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RELEVANT LEGAL FRAMEWORK for SCIENTIFIC RESEARCH UNDER GDPR[1]

LEGAL GROUND UNDER GDPR

Art. 5 GDPR

Principles relating to processing of personal data

(1) Personal data shall be:

….

(e) kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject (‘storage limitation’);

Art. 9 GDPR

Processing of special categories of personal data

(1) Processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person’s sex life or sexual orientation shall be prohibited.

(2) Paragraph 1 shall not apply if one of the following applies:

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….

(j) processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

Art. 21 GDPR

Right to object

(6) Where personal data are processed for scientific or historical research purposes or statistical purposes pursuant to Article 89(1), the data subject, on grounds relating to his or her particular situation, shall have the right to object to processing of personal data concerning him or her, **unless the processing is necessary for the performance of a task carried out for reasons of public interest**.

Art. 14 GDPR

Information to be provided where personal data have not been obtained from the data subject

(5) Paragraphs 1 to 4 (the rules of informing data subject) shall not apply where and insofar as:

…

(b) the provision of such information proves impossible or would involve a disproportionate effort, in particular for processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, subject to the conditions and safeguards referred to in Article 89(1) or in so far as the obligation referred to in paragraph 1 of this Article is likely to render impossible or seriously impair the achievement of the objectives of that processing. In such cases **the controller shall take appropriate measures** to protect the data subject's rights and freedoms and legitimate interests, including making the information publicly available;

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Art. 17 GDPR

Right to erasure ('right to be forgotten')

(3) Paragraphs 1 and 2 (the rules of implementation of this right) shall not apply to the extent that processing is necessary:

….

(d) for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) in so far as the right referred to in paragraph 1 is likely to render impossible or seriously impair the achievement of the objectives of that processing;

Art. 89 GDPR

Safeguards and derogations relating to processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes

1. Processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, shall be subject to appropriate safeguards, in accordance with this Regulation, for the rights and freedoms of the data subject. Those safeguards shall ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation. Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner.

2. Where personal data are processed for scientific or historical research purposes or statistical purposes, Union or Member State law may provide for derogations from the rights referred to in Articles 15, 16, 18 and 21 subject to the conditions and safeguards referred to in paragraph 1 of this Article in so far as such rights are likely to render impossible or seriously impair the achievement of the specific purposes, and such derogations are necessary for the fulfilment of those purposes.

3. Where personal data are processed for archiving purposes in the public interest, Union or Member State law may provide for derogations from the rights referred to in Articles 15, 16, 18, 19, 20 and 21 subject to the conditions and safeguards referred to in paragraph 1 of this Article in so far as

such rights are likely to render impossible or seriously impair the achievement of the specific purposes, and such derogations are necessary for the fulfilment of those purposes.

4. Where processing referred to in paragraphs 2 and 3 serves at the same time another purpose, the derogations shall apply only to processing for the purposes referred to in those paragraphs.

Recital 156

Processing for Archiving, Scientific or Historical Research or Statistical Purposes*

The processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes **should be subject to appropriate safeguards for the rights and freedoms of the data subject pursuant to this Regulation**. Those safeguards should ensure that technical and organisational measures are in place in order to ensure, in particular, the principle of data minimisation. The further processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes is to be carried out when the controller has assessed the feasibility to fulfil those purposes by processing data which do not permit or no longer permit the identification of data subjects, provided that appropriate safeguards exist (such as, for instance, pseudonymisation of the data). Member States should provide for appropriate safeguards for the processing of personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. Member States should be authorised to provide, under specific conditions and subject to appropriate safeguards for data subjects, specifications and derogations with regard to the information requirements and rights to rectification, to erasure, to be forgotten, to restriction of processing, to data portability, and to object when processing personal data for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. The conditions and safeguards in question may entail specific procedures for data subjects to exercise those rights if this is appropriate in the light of the purposes sought by the specific processing along with technical and organisational measures aimed at minimising the processing of personal data in pursuance of the proportionality and necessity principles. The processing of personal data for scientific purposes should also comply with other relevant legislation such as on clinical trials.

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Recital 157

Information from Registries and Scientific Research*

By coupling information from registries, researchers can obtain new knowledge of great value with regard to widespread medical conditions such as cardiovascular disease, cancer and depression. On the basis of registries, research results can be enhanced, as they draw on a larger population. Within social science, research on the basis of registries enables researchers to obtain essential knowledge about the long-term correlation of a number of social conditions such as unemployment and education with other life conditions. Research results obtained through registries provide solid, high-quality knowledge which can provide the basis for the formulation and implementation of knowledge-based policy, improve the quality of life for a number of people and improve the efficiency of social services. In order to facilitate scientific research, personal data can be processed for scientific research purposes, subject to appropriate conditions and safeguards set out in Union or Member State law.

Recital 158

Processing for Archiving Purposes*

Where personal data are processed for archiving purposes, this Regulation should also apply to that processing, bearing in mind that this Regulation should not apply to deceased persons. Public authorities or public or private bodies that hold records of public interest should be services which, pursuant to Union or Member State law, have a legal obligation to acquire, preserve, appraise, arrange, describe, communicate, promote, disseminate and provide access to records of enduring value for general public interest. Member States should also be authorised to provide for the further processing of personal data for archiving purposes, for example with a view to providing specific information related to the political behaviour under former totalitarian state regimes, genocide, crimes against humanity, in particular the Holocaust, or war crimes.

