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Two-faced Janus? Consent to participate in research and consent to data processing in the EHDS era: a comparative analysis of requirements and standards in eight European countries

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ABSTRACT

This study examines the complex and often ambiguous conceptualization of consent in European health research, focusing on the relationship between informed consent to participate in research and consent as a legal basis for personal data processing. Differences between these two forms of consent may lead to inconsistent procedures and requirements, thereby generating legal and practical challenges for researchers, ethics committees, data protection authorities, and other oversight bodies. Drawing on two use cases involving observational retrospective studies, the paper compares consent requirements and oversight practices in Belgium, the Czech Republic, Finland, France, Germany, Italy, Poland, and Spain, highlighting persistent fragmentation and uneven institutional coordination across national research governance systems. The paper also distinguishes between 'monist' conceptions of consent, which view research and data protection consent as expressions of a single normative concept, and 'dualist' conceptions, which treat them as distinct forms of authorization grounded in different ethical and legal rationales. The paper concludes by reflecting on the implications of the upcoming European Health Data Space Regulation, arguing that its approach to secondary data use may further accentuate existing tensions and highlighting the need for greater conceptual clarity and institutional coordination in European health research governance.

KEYWORDS: consent, opt-out, research ethics, data protection law, retrospective observational research, ethics committees, data protection authorities, European Health Data Space (EHDS)

I. INTRODUCTION

In the field of health research, the notion of consent is often characterized by ambiguity in both understanding and application. At a general level, this ambiguity can be attributed to the fact that the term 'consent' encompasses multiple meanings. On the one hand, there is 'informed consent' provided by research participants as a prerequisite for their involvement in research activities. This type of consent is rooted in a long tradition of research ethics guidelines and standards (hereafter: 'consent to participate in research,' or, as sometimes referred to, 'ethics consent'[1]). On the other hand, 'consent' also refers to one of the legal grounds for lawful data processing as outlined in data protection legislation (hereafter referred to as 'consent to personal data processing,' or 'GDPR consent').

1 As discussed below, notwithstanding the use of this term, consent to participate in research is often not merely an ethical, but also a legal requirement.

In practice, as attested by the current ethical and legal debate,[2,3,4] and as reviewed more in-depth in section 4 of this paper, this distinction can give rise to differing requirements for consent, with regard, for instance, to consent granularity and specificity (eg, what is the role and acceptability of broad consent across different jurisdictions?), information provision, and revocability, as well as the very necessity of obtaining research participants' consent prior to the use of their personal data for research purposes. This diversity of requirements can also lead to conflicts within the scope and enforcement practices of oversight bodies, such as ethics committees (ECs) and Data Protection Authorities (DPAs), including the crucial decision as to which legal basis to apply, as well as to inconsistent procedures that researchers are expected to follow. As contended by Dove and Chen,[5] from the perspective of participants and researchers alike, it may also lead to a 'consent misconception' whereby consent to participate in research is (often unduly) thought to also extend to the processing of personal data.

At a more fundamental theoretical meta-level, it remains unclear whether these two dimensions of consent should be understood as two different instantiations of a single underlying normative concept—what can be termed as a 'monist' conception of consent—or whether they instead refer to conceptually distinct practices (despite their shared terminology) that may only partially overlap in their practical effects, as implicitly posited in what can be termed 'dualist' conceptions of consent (we return to and further articulate this conceptual distinction in the discussion section of the paper).

To further complicate this picture, in March 2025, the Regulation on the European Health Data Space (EHDS) was signed into law.[6] This important legislation is aimed at harmonizing rules within the European Union (EU) and affiliated third countries for access to electronic health data for both 'primary' (ie, healthcare-related) and 'secondary' use (ie, related to research, innovation, and policymaking activities). The EHDS Regulation contains key provisions with respect to privacy rights and consent in the context of secondary use of health-related data.

Notably, the EHDS provides harmonized rules[7] for the processing of electronic health data across the EU.[8] Moreover, it moves away from a consent-based model towards statutory legal bases and a—still ill-defined—'opt-out' framework for the secondary use of health data, granting data subjects the 'right to opt out at any time, and without providing any reason, from the processing of personal electronic health

2 E. Gefenas et al., *Controversies Between Regulations of Research Ethics and Protection of Personal Data: Informed Consent at a Cross-road*, 25(1) 23–30 Med Health Care Philos (2022).

3 E. S. Dove & J. Chen, *Should Consent for Data Processing be Privileged in Health Research? A Comparative Legal Analysis*, 10 Int'l Data Privacy L. 117 (2020).

4 J. Chen, E. S. Dove & H. Bhakuni, *Explicit Consent and Alternative Data Protection Processing Grounds for Health Research*, in Research Handbook on Eu Data Protection Law 474–502 (Edward Elgar Publ'g 2022).

5 Dove and Chen, p. 128.

6 Regulation (EU) 2025/327 of the European Parliament and of the Council of Feb. 11, 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (Text with EEA relevance), http://data.europa.eu/eli/reg/2025/327/oj (accessed July 20, 2025).

7 The EHDS Regulation is likely going to harmonize legal bases for data users, though health data applicants should still demonstrate a valid GDPR Article 6 legal basis that allows them to request access to electronic health data pursuant to the EHDS Regulation.

8 *Id.*, rec. 52.

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data relating to them for secondary use under this Regulation.'[9] This means that, while personal electronic health data are intended to be 'fed into the EHDS' by default, data subjects should still retain the prerogative to refuse the use of their personal electronic health data for specific secondary purposes, such as research activities. Worth noting is that, notwithstanding this incisive attempt at overcoming the fragmentation of legal bases for secondary use across European countries, Member States still retain significant prerogatives to regulate secondary data uses, which may (re-)introduce further legal fragmentation and discrepancies in data governance practices. These prerogatives include: (i) defining the specific configuration and scope of the opt-out mechanism (eg, full opt-out covering all secondary uses, purpose-specific opt-out, opt-out for specific data types, opt-out per specific data holders, etc.); (ii) introducing provisions enabling the use of 'opted-out' data for specific purposes premised on public interest clauses; and (iii) introducing 'stricter measures and additional safeguards [...] aimed at safeguarding the sensitivity and value of certain data [such as genetic data] as laid down in this Regulation'.[10]

In addition, the EHDS Regulation establishes national Health Data Access Bodies (HDABs), primarily tasked to evaluate data access requests by prospective data users, thus creating a new data governance and oversight organization retaining—at least on paper—significant decisional prerogatives regarding secondary data uses.[11] Yet, while the Regulation sets out general decision-making criteria for HDABs, it leaves Member States with substantial discretion over their organizational arrangements, procedural rules, and the practical implementation of those criteria.

It is also worth noting that the EHDS Regulation does not replace existing data governance frameworks for secondary uses, but rather introduces an additional, harmonized EU-wide framework alongside those already in place. In practice, potential data users are not required to seek data access exclusively through the EHDS and may continue to rely on direct access requests to data holders. As a result, existing consent-based arrangements are not superseded by the EHDS and remain applicable. As such, the EHDS Regulation is expected to harmonize the exercise of privacy rights, consent, and data governance procedures across European countries. Yet, doubts persist as to whether it will, in fact, manage to achieve its envisaged objectives.[12]

Against this backdrop, this paper explores how the important issue of aligning requirements and practices around consent—which represents a major conundrum for researchers and oversight bodies alike—is dealt with in different countries within the European context. First, it provides an overview of how consent is differently conceptualized in research ethics documents and data protection legislation. Next, it presents the challenges that may emerge from misalignments in consent requirements, standards, and approaches across different 'types' of consent. Third, it presents two

9 *Id.*, Art. 71.

10 *Id.*, rec. 52.

11 Paul Quinn, *Health Data Access Bodies Under the European Health Data Space – A Technocratic Colossus or Rubber Stamp Forum?*, Tech. Reg. 60–80 (2025).

12 Luca Marelli et al., *The European Health Data Space: Too Big to Succeed?*, 135 Health Policy 104861 (2023). For a comprehensive overview of the legal, ethical and social challenges raised by the EHDS, see also Joseph Donia and Luca Marelli, *Anticipating Ethical and Social Dimensions of the European Health Data Space: A Rapid Systematic Review*, 162 Health Policy 105443 (2025).

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concrete use cases as a starting point to, fourth, comparatively explore and discuss how consent is dealt with in different European countries, namely Belgium, the Czech Republic, Finland, France, Germany, Italy, Poland, Spain; finally, it asks what may be at stake from the implementation of the EHDS Regulation, providing an anticipatory assessment of whether the EHDS is likely to mitigate the identified issues or in fact risks further exacerbating them.

