjects. While the omission of information can contribute to the data subject being surprised of a certain processing, the mere fulfilment of the information obligations set out in Articles 12, 13 and 14 GDPR is not sufficient in itself to consider that the data subjects can reasonably expect a given processing*.' Also the EDPB Guidelines 04/2019 clarify in Para 70 that the reasonable expectation of data subjects is part of the fairness principle. The reasonable expectation therefore is not the objective of the transparency principle. Rather the main objective of the principle of transparency is '*to ensure that the data subject is able fully to understand the information sent to him or her*'.[47]
Example 19	***Rejecting a request of erasure on the basis of Article 17(3)(d) of the GDPR*** *A private research institute is conducting scientific research on the historical development of a software...*	The Example seems to describe a historical rather than a scientific research project. An example more targeted at a scientific research question would be preferable.
133	*Where Union or MS law designates a controller, such designation is determinative for attributing responsibility*[196]*. The determination of the purposes and means of processing must not be explicit in the law but can be implicit.*	Presumably, the 'must not be' was meant to be 'does not need to be' or 'does not have to be'.
136	*Another example is if a trusted data holder processes personal data on behalf of one (or several) controllers*[202]	Ideally, the Guidelines should define what is meant by a trusted data holder and how it is different to a trusted health data holder under the EHDS Regulation.
Example 21	***A controller processing personal data for scientific research purposes – Commercial entity*** *When data subjects sign up for membership to a large chain of fitness studios, they are asked a question whether they provide*	It would be preferable if the Guidelines were not referring unnecessarily to a legal basis not reflected in the provisions of the GDPR.

[47] C-757/22 *Meta Platforms Ireland (Representative action),* Para 56.

	broad consent to provide their personal data (following pseudonymisation) for certain research projects in the research field of sports medicine.	
Example 23	***A processor processing personal data for scientific research purposes - contract research organisation (CRO)*** *The CRO provides the services on the basis of a service contract and processes personal data only as instructed by the sponsor, although the CRO has certain leeway in terms of non-essential means, for example deleting obtained research data that is not necessary for performing clinical trial. As a result, the CRO processes the personal data in the capacity as a processor on behalf of the sponsor.*	The statement regarding the decision on deletion may need more information: how would it be compliant with the data minimisation principle if more data is collected than needed for the project? And if so, is it for the CRO to decide that these data are no longer needed? As a processor, it is normally not expected that such assessments of what is needed is performed and that deletions could take place without explicit instruction. The Example in its current form is likely not helpful as a guidance because it leaves too many uncertainties as to the 'what are the instructions' and 'why can this situation actually happen?'
Example 24	***A processor processing personal data for scientific research purposes – Survey services*** *[…] In this situation, the university faculty is a controller and Rapid Surveys is a processor.*	This example may be confusing people. Faculties normally have no legal personality. Exceptions can be medical faculties where these have additional tasks in healthcare that justify a legal personality outside the university. The legislation assigning research missions is mostly done on the level of the entire university. The example may therefore raise questions as to why in this case the faculty and not the university is the controller.
145	*If any of the joint controllers intends to procure a processor to process personal data on their behalf, procurement should be done in line with conditions agreed upon by the joint controllers in their agreement, pursuant to Article 28(1) GDPR*[222].	This should be Article 26(1) GDPR.
Example 25	***Joint controllers processing personal data in the context of a non-interventional observational clinical study – Research consortium*** *Furthermore, because the processing of personal data in the database is decided on and operated jointly by all partners of the research consortium, and since all data retained in that database are inseparable for the purposes of conducting further research, all partners to the research consortium are joint controllers for the processing of personal in the federated database that is necessary to make personal data available*	The qualifications that lead to joint controllership are confusing in this example. The decisive criterion in the example is the joint decision on how to make data available for further research. An inseparable virtual database on the other hand is not necessary. It is also not realistic. Research could always be performed with a subset of the data, depending on the research question. By adding such additional but unnecessary qualifiers, it is more difficult for researchers to understand the principles that lead to joint controllership. It is appreciated that the example also aims to illustrate that for controllership, it does not matter where the data are held physically and

	to the consortium partners for future research activities.	by whom – a mistake often observed in discussions with researchers. Ideally, that explanation could be added to make sure the message 'hits home'.
151, 153	*151. The starting point for adopting appropriate safeguards, pursuant to Article 89(1) GDPR, is conducting a risk analysis or – when required – a DPIA[227]. [...]* *In particular in the field of medical research, if the processing of personal data for scientific research purposes impacts or may impact the provision of health care to a data subject (e.g. if a medical condition is identified), controllers should consider implementing measures for* *informing data subjects, taking into account the wishes of data subjects not to be informed about findings that are relevant for their health, in accordance with applicable Union or MS law[230].* *153. Potential consequences of the scientific research, such as adverse outcomes for the data subjects, should also be considered.*	It is confusing that the Guidelines suggest a data protection impact assessment should consider the impact of the research itself, not only the risks and impact of the processing operations. In the first place, the incidental finding itself does not pose any risk. It is more an opportunity that the data subject can benefit from. Processing of data for the reporting of incidental findings would fall outside the research purpose and take place for a different purpose with a need for a separate legal basis. Where incidental findings are not provided for by law, the processing typically relies on consent, in accordance with the suggested wishes of the data subject to informed or not to be informed. Adverse outcomes for data subjects is associated with clinical trials and the effect of drugs. It would need further explanation how adverse outcomes could affect data subjects when data are processed to create general knowledge.
170	*[...]* *Examples of such safeguards are:* *[...]* • *Adherence to ethical rules in the relevant field of science, including ethical approval, when applicable, or advice or oversight by ethics committees or boards;*	According to the key factors for scientific research, this proposed measure should be a default and not a safeguard. However, considering that none of the definitions of research relied on in EU law refers to the adherence of ethical rules as an intrinsic element but rather as a safeguard / additional requirement, it may be justified to list it here and remove it from the list of key factors, thereby bringing them closer to the concepts of research that, e.g., the Horizon Europe Regulation relies on.