Recital 159

Processing for Scientific Research Purposes*

Where personal data are processed for scientific research purposes, **this Regulation should also apply to that processing**. For the purposes of this Regulation, the processing of personal data for scientific research purposes should be interpreted in a broad manner including for example technological development

and demonstration, fundamental research, applied research and privately funded research. In addition, it should take into account the Union's objective under Article 179(1) TFEU of achieving a European Research Area. Scientific research purposes should also include studies conducted in the public interest in the area of public health. To meet the specificities of processing personal data for scientific research purposes, specific conditions should apply in particular as regards the publication or otherwise disclosure of personal data in the context of scientific research purposes. If the result of scientific research in particular in the health context gives reason for further measures in the interest of the data subject, the general rules of this Regulation should apply in view of those measures.

Recital 160

Processing for Historical Research Purposes*

Where personal data are processed for historical research purposes, this Regulation should also apply to that processing. This should also include historical research and research for genealogical purposes, bearing in mind that this Regulation should not apply to deceased persons.

Recital 161

Consenting to the Participation in Clinical Trials*

For the purpose of consenting to the participation in scientific research activities in clinical trials, the relevant provisions of Regulation (EU) No 536/2014 of the European Parliament and of the Council should apply.

HOW THE GENERAL DATA PROTECTION REGULATION CHANGES THE RULES FOR SCIENTIFIC RESEARCH[2]:

i. Scope of the Document

The purposes of the relevant document have been specified as follows:

[2] https://www.europarl.europa.eu/RegData/etudes/STUD/2019/634447/EPRS_STU(2019)634447_EN.pdf

- To investigate the impact of the new rights and obligations of GDPR for scientific research and to provide an early impact assessment of the major challenges and opportunities that GDPR poses to scientific research, particularly biomedical research.
- To identify measures that research institutions are putting in place to prepare for or cope with GDPR requirements and assess to what extent GDPR exceptions for science are sufficient.
- To monitor media-driven public perceptions associated with GDPR in relation to scientific research.
- To provide policy options about how scientific research can find common ground with the new legal rules on data protection and how the scientific community can prepare for GDPR compliance, with a special focus on regulatory, procedural and educational solutions.

ii. General Principles Regarding the Processing of Scientific Data

Under the GDPR, scientific research is considered a special category of data processing, subject to the safeguards that exist in Article 89(1). Edward Dove notes that the existing institutional mechanisms (such as ethics review boards and peer review) act as an inherent safeguard against the misuse of scientific data.

- Article 89(1) imposes upon data processors and controllers a positive obligation to respect all the rights and freedoms of data subjects when relying on research exceptions.
- In addition, Article 89(1) requires data processors to ensure that technical and organisational measures are in place to ensure the principle of data minimisation. In particular, Recital 26[3] explains how Article 89(1) provides a graduated approach for data minimisation. The controller or processor should first determine whether they can use non-personal data or anonymised data for their processing tasks. If non-personal or anonymised data cannot be used, Article 89(1) provides pseudonymisation as an example of a safeguard to protect data subject rights and prevent the use of personal identifiers (Molnár-Gábor, 2018).

The GDPR offers three categories of research exception subject to the obligations imposed by Article 89(1).

- **First, there are exceptions to the data processing principles and lawful grounds for processing.**

[3] *" …The principles of data protection should therefore not apply to anonymous information, namely information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable. This Regulation does not therefore concern the processing of such anonymous information, including for statistical or research purposes."*

In the GDPR, the data processing principles are defined in Article 5, and the lawful processing grounds are defined in Articles 6 and 9. Scientific researchers are required to comply with four of the data processing principles, irrespective of whether they are working in academic or scientific commercial research.

However, there are two exceptions to the data processing principles identified above for scientific or historical research purposes, archiving purposes or statistical purposes.

- First, there is an exception contained within the purpose limitation in Article 5(1)(b). The purpose limitation strictly limits the use of data to the purpose for which it was originally collected ('Article 29 Working Party Opinion 03/2013 on purpose limitation,' 2013).

  However, the exception within Article 5(1)(b) provides that processing for further research purposes pursuant to the obligations imposed by Article 89(1) is lawful. Accordingly, under this exception, medical data collected as part of hospitalisation could not be then used for research purposes without consent. By contrast, if data is collected as part of a research biobank, biobank administrators can use that data for other forms of scientific research (Simell et al., 2019).

  However, as for the previous Data Protection Directive, the onus is on the researcher or institution to demonstrate that the processing is for research purposes (Ruyter et al., 2010).

- Secondly, there is also an exception to the storage limitation in Article 5(1)(e). The storage limitation principle prevents personally identifying data being retained for any period longer than necessary to complete processing. Article 5(1)(e) then provides that data may be retained for a longer period than would otherwise be necessary to complete processing, where future processing will be solely for research purposes.

- **Secondly, there are exceptions to the data subject rights that are directly available under the GDPR.**
  Scientific researchers can directly rely on these exceptions without the need for these provisions to be implemented into national legislation.
  - The first direct exception applies to the right of information where personal data has not been obtained from the data subject, but have instead been obtained from other sources. The data processor or controller, on request, must provide at least general information about

where this data has been collected from. However, Article 14(5)(b) provides that the controller does not have to provide information to the data subject where appropriate safeguards are in place and it would otherwise significantly impede research.