II. 'CONSENT TO PARTICIPATE IN RESEARCH': THE BACKGROUND OF INFORMED CONSENT IN THE RESEARCH ETHICS TRADITION

In health research, informed consent can be defined as 'a process of communication involving both investigator and research participant that culminates in the authorization or refusal of participation in a research study.'[13] Up to the present day, there is a long (bioethical) tradition of considering informed consent as a cornerstone of ethically sound research practice, mainly premised on the two fold fundamental aim of protecting research participants' welfare and promoting their individual autonomy.[14] Several international documents recognize informed consent as a fundamental requirement for participant enrollment in (variously termed) medical, biomedical, and health research, initially—in particular—those entailing interventional (invasive) experiments. These include the Nuremberg Code (1947),[15] the WMA Declaration of Helsinki (1964 and subsequent revisions),[16] the Belmont Report (1979),[17] the CIOMS International Ethical Guidelines for Health-related Research Involving Humans (1982 and subsequent revisions),[18] the Convention on Human Rights and Biomedicine (Oviedo Convention[19]) by the Council of Europe (1997), and the Addi-

13 Christine Grady, *Enduring and Emerging Challenges of Informed Consent,* 372 New England Journal of Medicine 855–62 (2015).

14 E. J. Emanuel, D. Wendler & C. Grady, *What Makes Clinical Research Ethical?*, 283 JAMA 2701–11 (2000). Other normative rationales grounding informed consent can be identified in the promotion of trust towards researchers, the safeguard of non-welfare interests of participants, and self-ownership. See, among others: Onora O'Neill, Autonomy and Trust in Bioethics (Cambridge University Press 2002); Alan Wertheimer, Exploitation, Princeton University Press (1996); Joseph Raz, The Morality of Freedom (Oxford University Press 1986).

15 United States Holocaust Memorial Museum, *The Doctors Trial: The Medical Case of the Subsequent Nuremberg Proceedings*, https://www.ushmm.org/information/exhibitions/online-exhibitions/special-focus/doctors-trial/nuremberg-code (accessed Aug. 11, 2025).

16 WMA DECLARATION OF HELSINKI—Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964. The current version of the Declaration was signed in Helsinki in 2024, and is entitled *Ethical Principles for Medical Research Involving Human Participants*. Research on identifiable data was introduced to the Declaration in the year 2000 version.

17 The Belmont Report, Ethical Principles and Guidelines for the protection of human subjects of research, adopted by National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Apr. 18, 1979.

18 International Ethical Guidelines for Health-related Research Involving Humans, prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), 2002. See in particular Guideline 9: Informed consent is based on the principle that individuals capable of giving informed consent have a right to choose freely whether to participate in research. Informed consent protects the individual's freedom of choice and respects the individual's autonomy.

19 The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No 164), opened for signature on Apr. 4, 1997 in Oviedo (Spain).

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tional Protocol concerning Biomedical Research (2005)[20] (applicable to countries that ratified it). Hence, with few exceptions, informed consent is an ethical requirement to be complied with for participation in health research. Exceptions include participants not legally capable of providing consent (for which additional safeguards are foreseen, cf. Declaration of Helsinki, pt. 28–30); or cases in which research would be unfeasible or impracticable without a consent waiver (CIOMS guidelines 10–11); or again, 'exceptional' situations in which obtaining consent is impracticable or impossible (Declaration of Helsinki, pt. 32). In addition, ethics requirements on informed consent become outright legal requirements insofar as these ethics provisions enshrined in the soft laws are incorporated in legal acts and binding legislation, at the international and national level—as it is the case, for instance, with the EU Clinical Trial Regulation (Regulation 536/2014)[21] or Oviedo Convention,[22] ratified by 31 states within the Council of Europe, which sets requirement for documented consent prior to conducting research on a person. Thus, when the ethics requirement is embedded in a legal provision, the fact of intervening in a human body without consent can constitute a violation of the fundamental human right to autonomy, or can trigger criminal liability and lead to an obligation to compensate for damages. However, it should also be noted that several types of research exist. And whether in the case of invasive/interventional studies consent always represents a mandatory requirement, when it comes to other types of research (such as non-interventional retrospective studies, non-interventional prospective studies, register-based studies, etc.), different countries in Europe maintain different approaches, and consent for participation in research can either be required or not.

III. 'CONSENT TO DATA PROTECTION': THE BACKGROUND OF CONSENT IN DATA PROTECTION LAW

The notion that it is necessary to protect individuals' privacy against the collection of personal information by public agencies originated and gained significant momentum within the US context, particularly in the late 1960s and early 1970s. While the 'right to be left alone' was articulated by Warren and Brandeis in 1890,[23] the modern, specific focus on protecting citizens from government-based, automated data collection was primarily a response to expanding federal surveillance capabilities and the advent of computerized databases. The 1973 report 'Records, Computers and the Rights of Citizens' by the US Secretary's Advisory Committee on Automated Personal Data Systems[24] introduced Fair Information Practices (FIPs) to protect individuals from risks posed by computerized record-keeping. These principles, which influenced the Privacy Act of 1974, focus on limiting the collection, use, and disclosure of personal

20 Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (CETS No. 195), opened for signature on Jan. 25, 2005.

21 Regulation (EU) No 536/2014 of the European Parliament and of the Council of Apr. 16, 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, OJ L 158, 27.5.2014, p. 1–76.

22 Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, Apr. 4, 1997 ETS 164 (Oviedo Convention), Art. 16

23 Samuel D. Warren & Louis D. Brandeis, *The Right to Privacy*, 4 Harvard Law Review 193–220 (1890).

24 https://www.justice.gov/opcl/docs/rec-com-rights.pdf.

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information to what is necessary and proportionate to clearly defined purposes, while ensuring transparency, individual access, and accountability in data processing practices. The US model influenced the German law[25] and other instruments (OECD guidelines on data protection[26] and the Data Protection Convention (Convention 108/1981) from the Council of Europe.[27]), which also explicitly reflected core FIP principles.[28]

At the EU level, historically, the OECD guidelines on data protection[29] and the Data Protection Convention (Convention 108/1981) from the Council of Europe[30] set clear standards and have, hence, influenced the development of data protection legislation, leading to the adoption of Directive 95/46/EC,[31] of Art. 8 of the Charter of Fundamental Rights of the EU[32] (which formulated the right to privacy as such), of the EU Directive on Privacy and Electronic Communications (2002),[33] and of Regulation 611/2013 on the measures applicable to the notification of personal data breaches under Directive 2002/58/EC,[34] leading up to the GDPR (Regulation 679/2016).

Throughout these historical developments, consent was introduced as the means to allow individuals (called 'data subjects' in the GDPR) to have control over the collection and processing of his/her personal information ('informational self-determination').[35] Considering that the provisions of Convention 108/1981 suggest

25 See the German Federal Act on Data Protection in 1977.

26 OECD, Recommendation of the Council concerning Guidelines Governing the Protection of Privacy and Transborder Flows of Personal Data, 1980.

27 Council of Europe, Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, N. 108/1981.

28 For an overview, see De Hert, P., Gutwirth, S. Data Protection in the Case Law of Strasbourg and Luxemburg: Constitutionalisation in Action, in Reinventing Data Protection? (Gutwirth, S., Poullet, Y., De Hert, P., de Terwangne, C., Nouwt, S. eds, Springer 2009).

29 OECD, Recommendation of the Council concerning Guidelines Governing the Protection of Privacy and Transborder Flows of Personal Data, 1980.

30 Council of Europe, Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, N. 108/1981.

31 Directive 95/46/EC of the European Parliament and of the Council of Oct. 24, 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

32 Charter of Fundamental Rights of the European Union (2000/C 364/01).

33 Directive 2002/58/EC of the European Parliament and of the Council of July 12, 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications).

34 Commission Regulation (EU) No 611/2013 of June 24, 2013 on the measures applicable to the notification of personal data breaches under Directive 2002/58/EC of the European Parliament and of the Council on privacy and electronic communications, OJ L 173, 26.6.2013, p. 2–8.

35 See Eleni Kosta, Consent in european data protection law (Brill | Nijhoff. 2013). See also EDPB Guidelines 05/2020, para 3. However, a growing body of scholarship questions whether consent can meaningfully function as a mechanism of individual control in data protection law. For instance, Ari Ezra Waldman argues that the paradigm of 'consent as control' is largely illusory and may operate as a red herring, insofar as it enables data controllers to formally comply with legal requirements while effectively shifting responsibility and risk onto data subjects, thereby disempowering them in practice. Waldman further shows how rights-based and consent-centered approaches to privacy can paradoxically undermine substantive protection by placing unrealistic cognitive and informational burdens on individuals operating within complex data ecosystems. Relatedly, among others Barbara Prainsack contends that a narrow focus on individual consent is insufficient for contemporary data practices and that meaningful protection requires greater emphasis on data governance, collective safeguards, and institutional accountability. See Ari Ezra Waldman, *Privacy's Rights Trap*, 91 Washington Law Review 505 (2018); Ari Ezra Waldman, Privacy as Trust: Information Privacy for an Information Age (Cambridge University Press 2018);

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that personal data processing should be based on consent or the law (meaning that consent was not the only option for grounding lawful processing), Directive 95/46/EC listed consent as one of the possible legal allowances justifying the processing of personal data. This approach was maintained within the GDPR, which states that the processing of personal data is lawful only if there is a legal allowance/permission (defined as a 'legal basis'[36]). Other legal bases - beyond consent - can be provided by national legislation based on public interest, legitimate interest, or EU and national provisions enabling data processing on the grounds of scientific research purposes (esp. Art. 6.1 e and f, but always respecting the constraints in Art. 9.2.j). [37]

IV. 'CONSENT TO PARTICIPATE IN RESEARCH' VS 'CONSENT TO PERSONAL DATA PROCESSING': MAPPING THE CHALLENGES

This two-fold connotation of consent is at the root of practical difficulties in its use within current health research practices. The following sets of challenges, which constitute the focus of this paper, can be identified:

(1) A fundamental challenge is represented by the fact that, while consent to participate in research should be mostly regarded as a fundamental prerequisite for enrolling participants, consent to personal data processing only represents one option among the possible legal bases that could be used.[38] Hence, also depending on provisions in national legislation,[39] researchers may need a valid consent in place for enrolling participants, while they could resort to legal bases *alternative to* consent for processing personal data. Accordingly, a key challenge for researchers is to distinguish between consent to participate and legal bases for data processing, and to ensure that participants are properly informed, particularly where processing relies on legal bases other than consent.

(2) A related challenge concerns the enforcement of consent requirements and the institutional oversight of (data-intensive) research projects. At a general level, it should be noted that the GDPR does not confer upon ECs a

Barbara Prainsack & Alena Buyx, Solidarity in Biomedicine and Beyond (Cambridge University Press 2017).

36 In the GDPR, consent is defined as 'any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her' (Art. 4(11) of the GDPR). In the case of processing special categories of data, including health and genetic data, the consent provided is qualified as 'explicit' (Art. 9(2)(a) of the GDPR). On consent, see also the Guidelines on Consent under Regulation 2016/679 of the former Article 29 Working-Party from 10.04.2018, WP259 rev.01, 17EN (endorsed by the European Data Protection Board), https://ec.europa.eu/newsroom/article29/item-detail.cfm?item_id=623051.

37 See also Recital 7 of the GDPR: 'Natural persons should have control of their own personal data.' Please note that consent is not the only tool through which data subjects can exercise control over the processing of their data. Consent provides control at the time of data collection and after data collection, but the data subject rights provide control tools after data collection. For these aspects, see Teodora Lalova-Spinks et al., *Patients' Knowledge, Preferences, and Perspectives About Data Protection and Data Control: An Exploratory Survey*, 14-2023 Frontiers in Pharmacology (2024).

38 See Gefenas et al. (2022).

39 For a comparative overview, see Dove and Chen (2020) and Chen et al. (2022).

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mandate to assess data processing operations, and only refers to 'recognized ethical standards' for research in Recital 33. Nevertheless, the evaluation of data processing practices may indirectly fall within the remit of ECs, through national law or otherwise, insofar as such practices are relevant for assessing, *inter alia*, the risks associated with research activities, which traditionally lie at the core of ethics review practices.

At the level of research institutions, the configuration of ethics review and research oversight mechanisms varies considerably, especially for non-interventional studies. Some research activities that concern only data processing (and do not involve samples, interventional procedures, or medication intake by patients) require assessment by Data Access Bodies (DABs), Data Access Committees (DACs) or Data Governance Boards (DGB) specifically appointed for this task, while in other cases assessment is carried out solely by ECs.[40] In other instances, pursuant to the decentralized approach introduced by the GDPR,[41] the assessment of data protection issues is carried out by researchers and research organizations themselves, in the form of a risk assessment supported by a Data Protection Officer (DPOs) and the institution's legal department, potentially through a Data Protection Impact Assessment (DPIA).[42] These differences in approaches may lead to discrepancies in decisions regarding the need for valid consent and whether consent is required even when alternative legal bases are available. Indeed, where a DGB or even a national authority (such as a Data Protection Authority, DPA) allows data processing without consent, but the EC maintains a consent requirement for personal data processing despite the availability of alternative legal bases, conflicts between institutions and their respective assessments may arise.

(3) Furthermore, discrepancies arise regarding what counts as valid consent standards and, notably, the permissible use of broad consent. In research ethics guidance and legislation—from the CIOMS guidelines (10 and 11) to the Declaration of Taipei, through to the EU Clinical Trial Regulation (Recital 29, Article 28(2))[43]—the use of broad consent, allowing data use for research purposes not specifically identified at the time of data collection, has long since been established. Conversely, under the GDPR, the use of broad consent is challenged and contested. Recital 33 of the GDPR *prima facie* appears to support the use of broad consent where the

40 Sanchini et al. (2023). It should be noted that in some countries DGBs or DACs are often institutional boards without a legal mandate (eg, Italy), whereas in others (eg, Germany) they do have one. Conversely, RECs have a legal mandate in many countries defining what falls under their responsibility.

41 Luca Marelli & Giuseppe Testa, *Scrutinizing the EU General Data Protection Regulation*, 360 Science 496–498 (2018).

42 For instance, in Denmark, universities need a security and a DPIA by research project which the researcher does together with dedicated, expert staff from the university.

43 Note that the consent mentioned in art. 28 Clinical Trial Regulation is not consent for data processing but consent to participate in research, as the European Data Protection Board has also clarified in its Opinion 3/2019, para 15/16.

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requirement of specific consent for specific research purposes at the time of data collection cannot be met, as in the case of biobanking. However, Recital 33 is unclear as to whether this permission is limited to the purposes of the original data collection or extends to future, as yet unspecified, research purposes.[44] The European Data Protection Board (EDPB) has subjected Recital 33 to a 'high degree of scrutiny' and, in practice, adopted a much stricter interpretation.[45] Additionally, broad consent may be seen as challenging the standards for valid consent, which according to the GDPR should be clear, concise, specific and granular, freely given, and revocable.

(4) A final challenge arises from the fact that the right to refuse consent to participate in research and the right to withdraw consent to data processing, both key rights for individuals, may conflict with other interests, such as researchers' interest in continuing to process personal data for research purposes.[46] Different regulatory frameworks may deal with these issues in different ways, thus leading to further fragmentation of requirements and approaches. A specific case in point is represented by the upcoming implementation of the EHDS Regulation. As outlined above, while the EHDS introduces a right to opt out, this right is limited to opting out of data uses taking place within the EHDS framework and does not amount to a general opt-out that would prevent all secondary uses of a citizen's health data. As such, this provision risks generating additional uncertainty for researchers, research participants, and oversight bodies alike, and may intensify conflicts between ECs, DABs, and DPAs as to the role, necessity, and scope of consent in health research governance.[47]

While these challenges have been noted in current scholarship addressing the tension between research ethics and GDPR consent, to the best of our knowledge, no study has yet carried out a comprehensive, multi-country, practice-oriented analysis of how these dual consent regimes are interpreted, operationalized, and possibly reconciled across different institutional settings and research practices, particularly in light of the emerging EHDS framework. This paper addresses this gap by examining how tensions between consent to participate in research and consent to data processing materialize in concrete governance practices, with the aim to clarify the implications of divergent consent requirements for researchers and oversight bodies, and to contribute

44 See R. Becker et al., *Purpose Definition as a Crucial Step for Determining the Legal Basis Under the GDPR: Implications for Scientific Research*, 11 1–30 J. Law biosci. (2024).

45 EDPB (European Data Protection Board). 2020. Guidelines 05/2020 on consent under Regulation 2016/679, https://edpb.europa.eu/sites/edpb/files/files/file1/edpb_guidelines_202005_consent_en.pdf. Dara Hallinan, *Broad Consent Under the GDPR: An Optimistic Perspective on a Bright Future*, 16 Life Sci. Soc. Policy (2020). Luca Marelli & Giuseppe Testa, *Scrutinizing the EU General Data Protection Regulation*, 360 Science 496–498 (2018).

46 See Marcu Florea, *Withdrawal of Consent for Processing Personal Data in Biomedical Research*, 13 Int. Data Privacy Law 107–23 (2023).

47 See Marelli, L. et al. (2026). *Governing the European Health Data Space (EHDS). Ethical and Political Perspectives on the TEHDAS2 Public Consultation.* POLHIS White Paper 2026/01.