- The second direct exception applies to the particularly controversial right of erasure under Article 17 of the GDPR. The exception under Article 17(3)(d) allows researchers to ignore an erasure request where it would render impossible or seriously impair the processing of personal data for scientific purposes. Any legitimate grounds for refusing an erasure request must be proportionally balanced against legitimate reasons for retaining privately held data.
- The third direct exception applies to Article 21 of the GDPR. Article 21 permits data subjects to object to the processing of their data, including profiling, subject to the lawful grounds contained in Article 6(1)(e) or 6(1)(f). However, Article 21(6) permits a scientific researcher to ignore an objection request where the data processing is necessary for reasons of public interest.

- **Thirdly, there is the potential for member states to implement scientific exceptions into national law.**
  - These research exceptions can be introduced by individual member states into national law pursuant to the obligations imposed by Articles 89(2) and (3) of the GDPR. Specifically, for personal data processed for scientific or historical research purposes, exceptions can be introduced for the data subject rights under Articles 15 (Right of access by the data subject), 16 (Right to rectification), 18 (Right to restriction of processing) and 21 (Right to object).
  - However, Articles 89(2) and (3) require that national derogations are only permissible subject to the obligations imposed by Article 89(1) which requires the appropriate safeguards to be implemented. Further, Article 89(2) and (3) only permit derogations where the exercise of data subject rights would render impossible or significantly impede research.

iii. What Falls Under Art. 89 GDPR

Each of these categories of research are then defined within Recitals 157, 158, 159, 160 and 162. In particular, Recital 159 notes that scientific research should be interpreted broadly.

iv. Scientific processing outside Article 89(1) – non-personal data and anonymised/ pseudonymised data

- Personal and non-personal data:

To comply with the principle of data minimisation, scientific researchers should first consider whether it is possible to conduct data processing without using personal data.

- Anonymised and pseudonymised data:
  The next stage of the data minimisation approach requires processors and controllers to consider whether they can conduct processing with anonymised data as opposed to non-personal data. Recital 26 of the GDPR notes that the GDPR's requirements do not apply to anonymised data. However, it is important to note that anonymised data must be distinguished from pseudonymised data.

v. Sections without scientific research exceptions

- Data processing principles and the principle of accuracy:
  Outside the data processing principles with exceptions subject to the safeguards imposed Article 89(1), there are still ambiguities as to how scientific researchers should comply with the data processing principles.
  In this regard, it has been suggested that each research department should set an appropriate standard for data correctness or accuracy depending on their responsibilities.
- Relying on consent to conduct data processing:
  It is still possible for researchers to conduct research by relying on the informed consent of the data subject. However, in these circumstances, the researchers will be bound by the same requirements as other data processors, as well as the positive obligations imposed by Article 89(1).
    - ***AI specific issue:*** *For many scientific research projects it may be impossible or difficult to determine the purposes for which data may be used in advance. For example, when machine learning algorithms are used to collect data, the underlying trends that may be drawn from that data are not immediately apparent when the algorithm is designed. Therefore, explicitly stating the purposes for which data is being used may be impossible where the trends observable from that data are not apparent in advance (Butterworth, 2018).*
- Conflict and ambiguities between data subject rights:
  Outside the scientific research exceptions subject to Article 89(1), there are potential conflicts between relevant data subject rights and scientific research.
    - In particular, Article 22, which guarantees the right to opt out of automated profiling, may be relevant for scientific research. Scientific researchers should note that the relatively narrow scope of Article 22 does not entirely exculpate scientific research from the scope of Article

22. However, research ethics committees should pay careful attention to the framing of research projects to determine exactly how decisions will be made within the scope of the project.

- Data processor and controller obligations:
  - Researchers and universities should assume that when processing personal data, their activities render them data controllers. Further, researchers should plan for, and ethics review committees should mandate, data protection by design principles as part of any research proposals or approvals. This design should also be accompanied by controllers maintaining detailed records of processing, conducting data protection impact assessments before each processing operation, and appointing data protection officers.
  - The principles of joint liability under Article 26 apply equally to collaborations between public institutes as they do between private research companies or public-private collaborations. Any research collaborations should therefore be subject to a joint contractual agreement between each of the two parties.
  - In the context of scientific research, research collaborators, cloud processors or scientific computing centres can be classified as data processors and subject to their obligations.
- Transfers of data under the GDPR:
  - For researchers, adequacy decision exception is a comparatively narrow mechanism to rely upon given the relatively small number of countries that have been recognised as providing adequate data protection.
  - Researchers and research institutes may have better fortune relying upon the lawful grounds for transfer that are provided by Article 46, i.e. safeguards.
  - Derogations may be useful for small scale studies where it is possible to obtain the consent of the data subjects and where appropriate safeguards exist.

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European Data Protection Supervisor (EDPS) – A Preliminary Opinion on data protection and scientific research[4]

i. Scope of the Document

This document aims to narrow down what is understood by scientific research in the GDPR and outline the wider governance framework for research in the EU within which data protection is situated, particular as regards clinical trials. Plus, it presents a preliminary analysis of some key principles of the special regime for data processing for the purposes of scientific research as set down in the GDPR.

ii. General Principles Regarding the Processing of Scientific Data

Scope of Scientific research

The EU's 2019 Copyright Directive (Directive (EU) 2019/790) considers scientific research to cover 'both the natural sciences and the human sciences', and distinguishes between not-for-profit and public interest bodies and organisations operating under commercial influences:

Despite different legal forms and structures, research organisations in the Member States generally have in common that they act either on a not-for-profit basis or in the context of a public-interest mission recognised by the State. Such a public-interest mission could, for example, be reflected through public funding or through provisions in national laws or public contracts. Conversely, organisations upon which commercial undertakings have a decisive influence allowing such undertakings to exercise control because of structural situations, such as through their quality of shareholder or member, which could result in preferential access to the results of the research, should not be considered research organisations for the purposes of this Directive.