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Table 1. Description of use cases

A pharma company (acting as a data controller according to the GDPR definition) aims to conduct two non-interventional/observational studies to investigate efficacy and risks of various therapies for patients with infectious diseases in a real world setting, by checking two antibiotics already used in standard care. More in detail, the two studies are the following: (1) A non-interventional/observational study consists of re-using routine healthcare data, ie, patients-related data collected during a patients' hospitalization for the purpose of providing care after an injury. The study aims to assess whether the two antibiotics work on the selected set of patients in a real-life setting, or if antibiotic resistance is developed in clinical practice. No modification of care practice is carried out in order to conduct this study. (2) The second non-interventional/observational study consists of re-using research data that were previously collected from patients who, during hospitalization, were asked to participate in a research project for which consent for research participation as well as data processing was provided. So, under this study, the pharma company aims to use these data that were previously collected for research purposes. No change in the standard of care is carried out in order to conduct this study. The two non-interventional/observational studies will use data reported from public hospitals (located in Belgium, the Czech Republic, Finland, France, Germany, Italy, Poland, Spain, and acting as data processors). The hospitals will collect and transfer (pseudonymized) data to the pharmaceutical company for further analysis.

to ongoing debates on the design of coherent, proportionate, and ethically robust governance models for data-intensive health research in Europe.

V. COUNTRY EXPERIENCES—METHODOLOGY

To make our analysis of consent empirically tractable in view of the different requirements about consent existing across distinct types of research, two stylized (fictional) use cases have been identified (see Table 1). These use cases concern non-interventional/observational studies, premised on secondary uses of data already collected for a different purpose. The choice of these two use cases is motivated by the following considerations. First, we sought to focus on two scenarios that, in most cases, differ markedly in terms of consent arrangements, namely the re-use of routine healthcare data and the re-use of data originally collected for research purposes. Second, we focus on retrospective observational research, rather than interventional studies, since the former typically raises more complex issues regarding the alignment of consent; by contrast, in most countries, provisions governing consent to participate in interventional research and consent to data processing tend to be more closely aligned. Third, pragmatic considerations of feasibility guided our selection, as covering all types of research would have been unfeasible. Finally, these use cases are particularly prevalent in contemporary health data ecosystems and lend themselves to cross-country comparison, thereby enhancing the empirical and policy relevance of the analysis, especially in light of large-scale data initiatives such as the EHDS.

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Table 2. Guiding questions addressed in country reports

(Q1) Legal bases: What is the legal basis to adopt for reusing healthcare data and for reusing research data? What is the legal basis for disclosing data to the pharmaceutical company? Is official guidance being provided to address these questions?
(Q2) Consent to participate in research and information requirements: Does the public hospital need a specific informed consent for the participation/enrolment of patients (ie, consent to participate to research) in the retrospective study, and how researchers can duly inform research participants about both research purposes and data processing (information requirements) especially in cases where consent is NOT needed?
(Q3) Broad consent: Is broad consent allowed in the country? What falls under the rubric of 'broad consent,' and how 'broad' is it?
(Q4) Potential conflicts between consent denial and withdrawal, and use of data for research purposes: What happens if participants respond negatively to the request for consent or withdraw their consent (both refusal to give consent of participation in research and refusal or withdraw of GDPR consent): can researchers still use the data for research purposes, based on another available legal basis? How to solve the possible conflict between the right to withdrawal of consent versus the possibility to use data for research purposes?
(Q5) Relevant oversight bodies and public authorities: What are the oversight bodies and public authorities involved in the authorization process for conducting a non-interventional study or retrospective research in the country (ECs, DPAs, . . .)?
(Q6) Differences between the law and practice: Are there any discrepancies among legislative provisions, the position of the DPA, and ECs' practices regarding consent (eg, if in the country a legal basis alternative to consent can be used, but oversight bodies such as ECs insist on requiring consent)? If so, how are these discrepancies addressed?
(Q7) Impact of the EHDS: Is the EHDS expected to change the current practice in the country? If so, how?

In what follows, we describe how different European countries deal with such use cases, and specifically how different issues, outlined in Table 2, are addressed in each country with respect to such use cases. The choice of countries included in the study was intended to account for both geographical diversity within Europe and substantial differences in national approaches to consent.

Findings were derived from standardized country reports prepared by national teams using a common set of questions (Table 2). The full country reports are provided in Appendix 1. Each report was authored by one or more national experts with substantial experience in the regulation of health data, including academic research, healthcare practice, oversight and supervisory authorities, and ministerial or regulatory bodies, as well as in-depth familiarity with national and European legal frameworks and data governance practices. Relevant issues were identified through iterative rounds of discussion within the BBMRI-ERIC Code of Conduct for Health Research Expert Group, which has held regular meetings since 2022 to examine practical and regulatory challenges arising from the application of the GDPR in health research.

This study nonetheless has important limitations. It does not cover all European countries, nor does it encompass all types of health research. In addition, the analysis

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reflects the legal and regulatory frameworks in force as of early 2026; given the dynamic nature of health data governance and data protection law, subsequent legislative or interpretive developments may affect the continuing validity of some 'specific' findings (though, we contend, not undermine the general argument of the paper).

V.A. Country Experiences — Findings

A comparative overview of the research findings is provided in Table 4. Here, we present and discuss the main issues that emerge from the analysis of country reports (provided in Appendix 1).

1. Consent for data processing: different legal bases and standards (use of broad consent)

Unsurprisingly, the countries considered in this study have different legal bases for observational studies, but also different standards on how valid consent for data processing should look like. In the first set of countries (Spain, Finland, and France), other legal bases beyond consent are generally available to re-use data previously collected for both routine healthcare and research purposes. In other countries (Belgium, Italy, and the Czech Republic), alternative legal bases are only available, under certain circumstances, for data previously collected for routine healthcare purposes; the re-use of research data is, instead, predicated on (re-) consent.

Specifically, in its national data protection law, Italy has adopted a provision allowing the 54 research hospitals accredited with the Ministry of Health (ie, the *Istituti di Ricovero e Cura a Carattere Scientifico*, 'IRCCS') to re-purpose for research the data originally collected for routine healthcare purposes, or collected and stored within the hospitals' biobanks (D.lgs 101/2018, Art. 110-bis comma 4); on the contrary, the re-use of data originally collected for research purposes would need the re-consenting of the participant. In Belgium, a guidance document adopted by the seven Belgian university hospitals[48] clarifies that failing to request re-consent for the re-use of data originally collected for research purposes could hurt patients' trust, as 'sensitive data are further used for purposes beyond the expectations created in patients based on the original consent form.' In the use case discussed in this paper, the re-use of research data collected originally on the basis of consent would, therefore, require re-consenting from the participants. In the Czech Republic, alternative legal bases are available based on the research exemption in the Act on Personal Data Processing.[49] However, its application requires a detailed case-by-case assessment (eg, type of research, goals, funding, safeguards put in place, or the legitimate expectations of data subjects). Finally, a third set of countries (Poland, Germany, and Italy for research institutions other than accredited research hospitals - IRCCS) premise the re-use of data for observational research (such as in the two use cases of this paper) on consent as the only allowed legal basis.

In addition, consent standards also differ significantly across countries, and the admissibility of broad consent as a valid legal basis (or not) represents a significant point of attention in this regard. In most countries included in the study (Belgium,

48 See *ruzb chab—Common Position Establishing a Framework for Secondary Use of Real-World Data (Routinely) Collected in Hospitals*, https://www.univ-hospitals.be/common-position-establishing-a-framework-for-secondary-use-of-real-world-data-routinely-collected-in-hospitals/ (accessed Aug. 8, 2025).

49 Act No. 110/2019 Coll.,on Personal Data Processing, as amended, § 16.

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the Czech Republic, Poland, and Italy), broad consent is not allowed as a valid legal basis for re-using data in observational research, mostly in light of the EDPB guidelines on consent that have enforced a strict interpretation of Recital 33 of the GDPR. In the Czech Republic, for instance, the term 'broad consent' is not legally defined, though in practice it is used to describe consent given for research in certain fields (eg, oncology research) accompanied by information on the possible purpose, nature, risks, or benefits of such broad types of research. In this country, broad consent as a legal basis is assumed not to be applicable. Czech national legislation does not impose any other conditions for consent beyond the scope of Art. 7 of the GDPR. The Czech DPA also stresses that consent must be specific and does not provide further guidelines on consent besides referring to the EDPB guidelines on consent.[50] Conversely, while not explicitly mentioned in the national legislation, broad consent in France has been tolerated by the national DPA, provided that a set of conditions are met (including providing information before and during the study). Spain as well as Germany have adopted broad consent as a valid and standard legal basis for most types of research (for a discussion on the case of Germany, see below).

2. *Differing requirements around consent for participation in research*

Likewise, different provisions are in place across countries concerning requirements for consent for participation in research. In a number of countries (Belgium and the Czech Republic), requirements concerning consent for participation in (observational) research are provided by law. The Belgian law explicitly distinguishes between informed consent as a legal basis for the processing of personal data and informed consent as a legal and ethical requirement to participate in a study (ie, consent for participation in research). For non-interventional studies, in general, informed consent is required, ensuring participants understand the purpose, risks, and data usage of the study. However, an EC can approve a waiver if the study poses minimal risk to participants or if obtaining consent is impractical. For retrospective research with healthcare data, no research ethics consent would be required, but the favorable opinion of an EC might be needed. For retrospective research with data collected for a previous research study, consent for participation in research must be collected again, unless the favorable opinion of an EC provides an exemption. The Czech law does not require specific informed consent for the enrollment of participants in non-interventional research, as regulation focused specifically on non-interventional research does not exist. However, consent for access to data in medical records for the purpose of research (which can also be broad) is needed under the Act on Health Services, if the data to be used are not anonymized.[51] Furthermore, from an ethical point of view (but also from a legal point of view, as informed consent may be seen as an appropriate safeguard to protect data subjects' rights and interests under the GDPR) specific informed consent may be required when the sponsor of observational research is a pharmaceutical company and the intent of the research is commercial, and we cannot presume the reasonable patients' expectation of future use of their data for commercial research. Concerning

50 See *Office for Personal Data Protection—EDPB Guidelines*, https://uoou.gov.cz/en/edpb-guidelines (accessed Aug. 12, 2025).

51 Art. 55b and 65 of Act No. 372/2011 Coll., on health services and conditions of their provision (Health Services Act).

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the re-use of research data, the interpretation of the initial consent is crucial. If it covers participation in further research studies and describes these studies (at least broadly by field of research, purpose, nature - academic, commercial), then it might be sufficient to also cover research data re-use and no re-consent is needed.

In other countries, there are no binding legal requirements concerning consent for participation in research, and the issue is regulated through a mix of soft law requirements and institutional provisions enacted by ECs. In Finland, there is no national legal requirement for consent for patient enrolment in a non-interventional study. In Italy, ECs have traditionally enforced an obligation for obtaining consent as a prerequisite to carry out observational studies, and it wasn't until recently that the National Coordination Center for ECs suggested that alternative approaches to consent, with a strong role for oversight bodies, could be better suited to the needs of observational research.[52] In practice, nevertheless, Italy has traditionally maintained a strong focus on consent for participation in research. This approach is in line both with the national data protection legislation (the sole binding provision that applies to observational research) and the rulings of the national DPA, which has traditionally adopted a strict approach based on consent, and also with the approach of many research institutions, which may find it administratively easier to adopt a standard consent-based approach for all their studies, even those for which consent may not be required as a legal basis. In France, consent is not required, though research participants must be informed about the research and data processing. Finally, as we discuss more in-depth below, a country like Germany has shaped its consent requirement around those enshrined in data protection law exclusively, and thereby does not differentiate between consent to data processing and consent to participate in research. In Poland, consent is based on the general data processing regulations under the GDPR. Additionally, research funding institutions (eg, the National Science Centre) or entities where research is conducted, such as universities, require that consent be accompanied by an opinion from an EC, which is most often established as an internal unit at research institutes or universities.

3. *Transparency requirements*

Transparency requirements also differ across countries, albeit to a less varied degree. All countries have GDPR requirements (pursuant to Art. 13 and 14) on information provision in place. In addition to GDPR requirements, other countries implement additional or more fine-grained measures to enhance transparency, especially for data repurposing within secondary research. In Germany, transparency requirements are high in order to balance the broadness of the consent and make sure that research participants can decide, at any time, if they are still in agreement with the research being conducted or if they wish to withdraw. In Belgium, the right to information is of particular importance in the framework established by the Belgian university hospitals. Transparency should be achieved by combining different approaches to information provision: (i) general information about the secondary use of data (eg, provided in the hospital's privacy policy and information brochures), (ii) individually

52 See *CCNCE*, https://www.aifa.gov.it/documents/20142/1808580/Criticita_etiche_ricerca_osservazionale_06.04.2023.pdf (accessed Aug. 12, 2025).

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provided information on the specific projects that use data concerning patients (eg, ideally via digital solutions that allow patients to obtain direct access to their health record), and (iii) in the case of prospective (interventional) experiments, individually provided information about the processing of personal data which should be provided together with the informed consent for participation in the study. In France, prospective participants are to be informed about the research project prior to its start, both with regard to the research study (provision related to the observational studies) and the processing of (health-related) personal data (as foreseen in the GDPR).

4. The role of oversight bodies (and ECs specifically)

In addition, the role of ECs varies significantly. In some countries (Italy, Belgium, and Spain) their approval is required for every study involving humans or personal data, as it is seen as a necessary oversight measure where, for instance, research can be carried out without consent.

In Germany, ECs are explicitly charged, among other tasks, with the responsibility of checking whether all GDPR rules have been considered and if research participants are appropriately informed. There may be cases where a local EC disagrees with the submitting researcher about the scope of a legal basis and requires consent for what it assumes to be not covered. But these should be considered as common debates about the interpretation of the law. No EC requires consent on top of a clearly existing legal basis. ECs are organized in an association and issue aligned positions and templates. They maintain a constant dialogue with the research departments of the DPAs throughout Germany.

In other countries (eg, Poland, the Czech Republic, and Finland), no legal obligation exists to seek ethics approval for non-interventional studies, and ECs do not have an explicit legal mandate to suggest legal bases or require their changes. However, in practice, ECs' approval (or, in the case of Poland, by a 'research committee' appointed by research institutes) is often required under local soft law regulations, or in light of the necessity to be able to prove ethics clearance to have research published in scientific journals. In these cases, the review of legal bases is part of the overall ethics review process, and it is possible to identify situations where ECs find appropriate legal bases that differ from the ones identified by researchers. In such cases, while researchers can theoretically decide not to follow the opinion of the EC (as the GDPR clearly states that it is the controller's responsibility to ensure compliance of data processing with the Regulation), in practice, the EC's refusal to give approval is seen as a 'stop' sign for research.

5. Current status of national EHDS implementation

At the time of writing, the preparedness of European countries concerning the EHDS shows great variation. Some countries have implemented measures to prepare for the EHDS. Belgium, for instance, has already established its national HDAB, ie, the Belgian Health Data Agency (HDA).[53] With respect to the HDA's relation to Ethical Committees, the HDA will examine how it can contribute to harmonizing the operations of

53 The HDA was established by the law of Mar. 14, 2023 (hereafter the HDA Law) as an ASAA (administrative service with accounting autonomy) with enterprise number 0800309782. The law is available at https://www.ejustice.just.fgov.be/eli/wet/2023/03/14/2023041135/staatsblad. Last accessed 17 April 2026.

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existing ECs in collaboration with hospitals to ensure a consistent evaluation process.[54] Preparatory work for the implementation of the EHDS is underway in Poland. A pilot project led by the Medical Research Agency is scheduled to begin later in 2026. It will allow Polish scientists to access medical data collected at Regional Digital Medicine Centers. The Medical Research Agency's project will be based on the Integrated Analytical Platform, managed by the Ministry of Digital Affairs. The basis for data collection by the Regional Digital Medicine Centers is consent to the processing of shared analytical data by the Medical Research Agency or entities designated by it for the purposes of future scientific research or research and development.

For most countries, though, it is not yet clear whether and how the current practices related to consent for re-use of personal data for scientific research will change. In the Czech Republic, implementing legislation will be prepared by the Ministry of Health and is expected to be published in 2026. Analysis of conditions for the secondary processing of health data is currently being conducted by the Ministry of Health, while further details are not being publicly available at the time of writing.

In Finland, implementation is ongoing and the Ministry of Social Affairs and Health has set up a steering group and two working groups to aid in this task. For the secondary use of health data, Finland already has an infrastructure very similar to what the EHDS Regulation requires, with data permit authorities governing access to health and social care data for research and other secondary use purposes.[55] Finland is also coordinating TEHDAS2, the joint action preparing the ground for the harmonized implementation of secondary use of health data in the EHDS.[56]

In light of the findings of this paper, timely and thoughtful implementation appears as a necessary prerequisite for the smooth functioning of the EHDS, as there are potential ambiguities that should be addressed at the national level. For example, it should be clarified how to proceed in the case of the withdrawal of consent to participate in research (if required by national laws, ECs, or the HDAB in our cases), or in the case of the withdrawal of GDPR consent. Such withdrawals cannot be considered as an opt-out from secondary processing and should be assessed separately. In general terms, it is important for national states to focus on clarifying the interplay between some newly established EHDS mechanisms, including opt-out, and existing ethical and legal mechanisms, which is paramount to avoid suboptimal ethical approaches as well as legal uncertainty.