Scope of the special data protection regime for scientific research

Under the GDPR, the role of research is understood to provide knowledge that can in turn 'improve the quality of life for a number of people and improve the efficiency of social services'. The GDPR assumes a broad conception of research, including technological development, fundamental and applied research and privately funded research and 'studies conducted in the public interest in the area of public health'. It also recommends that data processing 'take into account

[4] https://edps.europa.eu/sites/edp/files/publication/20-01-06_opinion_research_en.pdf

the EU's objective under Article 179(1) TFEU of achieving a European Research Area'. Therefore, not only academic researchers but also not-for-profit organisations, governmental institutions or profit-seeking commercial companies can carry out scientific research.

It is a common assumption that scientific research is beneficial to the whole of society and that scientific knowledge is a public good to be encouraged and supported. This translates into a form of 'social contract', rooted as such in trust. From a data protection viewpoint, the principles of **necessity** and **proportionality** are essential. **For a controller to simply claim to process data for the purposes of scientific research is not sufficient**.

iii. What Falls Under Art. 89 GDPR

The Article 29 Working Party, in its guidelines on consent, understood scientific research as a '**research project set up in accordance with relevant sector-related methodological and ethical standards'**. Under this approach, only scientific research performed within an established ethical framework would therefore qualify as activities falling within the special data protection regime. For the purposes of **this Preliminary Opinion**, therefore, the special data protection regime for scientific research is understood to apply where each of the **three criteria** are met:

1) personal data are processed;
2) relevant sectoral standards of methodology and ethics apply, including the notion of informed consent, accountability and oversight;
3) the research is carried out with the aim of growing society's collective knowledge and wellbeing, as opposed to serving primarily one or several private interests.

iv. Scientific research and the GDPR: Selected issues

- Special regime for scientific research

  Each of the general principles under the GDPR apply to all data processing, including processing for research purposes.

- Consent as a legal basis for data processing

  It has been noted above that researchers have sought to rely on 'broad consent' to the use of data. Recital 33 of the GDPR indeed acknowledges that

  > *"it is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical*

standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose."

Specific consent normally required under the GDPR may therefore become less appropriate in the case of collected and inferred data and especially in the case of special categories of data on which much scientific research relies. When research purposes cannot be fully specified, a controller would be expected to do more to ensure the essence of the data subject rights to valid consent are served, including through as much transparency as possible and other safeguards.

<u>If consent is the lawful ground for processing, the data subject must be able to withdraw that consent at any time; there is no exception to this requirement for scientific research.</u>

- <u>Consent as an appropriate safeguard</u>

  There may be circumstances in which consent is not the most suitable legal basis for data processing, and other lawful grounds under both Articles 6 and 9 GDPR should be considered. However, even where consent is not appropriate as a legal basis under GDPR, **informed consent as a human research participant could still serve as an 'appropriate safeguard' of the rights of the data subject.** Under what conditions such informed consent might be deemed an appropriate safeguard is still unclear. Certainly, innovative forms of consent in research activities, like tiered and dynamic consent, are promising practices that should be further encouraged and developed.

- <u>Right to information</u>

  The principles of fairness and transparency (Article 5(1) GDPR) echo to a large extent the foundational principle of informed consent in research ethics, according to which participants should understand that they are taking part in research and what the research requires of them, without having been coerced or deceived. Such information may include the purpose of the research, the methods being used, the possible outcomes of the research, as well as associated demands, discomforts, inconveniences and risks that the participants may face.

However, under Article 14(5)(b), the obligation to provide information **does not apply if it 'proves impossible or would involve a disproportionate effort, in particular for processing for scientific research purposes when the conditions of Article 89 are satisfied or when this is likely to render impossible or seriously impair the achievement of the objective of that processing'**.

- Derogations possible under the special regime for scientific research

Article 89(2) of the GDPR outlines the more specific conditions under which EU or Member State law may derogate from the data subject's right of access (Article 15), right to rectification (Article 16), right to restriction (Article 18) and right to object (Article 21).

The rights of access and rectification are set out in Article 8(2) of the European Charter itself, and are generally considered essential components of the right to the protection of personal data. The right of access is of particular importance as it enables the data subjects to exercise the other rights provided for by data protection legislation. Therefore, any derogation from these essential data subject rights must be subject to a particularly high level of scrutiny in line with the standards required by Article 52(1) of the European Charter. Derogations under GDPR Article 89(2) are only possible if the conditions and safeguards required under Article 89(1) are satisfied, which require appropriate safeguards to be taken.

Furthermore, under Article 89(2), derogations can be applied only 'in so far as' the rights to be derogated from are **'likely to render impossible or seriously impair the achievement of the specific purposes, and such derogations are necessary for the fulfilment of those purposes'.** Enabling individuals to exercise their rights of access, rectification, restriction and objection undeniably requires a number of technical and organisational measures to be put in place by the controller.