VI. DISCUSSION

VI.A. Preliminary Summary of Findings

Through a comparative analysis of consent requirements and approaches in eight European countries, this work has identified the following key emerging issues:

54 See HDA Frequently Asked Questions—'How does the HDA relate to the ethical committees?,'https://www.hda.belgium.be/en/faqs/how-does-hda-relate-ethical-committees (accessed Aug. 12, 2025).

55 See https://stm.fi/hanke?tunnus=STM174:00/2025

56 https://tehdas.eu/ (It should be noted that 'TEHDAS' comes from Towards European Health Data Space, but also means factory in Finnish).

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- The use of legal bases for observational studies largely differs across countries, also in relation to the types of data repurposed for secondary uses (repurposing of data collected in healthcare settings versus reuse of data originally collected for a different research project).
- When consent is used as a legal basis, standards also differ considerably—notably regarding the admissibility of broad consent: while some countries legally sanction the use of broad consent, others tolerate it in practice (in the absence of defined legal provisions), and some others do not allow it.
- As to consent to participate in research ('ethics' consent), almost all countries (except for Germany) maintain a distinction between this type of consent and consent as a legal basis for data processing. Yet, while some countries have clear requirements in place regulating the use of consent for participation in research, others do not have defined provisions in place. This situation ends up endowing oversight bodies, notably ECs, with a 'quasi-policymaking' role (ie, ECs step in to fill the vacuum left by legislation, enforcing their own, and sometimes differing, requirements as to the use of consent to participate in research).
- Relatedly, across these countries, ECs do not have an explicit legal mandate to require the use of specific legal bases. However, as the ECs' approval may be needed (either under soft law regulations, or in order to have research published in scientific journals), ECs often retain, in practice if not legally, the ability to enforce specific legal bases, such as consent.
- All countries have GDPR requirements (pursuant to Art. 13 and 14) on information provision in place. In addition to GDPR requirements, other countries implement additional or more fine-grained measures to enhance transparency, especially for data repurposing within secondary research.
- As of early 2026, we witness a varied level of readiness towards EHDS implementation across European countries. No definitive arrangements have been made, in most countries, with regard to how opt-out mechanisms will be implemented, and how these will interplay with existing consent requirements.

In what follows, we further problematize and discuss these key issues. Notably, we further thematize the distinction between 'monist' versus 'dualist' approaches to consent; we then focus on challenges that emerge in those jurisdictions adopting 'dualist' approaches to consent; and we then ask what may be at stake in light of the upcoming implementation of the EHDS Regulation.

VI.B. 'Monist' Versus 'Dualist' Approaches to Consent

Importantly, the points discussed above lead to the observation that the fundamental conceptual issue on which this work is premised—namely whether we can legitimately speak (or not) of different types of consent—is addressed in different countries in distinct ways. On the one hand, Germany stands out in light of its 'monist' approach to consent. From the German perspective, it is the standpoint of the research participant that counts, and the principle is: 'one choice, one tick box.' A 'yes' means 'I agree to take part in the study and in the processing of my data for this purpose' under all applicable laws, and hence, from the perspective of the research participant, it would make no conceptual sense to distinguish between two different authorizations for the

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same procedure. This is why Germany does not present two different consent forms to the research participant, one being consent to the processing of personal data and the other consent to participation in research. Participants instead declare that they agree to take part in the research project—including the processing of their data for the purpose of the project. This one consent form has of course to comply with all applicable laws and ethical standards, eg, the Helsinki Declaration as well as the GDPR. Thus, the legal expert will examine the consent document from all legal perspectives; even eg, ownership issues relating to biological samples will be addressed in the same document. The German approach—which conflates, more in practice than in legal terms, what, in other countries, is recognized as two distinct types of consent—is in line with the type of 'broad' consent, which has been used for many years as the legal basis in biobanking and beyond, for example to access routine patient data from the network of all university hospitals.[57] This consent template has been agreed within a two-year process involving research and care institutions, all DPAs, and ECs in Germany. The purpose of data use is defined as 'research to improve prevention, diagnosis and treatment.' Research participants are provided with different options to choose from, but specifically excluding the industry from using data is not an option. This solution, while not exempt from debates, has been seen by the legislator and the oversight authorities as preferable to either an opt-out or an alternative legal basis that prevents research participants from having a say and providing authorization. As the EHDS has now introduced an opt-out as a general approach, the discussion has shifted to how to implement this principle in a meaningful manner and to integrate this option into research consent forms. It will presumably render the consent templates more complex instead of reducing complexity.

On the other hand, most countries (Belgium, Italy, the Czech Republic, Poland, and Spain) adopt a 'dualist' approach to consent, making an explicit distinction between informed consent as a legal basis for the processing of personal data ('GDPR consent'), and informed consent as a legal and ethical requirement to participate in a study ('ethics consent'). In turn, countries that make a distinction between the two types of consent may face several challenges, the most relevant of which appear to be the following:

- Different standards exist between 'GDPR consent' and 'ethics consent': in the Czech Republic, broad consent is not allowed as a valid legal basis. Yet, broad consent for participation in non-interventional studies is generally admissible (though its admissibility in particular types of research—including commercial research—requires more detailed and case-by-case assessments). This leads to potential conflicts where consent is used as a legal basis, as researchers might be put in a difficult position where broad consent is admissible as a prerequisite for participation in a non-interventional study, yet not as a legal basis for data processing. In such cases, researchers must prove other legal bases than broad consent (eg, explicit consent, scientific research exemption).

57 See Zenker et al., *Data Protection-Compliant Broad Consent for Secondary Use of Health Care Data and Human Biosamples for (Bio)medical Research: Towards a New German National Standard*, J. Biomed. Informatics, 131, 104096 (2022). The consent template is available at https://www.medizininformatik-initiative.de/sites/default/files/2020-11/MII_WG-Consent_Patient-Consent-Form_v1.6d_engl-version.pdf.

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In other countries, such as Italy, where consent is (or has traditionally been) the only legal basis for certain types of research, the two types of consent are *de facto* conflated, even though, in practice, participants receive two different templates, a privacy notice and a 'GDPR consent,' on the one hand, and information about the study and 'ethics consent', on the other hand. However, while broad consent has been generally considered admissible by ECs, the national DPA has traditionally argued against its use. This creates a regulatory gray zone, which different institutions navigate in different ways.[58]

- 'Ethics consent' is required, but other legal bases for data processing are available. In the Czech Republic, where legal bases other than consent are available for observational research under certain circumstances, it is unclear how to proceed in the case of a withdrawal of consent to participate in research (ie, the withdrawal of 'ethics consent'). In cases where the processing of personal data is necessary for research (as are the two use cases) the separation of consent to data processing and consent to participation in research seems to be artificial. However, from a regulatory perspective, these two types of consent are two different requirements covered by different rules (ethics/medical law versus data protection law). Contrary to the GDPR, the law does not state explicitly how to handle data in the case of a withdrawal of consent to participation in research. It is, therefore, unclear which (if any) processing operations are allowed. In the two cases considered in this paper, where research is dependent on data processing, a recommendation can be made to ask the patient explicitly for his/her authorization regarding data processing.

At a theoretical level, our findings bring into sharp relief the enduring tension between 'monist' and 'dualist' conceptions of consent, as well as the internal frictions that characterize the latter. In monist approaches, exemplified by the German case, normative priority is accorded to an individual's agreement to participate in research: insofar as data use is understood as an integral component of (data-intensive) health research, the respect for autonomy is taken to entail a corresponding degree of individual control over data, making it conceptually unnecessary—and in fact misleading—to distinguish between different forms of consent.

By contrast, in all other countries examined, dualist conceptions of consent persist, insofar as consent is not understood from the standpoint of the individual research participant, but rather conceptualized as the procedural instantiation of distinct normative principles deriving from two different regulatory traditions, namely research ethics and data protection law. In these contexts, consent is not treated as a single, participant-centered act that exhaustively legitimizes 'both' research participation and data use, but rather as the outcome of *separate* normative regimes that attribute different meanings, functions, and requirements to consent, depending on whether it relates to participation in research or to the processing of personal data. Dualist approaches thus foreground the differentiated functions and justificatory logics of consent: while consent to participate in research primarily serves to safeguard bodily integrity and

58 For an example, see Virginia Sanchini et al., *A Comprehensive Ethics and Data Governance Framework for Data-intensive Health Research: Lessons from an Italian Cancer Research Institute*, 32.1 Account. Res. 59–76 (2025).