Some of these technical and organisational measures may involve significant investment of human and financial resources in order to provide access and other rights to individuals. This is, however, not unique to companies or organisations involved in statistical or scientific research activities**. Having to invest resources in itself does not justify derogating from the rights of individuals under Article 89(2) of the GDPR**.

As far as the rights to restriction and objection are concerned, EDPS recognises that in specific circumstances, a large number of individuals objecting to all or part of a scientific research, may have a negative effect on the representativeness and reliability of the research data, and thus on the integrity

of research. However, **the scope of the derogations to the rights to restriction and objection in the field of scientific research should remain limited to cases where the integrity of research would be compromised by the exercise of data subjects' rights**.

- Presumption of compatibility

  Reflecting the strategic importance of reuse of data under the EU's research policies, EU data protection law, since the 1995 directive and continuing with the GDPR, has included the so-called presumption of compatibility (GDPR Article 5(1)(b)130 according to which:

  > *"further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes"*

  This presumption depends on the requirement in Article 89(1) to ensure appropriate technical and organisational safeguards, such as pseudonymisation and access limitations. The Article 29 Working Party furthermore argued for ensuring that the data would not be used to support measures or decisions regarding any particular individuals.

  The presumption is not a general authorisation to further process data in all cases for historical, statistical or scientific purposes. Each case must be considered on its own merits and circumstances.

- Lawfulness and purpose limitation

  Any re-use of data for scientific research purposes, even with the presumption of compatibility, would still require a specific lawful ground.

- Storage limitation

  Personal data should be 'kept in a form which permits identification of data subjects for no longer than is necessary' (Article 5(1)(e) GDPR). The GDPR permits 'storage for longer periods' if the sole purpose is scientific research (or archiving in the public interest, historical research or statistical purposes).

- Accountability

  Data protection rules are a framework for, not an obstacle to, proportionate disclosure of information to researchers, where there is a valid legal basis and appropriate safeguards depending on the risk.

  Professional ethical standards governing a particular research project would also be considered a safeguard. Where researchers deploy Artificial Intelligence systems, there is the same need for safeguards and oversight. IT and engineering research often lack ethical oversight, so the European Commission committed to embed 'ethics by design' for all future EU-funded AI projects.

v. Recommendations

- Data protection authorities and data protection officers increasingly engage with ethical questions in the development and deployment of digital technologies. They should engage more closely with ethical review boards.
- Member States, supervisory authorities, the EDPB and the Commission should draw up of codes of conduct to contribute to the proper application of the GDPR. Such codes of conduct and certifications under the GDPR could usefully address:
  - requirements of valid consent as a lawful basis for data processing and/or safeguard;
  - regime for special categories of personal data;
  - legitimate interests pursued by researchers;
  - pseudonymisation of research data and scientific publications;
  - exercise of the rights of the data subjects in the context of the potential limitations of
  - those rights;
  - implementation of data protection by design in the field of research;
  - transfers of personal data to third countries or international organisations
  - provision by private companies, particularly tech platforms, of data to independent researchers for specific projects, such as examining online manipulation and the dissemination of misinformation

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ARTICLE 29 WORKING PARTY – DATA PROTECTION WORKING PARTY – Opinion 03/2013 on purpose limitation[5]

i. Scope of the Document

This Opinion analyses the principle of purpose limitation. It provides guidance for the principle's practical application under the current legal framework and formulates policy recommendations for the future.

ii. General Principles Regarding the Processing of Scientific Data

Functional separation: The data used for statistical purposes or other research purposes should not be available to 'support measures or decisions' that are taken with regard to the individual data subjects concerned (unless specifically authorized by the individuals concerned). To comply with this requirement, controllers need to guarantee the security of the data, and take all other necessary technical and organisational measures to ensure functional separation.

Full or partial anonymisation, in particular, can be relevant to the safe use or sharing of data within organisations, particularly large ones with diverse functions. When full anonymisation and use of aggregated data (at a sufficiently high level of aggregation) are not possible, data will often at least need to be partially anonymised (e.g. pseudo-anonymised, key-coded, and stripped of direct identifiers) and additional safeguards may also be required.

Article 29 Working Party suggests that different scenarios require different safeguards and it is helpful to distinguish different scenarios for further analysis:

- **Scenario 1:** unidentifiable personal data: data are anonymised or aggregated in such a way that there is no remaining possibility to (reasonably) identify the data subjects.
- **Scenario 2:** indirectly identifiable personal data: lower level of aggregation, partial anonymisation, pseudonymisation or key-coded data.
- **Scenario 3:** situations where directly identifiable personal data are needed due to the nature of the research.

[5] https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2013/wp203_en.pdf

As a general rule, this leads to the following considerations of the Article 29 Working Party:

1) Full anonymisation (including a high level of aggregation) is the most definitive solution. It implies that there is no more processing of personal data and that the Directive, which was repealed by the GDPR, is no longer applicable.
2) Partial anonymisation or partial de-identification may be the appropriate solution in some situations when complete anonymisation is not practically feasible. In these cases, various techniques (including pseudo-anonymisation, key-coding, keyed-hashing, using rotating salts, removal of direct identifiers and outliers, replacing unique IDs, introduction of 'noise', and others) should be used to reduce the risk that data subjects can be re-identified, and subsequently, that any measures or decisions can be taken in their regard. In addition, there will also often be a need to complement these techniques with other safeguards in order to adequately protect the data subjects. These include data minimisation, as well as appropriate organisational and technical measures, including effective 'data silo'-ing, to ensure functional separation.
3) Directly identifiable personal data may be processed only if anonymisation or partial anonymisation is not possible without frustrating the purpose of the processing, and further provided that other appropriate and effective safeguards are in place.