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individual autonomy, consent to personal data processing operates within a regulatory framework aimed at ensuring lawful data processing, and protecting fundamental rights, ensuring transparency and purpose limitation, preventing arbitrary or abusive data practices, and enabling accountability within complex data governance systems.

Within such dualist frameworks, consent effectively functions as a 'boundary object,' that is, a concept sufficiently flexible to sustain coordination across normatively distinct regulatory regimes while accommodating divergent meanings and purposes.[59] This very flexibility, however, also helps explain the persistent tensions identified in this study, as the coexistence of different consent regimes translates into divergent consent requirements and expectations in practice.

More fundamentally, our analysis thus suggests that current difficulties surrounding consent do not merely arise from regulatory fragmentation across jurisdictions, but stem from a deeper and prior ambivalence inherent in the concept of consent itself, which is simultaneously used to denote distinct normative acts and legal functions. As we argue in the next section, unless this underlying ambivalence is explicitly addressed, even harmonized regulatory frameworks, such as the EHDS risk reproducing, rather than resolving, the structural problems discussed in this paper.

VI.C. Expected Impact of the EHDS

How, then, is the EHDS expected to impact these long-standing issues surrounding consent? As discussed above, the EHDS will introduce harmonized legal rules for the secondary use of health data. Accordingly, all data access requests falling within the scope of the EHDS framework for permitted secondary uses, including research, will rely on harmonized rules, coupled with the possibility for individuals to opt out. At the same time, however, not all secondary uses of health data will take place within the EHDS framework. For those uses occurring outside the EHDS, fragmentation of legal bases is, therefore, likely to persist. Moreover, as of early 2026, the opt-out mechanism itself remains a relatively indeterminate concept. While the European Commission's Joint Action TEHDAS2 has issued guidelines outlining a general framework for opt-out implementation,[60] key operational details remain unresolved, and Member States retain significant discretion in shaping opt-out mechanisms at the national level. This discretion may lead to divergent national implementation pathways, thereby reproducing forms of regulatory fragmentation—precisely the ones that the EHDS set out to overcome. Additional sources of fragmentation may arise with regard to the governance of specific categories of data, particularly sensitive data. As currently framed, the Regulation does not appear to preclude Member States from introducing opt-in requirements for certain data types, such as genetic data, omics data, or biobank data, potentially resulting in uneven consent and access regimes across Europe. Governance mechanisms, more broadly, are also likely to remain fragmented across Member States, most notably with respect to data access review procedures and ethics reviews: it remains unclear how ethical oversight will be operationalized

59 Star, Susan L. & James R. Griesemer. *Institutional Ecology, "Translations," and Boundary Objects: Amateurs and Professionals in Berkeley's Museum of Vertebrate Zoology*, 1907–39. 19 Soc. Stud. Sci. 387–420 (1989).

60 *Draft Guideline for Health Data Access Bodies on Implementing Opt-Out from the Secondary Use of Health Data* (TEHDAS2 Joint Action draft guideline, Public Consultation, Sept. 30 – Nov. 30, 2025), available at tehdas.eu.

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Table 3. Overview of challenges in reconciling EHDS with existing frameworks

Legal bases & consent	EHDS opt-out vs consent regimes	EHDS allows secondary use unless individuals opt out, while some national frameworks (and research ethics) rely on consent to participate and/or GDPR consent. This may create conflicts when a data subject refuses use but EHDS would otherwise allow it.
Individual rights	GDPR right to object vs EHDS opt-out	These mechanisms differ in scope and legal effects. It is unclear how they interact and which prevails in practice.
National variability	Divergent opt-out models and stricter requirements	Member States may implement opt-out differently (eg granular vs blanket) and may impose stricter national requirements, including requiring consent for certain special categories of data.
Ethics review	Divergent national requirements	Ethics review processes may remain heterogeneous across countries, despite the EHDS framework.
Procedures & access	Parallel authorization pathways	Risk of duplicative procedures when the same dataset is accessed within and outside the EHDS system (eg EHDS permit vs national or institutional approvals).

within the EHDS under national provisions,[61] and the most plausible scenario is one in which some Member States retain ethics review requirements while others do not, thereby perpetuating cross-national divergence. As a result, notwithstanding the EHDS's declared ambition to harmonize health data legislation for secondary uses across Europe, and despite the significant progress represented by the introduction of a standardized legal basis, substantial challenges seem to remain unresolved (for an overview, see Table 3).

As noted in the preceding section, however, the most significant challenge lies elsewhere. It remains unclear how the EHDS will address the fundamental tensions that characterize countries adopting consent practices premised on dualist conceptions of consent. In contexts where consent under research ethics and consent under data protection law diverge, complex questions persist as to how these regimes will interact. In particular, it is unclear what will occur when a research participant has explicitly 'not consented' to the secondary use of their data, while the EHDS nonetheless provides a legal basis for such use. Likewise, the interplay between the EHDS and other applicable ethical and legal provisions should also be carefully examined, for instance, when it comes to the practical implications of the right to withdraw consent or the right to object to data processing.

61 EHDS Regulation, Art. 67(2)(j).

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Table 4. Synoptic comparison of findings

	Q1. Legal bases for the use case	Q2. Consent for participation in research and information provision	Q3. Broad consent	Q4. Alternative legal bases in the case of consent denial or withdrawal	Q5. Oversight bodies	Q6. Differences between legal requirements and the practice of oversight bodies	Q7. Foreseen impact of the EHDS
Belgium	- All GDPR legal bases available - Consent not the preferable legal basis for research - But: (re-)consent needed for (i) secondary use of research data originally collected on the basis of consent, and (ii) purely commercial research devoid of public interest	- Retrospective research with healthcare data: no consent needed, only ethics approval - Retrospective research with research data: consent is needed unless EC provides a waiver (as it is assumed that not asking for consent would hinder participants' trust) - General and individual-level information to be provided	- Not allowed	- No alternative legal basis can be used	- EC approval required	- ECs may have different approaches towards preferred legal basis	Not yet clear
Czech Republic	- Different legal bases available under certain conditions; - In practice, consent is likely to be the preferred option in this specific case	- Consent preferred for healthcare data re-use in commercial research - Consent not needed if research data re-used is covered by original consent - GDPR applies for information provisions	- The term 'broad consent' is not legally defined - It is assumed that broad consent as legal basis is not applicable (pursuant to EDPB guidelines)	- Not possible to 'silently migrate' towards another legal basis - It is unclear how to proceed in the case of a withdrawal of consent to participate in research (ie, withdrawal of 'ethics' or 'Helsinki consent')	- No EC approval legally required for non-interventional studies, local soft law regulations apply (and EC approval is often required)	- ECs do not have explicit legal mandate to suggest legal bases or require their changes. However, in practice, the review of legal bases is part of the overall project review. There could be situations where EC finds appropriate different legal bases than the researchers (which, depending on the situation, may or may not have the possibility to disregard the EC opinion)	Expected to influence the rules for electronic health data reuse significantly

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Table 4. Continued.

	Q1. Legal bases for the use case	Q2. Consent for participation in research and information provision	Q3. Broad consent	Q4. Alternative legal bases in the case of consent denial or withdrawal	Q5. Oversight bodies	Q6. Differences between legal requirements and the practice of oversight bodies	Q7. Foreseen impact of the EHDS
Finland	- Different GDPR legal bases available	- No national legal requirement for consent for patient enrolment in a non-interventional study	Undefined, but relatively broadly defined research plans are typically accepted in ethics consents and still considered informed; consent is seldom used as a GDPR legal basis	- Secondary use is typically not based on consent. GDPR right to object applies	- EC approval is typically a prerequisite for getting samples/data from biobanks only. Other DAB (eg, Findata) maintain oversight on access request for other data types (eg, register data)	- While consent is generally not considered to be the preferred legal basis for health research, an EC could insist on specific legal bases for a research project where their statement is required by law	- Still unclear (although Finland's model is taken as a blueprint for the EHDS)
France	- Different GDPR legal bases available	Consent not required, although research participants must be informed about research and data processing	- Broad consent not mentioned in national legislation but allowed by DPA under certain conditions (fulfillment of information requirements; transparency)	- Not clear under the legislation if the data already collected by the sponsor can or cannot be further processed. The common practice is to restrict the use of objected patients data collected before the objection for the statistical analysis of the project to not bias the analysis, provided that it is already foreseen in the information notice	- If study is compliant with Cnil guidance (MR-004), no DPA involvement is foreseen. EC opinion required for non-interventional studies	- Not clear under the legislation whether ECs may require consent as legal basis, even though other legal bases are permitted by law. Cnil has attempted to clarify this issue to ECs	- Still unclear - The French model is being considered by other countries as a potential solution for implementing the EHDS opt-out process

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Table 4. Continued.