<u>Additional safeguards beyond anonymization</u>

- Easier the data subject can be identified, the more additional safeguards will be needed.
- Among the appropriate safeguards which may bring additional protection to the data subjects, the following could be considered:
  - taking specific additional security measures (such as encryption);
  - in case of pseudonymisation, making sure that data enabling the linking of information to a data subject (the keys) are themselves also coded or encrypted and stored separately;
  - entering into a trusted third party (TTP) arrangement in situations where a number of organisations each want to anonymise the personal data they hold for use in a collaborative project;
  - restricting access to personal data only on a need-to-know basis, carefully balancing the benefits of wider dissemination against the risks of inadvertent disclosure of personal data to unauthorised persons. This may include, for example, allowing read only access on controlled premises. Alternatively, arrangements could be made for limited disclosure in a secure local environment to properly constituted closed communities. Legally enforceable confidentiality obligations placed on the recipients of the data, including prohibiting publication of identifiable information, are also important. It is also noted that in high-risk situations, where the

inadvertent disclosure of personal data would have serious or harmful consequences for individuals, even this type of access or restriction may not be suitable.

- further processing of personal data concerning health, data about children, other vulnerable individuals, or other highly sensitive information should, in principle, be permitted only with the consent of the data subject;
- any exceptions to this requirement for consent should be specified in law, with appropriate safeguards, including technical and organisational measures to prevent undue impact on the data subjects (in case of doubt, the processing should be subject to prior authorisation of the competent data protection authority); exceptions should only apply with regard to research that serves an important public interest, and only if that research cannot possibly be carried out otherwise.

GUIDELINES 03/2020 ON THE PROCESSING OF DATA CONCERNING HEALTH FOR THE PURPOSE OF SCIENTIFIC RESEARCH IN THE CONTEXT OF THE COVID-19 OUTBREAK[6]

i. Scope of the Document

The guidelines aim to shed light on certain urgent questions such as the legal basis, the implementation of adequate safeguards for processing of health data for the purposes of scientific research efforts in the fight against the SARS-CoV-2 and the exercise of the data subject rights.

[6] https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_guidelines_202003_healthdatascientificresearchcovid19_en.pdf

ii. General Principles Regarding the Processing of Scientific Data

All processing of personal data concerning health must comply with the principles relating to processing set out in Article 5 GDPR and with one of the legal grounds and the specific derogations listed respectively in Article 6 and Article 9 GDPR for the lawful processing of this special category of personal data. Legal bases and applicable derogations for processing health data for the purpose of scientific research are provided for respectively in Article 6 and Article 9. It has to be noted that there is no ranking between the legal bases stipulated in the GDPR.

The principles relating to processing of personal data pursuant to Article 5 GDPR shall be respected by the controller and processor, especially considering that a great amount of personal data may be processed for the purpose of scientific research. These principles are:

- Transparency and information to data subjects,
- Purpose limitation and presumption of compatibility,
- Data minimisation and storage limitation,
- Integrity and confidentiality.

The exemptions under GDPR Art. 89 (2) regarding the transparency and information to data subjects:

- The former Article 29-Working-Party has already pointed out that "the situation where it "proves impossible" under Article 14 (5) (b) to provide the information is an all or nothing situation because something is either impossible or it is not; there are no degrees of impossibility. If a data controller seeks to rely on this exemption **it must demonstrate the factors that actually prevent it from providing the information in question to data subjects**. If, after a certain period of time, the factors that caused the "impossibility" no longer exist and it becomes possible to provide the information to data subjects then the data controller should immediately do so. In practice, there will be very few situations in which a data controller can demonstrate that it is actually impossible to provide the information to data subjects."
- In determining what constitutes disproportionate effort, Recital 62 refers to the number of data subjects, the age of the data and appropriate safeguards in place as possible indicative factors. It is recommended that the controller should therefore carry out a balancing exercise to assess the effort involved to provide the information to data subjects against the impact and effects on the data subject if they are not provided with the information.

- Data controllers must demonstrate that the provision of the information set out in Article 14 (1*) (Information to be provided where personal data have not been obtained from the data subject)* per se would render impossible or seriously impair the achievement of the objectives of the processing. In a case where the exemption of Article (14) (5) (b) GDPR applies, "the controller shall take appropriate measures to protect the data subject's rights and freedoms and legitimate interests, including making the information publicly available".

Exemptions regarding purpose limitation and presumption of compatibility:

The "compatibility presumption" provided by Article 5 (1) (b) GDPR states that *"further processing for […] scientific research purposes […] shall, in accordance with Article 89 (1), not be considered to be incompatible with the initial purposes".* The requirements of Article 89 (1) GDPR emphasise the importance of the data minimisation principle and the principle of integrity and confidentiality as well as the principle of data protection by design and by default. Consequently, considering the sensitive nature of health data and the risks when re-using health data for the purpose of scientific research, strong measures must be taken in order to ensure an appropriate level of security as required by Article 32 (1) GDPR.

Exemptions regarding data minimisation and storage limitation:

As stipulated by Article 5 (1) (e) GDPR "personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving […] scientific purposes […] in accordance with Article 89 (1) subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject". In order to define storage periods (timelines), criteria such as the length and the purpose of the research should be taken into account.

Exemptions regarding integrity and confidentiality:

- It has to be noted that the principle of integrity and confidentiality must be read in conjunction with the requirements of Article 32 (1) GDPR (Security of processing) and Article 89 (1) GDPR. The cited provisions must be fully complied with. Therefore, considering the high risks as outlined, appropriate technical and organisational up-to-date measures must be implemented to ensure a sufficient level of security.
- Such measures should at least consist of pseudonymisation, encryption, non-disclosure agreements and strict access role distribution, access role restrictions as well as access logs. It has to be noted that national provisions may stipulate concrete technical requirements or other safeguards such as adherence to professional secrecy rules.

- Furthermore, a data protection impact assessment pursuant to Article 35 GDPR must be carried out when such processing is "likely to result in a high risk to the rights and freedoms of natural persons" pursuant to Article 35 (1) GDPR. The lists pursuant to Article 35 (4) and (5) GDPR shall be taken into account.
- Finally, the adopted measures to protect data (including during transfers) should be properly documented in the record of processing activities.

Exemptions regarding exercise of the rights of data subjects:

It has to be noted that, in the light of the jurisprudence of the ECJ, all restrictions of the rights of data subjects must apply only in so far as it is strictly necessary.[7]

iii. What Falls Under Art. 89 GDPR

As indicated by Recital 159, *"the term processing of personal data for scientific research purposes should be interpreted in a broad manner including for example technological development and demonstration, fundamental research, applied research and privately funded research. In addition, it should take into account the Union's objective under Article 179 (1) TFEU of achieving a European Research Area. Scientific research purposes should also include studies conducted in the public interest in the area of public health."* The former Article 29-Working-Party has already pointed out that the term may not be stretched beyond its common meaning though and understands that "scientific research" in this context means *"a research project set up in accordance with relevant sector-related methodological and ethical standards, in conformity with good practice"*.

[7] See for example,regarding the Directive 95/46/EC ECJ 14.2.2019, C–345/17 (Buivids) para. 64: http://curia.europa.eu/juris/document/document.jsf?text=&docid=210766&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=998975

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EDPS – OPINION 10/2017 EDPS OPINION ON SAFEGUARDS AND DEROGATIONS UNDER ARTICLE 89 GDPR IN THE CONTEXT OF A PROPOSAL FOR A REGULATION ON INTEGRATED FARM STATISTICS[8]

i. Scope of the Document

Scope of the document is an EDPS Opinion on safeguards and derogations under Article 89 GDPR in the context of a proposal for a Regulation on integrated farm statistics.

ii. General Principles Regarding the Processing of Scientific Data

The EDPS, first, emphasises that any derogations from the right to the protection of personal data must not go beyond what is strictly necessary to achieve their objectives and must meet the high standards required by Article 52(1) of the Charter. This document provides that 'any limitation on the exercise of the rights and freedoms recognised by this Charter must be provided for by law and respect the essence of those rights and freedoms. Subject to the principle of proportionality, limitations may be made only if they are necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others'. Article 8(2) of the Charter specifically sets out that 'everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified'. The right of access is of particular importance as it enables the data subjects to exercise the other rights provided for by data protection legislation. Therefore, any derogation from these essential data subject rights must be subject to a particularly high level of scrutiny.

iii. What Falls Under Art. 89 GDPR

Article 89(2) of the GDPR outlines the - more specific - conditions under which Union or Member State law may derogate from certain provisions of the GDPR.

In order to justify the need for the derogations, the European Council proposes the following:

- 'application of certain rights set out [in the GDPR] would render the production of Union statistics impossible or would seriously impair the production of such statistics in line with applicable statistical principles';

[8] https://edps.europa.eu/sites/edp/files/publication/17-11-20_opinion_farm_statistics_en_0.pdf#page12

- these principles include, in relevant part, the principles of 'objectivity, reliability, cost-effectiveness and statistical quality, including timeliness';
- 'granting an access to personal data in all circumstances would be technically extremely difficult given that personal data relating to a particular data subject are dissociated from the identification of the data subject';
- 're-linking of data to a particular national identification number would in most cases require a linking of a large number of statistical files into which those data have been previously dissociated'; it would also require 'keeping track of the original format in which data records have been received';
- 'the exercise of [the right to object and right of restriction], especially when exercised by a large number of subjects, would defeat the purpose of the production of Union statistics, more particularly as regards their representativeness and reliability'.

To benefit from the derogation, the draft regulation provides for the following safeguards:

- the personal data shall only be used for statistical purposes;
- the personal data shall not be used for taking measures or decision regarding any particular data subject;
- the personal data shall be subject to pseudonymisation or other appropriate safeguards within the meaning of Article 89(1) of the [GDPR]; and
- the personal data (sic) shall comply with the requirements of statistical confidentiality laid down in Regulation (EC) No 223/2009.

In this regard, the EDPS recommendations on the safeguards proposed provides the following conditions for the derogations to apply:

- personal data must be processed by national statistical offices and/or other national authorities;
- personal data must be processed in the public interest for the statistical purposes falling within the scope of the [Farm Statistics Regulation];
- personal data must be kept in a form which permits identification of data subjects for no longer than is necessary for the sole purpose of creating Union statistics.

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TABLE – BENCHMARK FOR IMPLEMENTATION OF ARTICLE 89[9]

EUROPEAN COUNTRY	IMPLEMENTATION
United Kingdom	In terms of special category data, the Schedule 1 condition 4 of the Data Protection Act 2018 requires data controller to: • demonstrate that the processing is necessary for archiving, research or statistical purposes • it must be a reasonable and proportionate way of achieving one of these purposes, and data controller must not have more data than you need; • comply with the safeguards and restrictions set out in Article 89(1) of the UK GDPR and section 19 of the DPA 2018; and • demonstrate that the processing is in the public interest. Section 19 of the DPA contains safeguards and restrictions. In particular, this means data controller must: • be able to demonstrate why it cannot use anonymised data; • consider whether it could use pseudonymisation to make it more difficult to link the personal data back to specific individuals; • be able to demonstrate that the processing is not likely to cause substantial damage or distress to individuals; • not use the data to take any action or make decisions in relation to the individuals concerned (unless it is carrying out approved medical research as defined in section 19(4) of the DPA 2018); and

[9] https://whitelabelconsultancy.com/2020/04/research-exemption-and-restrictions-to-data-subject-rights/
https://gallery.mailchimp.com/e2039d5b8bd9f7751e553357f/files/e8da6ca0-e7f1-4a4f-9fc5-42f880e2e9c0/20190521_Scientific_research_health_data_country_chart_copy_cl.pdf?utm_source=GA4GH+Member+Newsletter&utm_campaign=d707a8cc39-EMAIL_CAMPAIGN_2018_10_31_02_38_COPY_01&utm_medium=email&utm_term=0_d52573ead8-d707a8cc39-495197029
https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/special-category-data/what-are-the-conditions-for-processing/#conditions10

	• consider other appropriate safeguards and security measures. Moreover, under the Article 15(2)(f) and Schedule 2 - Part 6 of the DPA 2018, it is regulated that the rights enshrined in Articles 15, 16, 18 and 21 GDPR can be subject to derogation as long as personal data are processed considering the technical and organisational measures mentioned in Article 89(1) of GDPR. The Act also requires that the results of the research or any resulting statistics are not made available in a form that identifies or allows the identification a data subject.
Estonia	Where personal data are processed for the purpose of research, the controller or processor may restrict the rights of data subjects provided for in Articles 15, 16, 18 and 21 GDPR insofar as the exercise of these rights is likely to make the achievement of the objectives of the research impossible or impedes it to a significant extent. Article 6 of the Estonian Data Protection Act clearly makes preference for processing personal data in pseudonymised form (or in a format that would provide a similar level of protection) for research purposes. In theory de-pseudonymisation is permitted but only for the needs of additional scientific research or official statistics. If a company wants to process such non-pseudonymised data they must designate one person (identified by name) who will have access to information that would allow the re-identification. Processing data that identify data subjects in only possible when: • It would be impossible to achieve the results with pseudonymised data, • There is an overriding public interest, and • When data subject rights are not excessively damaged.
Finland	The Finnish Data Protection Act regulates that three conditions must be met before these rights can be waived: • the processing is based on an appropriate research plan;

	• a person or group responsible for the research has been designated; and • the personal data are used and disclosed only for scientific or historical research purposes or for other compatible purposes, and the procedure followed is also otherwise such that data concerning a given individual are not revealed to outsiders.
Netherlands	Which safeguards need to be taken will depend on the risk assessment in the specific case. Examples include access controls, confidentiality, anonymisation/pseudonymisation and the presentation of the results of the investigation. Only with historical research will it be possible to make personal data public in the results. The benchmark is always that the privacy of the data subject may not be disproportionately damaged. Under the Article 44 of the Dutch Implementation Act GDPR, where a processing is carried out by scientific research or statistics institutions or services, and the necessary provisions have been made to ensure that the personal data can only be used for statistical or scientific purposes, the controller may choose not to apply Articles 15 (access), 16 (rectification) and 18 (suspension of processing). The requirement to take the necessary provisions aims to ensure that the personal data can only be used for statistical and scientific purposes, and not for other purposes. The controller needs to make a risk assessment and take proportional measures to protect the personal data, taking into the risks and the costs involved. Examples include access controls, confidentiality, anonymisation/pseudonymization.
Spain	Access, rectification, purpose limitation and objection may be limited when carrying out a health investigation when: (i) rights are exercised against the investigating individuals/entities using pseudo/anonymised data, (ii) the exercise of the rights may jeopardise the results of the investigation; or (iii) the purpose of the investigation is a matter of essential public interest related to national security or other general public interests as provided by applicable law.
Germany	Controllers interest must significantly outweigh data subjects. Controllers must apply suitable and specific measures which may include,

	• technical and organisational measures • audit measures for data input, alteration & removal • staff training • designation of DPO • access control • encryption • measures to ensure confidentiality, integrity, availability and resilience • process to regularly test and assess security measures • rules re: data transfers and purpose limitation The issues with respect to anonymisation are regulated as follows: • Anonymisation shall be made as soon as the research or statistical purpose allows, unless this conflicts with individual's legitimate interests. • Until anonymisation is ensures, identifiable characteristics to be stored separately. They may be combined with other information only to the extent required by the research or statistical purpose. • Publication of personal data only with consent or if doing so is indispensable for the presentation of research findings on contemporary events.
Denmark	In the Danish Data Protection Act, Article 22(5), it is clearly stated that Articles 15, 16, 18 and 21 GDPR do not apply if the processing of data takes place exclusively for scientific or statistical purposes.