	Q1. Legal bases for the use case	Q2. Consent for participation in research and information provision	Q3. Broad consent	Q4. Alternative legal bases in the case of consent denial or withdrawal	Q5. Oversight bodies	Q6. Differences between legal requirements and the practice of oversight bodies	Q7. Foreseen impact of the EHDS
Germany	- (Broad) consent (if applicable) provided at the moment of data collection	- (Broad) consent (if applicable) provided at the moment of data collection (no distinction between types of consent) - Individual-level information as well as information through public portal to be provided	- Yes (it is standard consent model)	- No alternative legal basis can be used if the participant says 'no'	- DPOs and ECs, DPA only for specific (large-scale) projects	- No EC can circumvent legal requirements	The EHDS will introduce opt-out instead of consent for all applications to access data through the EHDS infrastructure
Italy	- Other legal bases may be available if research is carried out by research hospitals accredited with the Ministry of Health (ie, IRCCS) or if obtaining reconsent proves impossible or exceedingly burdensome	- Traditionally enforced by ECs	- Generally not allowed in light of strict approach by national DPA	- No alternative legal basis can be used if participant objects and withdraws consent	- ECs approval required - Additional bodies (eg, DGB) introduced by single institutions as additional layer of oversight	- National DPA traditionally maintains a strict approach, and ECs often maintain an equally cautious approach accordingly	- EHDS preparedness level is low

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Table 4. Continued.

	Q1. Legal bases for the use case	Q2. Consent for participation in research and information provision	Q3. Broad consent	Q4. Alternative legal bases in the case of consent denial or withdrawal	Q5. Oversight bodies	Q6. Differences between legal requirements and the practice of oversight bodies	Q7. Foreseen impact of the EHDS
Poland	- Consent - If the company has the status of a research institute or university, another legal basis is available but only in the case of non-identifying data	- Consent - GDPR applies for information provisions	- Not allowed (even though the specificity of consent may refer, for instance, to the scope of operation of a biobank or institution)	- No alternative legal basis can be used	- No EC approval legally required for non-interventional studies, local soft law regulations apply (and EC approval is often required or the approval of research committee is required)	Although the requirement to obtain a bioethics committee opinion for research involving personal data is not legally mandated, it is often a requirement of the institution conducting the research or the funding institution. Despite the rather narrowly regulated conditions for the operation of bioethics committees, bioethics committees issue opinions on research involving patient data, including assessing consent to participate in the research and the processing of personal data	Not yet clear
Spain	- Different legal bases available	- GDPR applies for information provisions	- Yes	- No alternative legal basis can be used if research was based on consent	- ECs	- In general, the law does not foresee the need for consent for non-interventional studies, but ECs usually require it	

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VI.D. From Diagnosis to Regulatory Design: A Modest Proposal

As a modest proposal to chart the way forward, we suggest that any meaningful implementation of the EHDS must begin with a clear acknowledgment of the challenges identified and discussed above, particularly the structural diversity of national legal and ethical frameworks. Such fragmentation cannot reasonably be expected to disappear automatically with the introduction of the EHDS secondary use mechanism (see Table 3). Without careful national assessment and preparatory alignment, the risk is not the elimination of fragmentation, but its continuation under a formally harmonized European framework.

The Regulation establishes a harmonized access infrastructure, but several critical aspects remain within national competence. For instance, the implementation of the opt-out regime is left to Member States and may vary considerably, including through the introduction of granular opt-out models. Moreover, the interplay between the EHDS and existing national legal instruments, such as consent withdrawal or the right to object to data processing, remains insufficiently clarified. Member States may also introduce stricter measures and additional safeguards for particularly sensitive, yet highly valuable, categories of data, including genetic, omics, and biobank data.

In addition, in light of our comparative findings, the persistence of divergent and partially incompatible consent regimes across research ethics and data protection law can no longer be treated as a merely technical or transitional problem. Rather, it points to a structural deficiency in the current national and European regulatory landscapes governing health research. To avoid the persistence of a 'two-faced Janus' of consent—simultaneously grounded in research ethics traditions and data protection law—national and EU legislators should pursue a clearer conceptual and normative alignment between these regimes. This requires, at a minimum, an explicit acknowledgment that consent in the context of health research serves different functions, which should not be artificially disentangled but armonically integrated into a coherent authorizing or safeguard mechanism.

Against this background, the implementation of the EHDS Regulation should be further accompanied by targeted legislative and regulatory measures at both the EU and Member State levels. In particular, the introduction of an opt-out model for secondary data use should be coupled with clear guidance on the status and continued relevance of pre-existing research consents, including broad consent obtained under national research ethics frameworks. Possible harmonized criteria should be developed to determine when such consents may be relied upon, supplemented, or overridden by EHDS-based governance mechanisms. Moreover, consistent interpretative guidance for HDABs, DPAs, and research ECs is needed to prevent further fragmentation in practice. Without such coordinated action, there is a risk that the EHDS will not resolve existing tensions, but instead add an additional layer of regulatory complexity to an already fragmented consent landscape, thereby undermining its harmonization objectives.

VII. CONCLUSIONS

In this paper, we have examined the regulatory frameworks and approaches across eight European countries concerning a complex issue that has long posed significant challenges for both researchers and oversight authorities: the alignment of consent

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requirements across research ethics and data protection regimes. With the increasing prevalence of data-intensive research, this instrument has become increasingly ambiguous, particularly regarding the conceptualization and application of different types of consent—one rooted in research ethics traditions, and the other derived from data protection legislation—as well as divergent standards, requirements, and methodologies. Utilizing two specific use cases involving non-interventional research, our study demonstrates that European countries adopt markedly different approaches, both legally and in practice, as enforced by oversight bodies. The difficulties associated with this situation are likely to intensify with the anticipated implementation of the EHDS Regulation, which will introduce a general opt-out mechanism for secondary data use and establish new data governance institutions pivoting around HDABs. Although the EHDS aims to harmonize various aspects—including the exercise of privacy rights and consent procedures across Europe—our analysis reveals persistent uncertainties regarding the scope and implications of this regulatory instrument. While some countries may achieve the intended harmonization through the EHDS, others may face additional complexities, as it could impose further requirements beyond existing regulations on research practices.

VII.A. Post Scriptum

A final point deserves mention, as it emerges not from the substantive findings of this study, but from the authors' own experience in conducting it. Throughout the research process, the expert group encountered recurring difficulties in identifying concepts, analytical lenses, and terminological choices that could be meaningfully shared and consistently understood across the entire group. Not only we identified—unsurprisingly—several differences in the national implementation of consent requirements. Also, we realized that the very terms and concepts used to formulate research questions and describe the respective experiences differed profoundly across countries. For instance, as we discussed above, while the existence of the two consents is taken for granted in most countries (ie, dualist conceptions of consent), the same does not apply in Germany, where the issue is conceptualized and implemented in an altogether different way (ie, monist conception of consent). This not only represents a self-reflective, albeit anecdotal, notation about our work process, but it is also something that, we contend, reflects entrenched cultural differences on this issue of major ethical import across the different European countries. In turn, this should raise a note of caution about how attempts at thorough harmonization across Europe, such as with the prospective EHDS Regulation, are rolled out—as, if not managed attentively, they could run the risk of erasing differences, elicit resistance, and ultimately being met with failure.

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APPENDIX 1. COUNTRY REPORTS

Belgium

Q1. In principle, all legal bases under the GDPR are available to legitimize the further processing of personal data for scientific research, as the Belgian Law on the processing of personal data of July 30, 2018 does not impose neither consent, nor another legal basis. In fact, in a recent guidance document establishing a framework for the secondary use of real-world data (RWD) collected in hospitals, adopted by the seven Belgian university hospitals, consent as legal basis for the secondary use of RWD for research appears to be discouraged.[62] This is due to the challenges for obtaining a valid informed consent under the GDPR requirements. The guidance document highlights, in particular, that consent cannot be considered freely given in lack of a genuine choice or in the case of a clear imbalance of power between the data subject (patient) and controller (party wishing to further process the data); and that consent cannot be considered specific nor informed unless the specific purpose of the processing is defined and transparently communicated.

Importantly, if the hospitals were to rely on consent for the primary data collection, the guidance considers that failing to request re-consent for the re-use could hurt patients' trust as 'sensitive data are further used for purposes beyond the expectations created in patients based on the original consent form.' In the use case discussed in this paper, the re-use of research data collected originally on the basis of consent would therefore require re-consenting the patients. Additionally, consent could also have a role to play when no alternative exemption from the general obligation to process health-related data under Article 9 of the GDPR is available, eg, if the request to process RWD has purely commercial objectives that cannot be qualified as research nor as an obligation in the public interest.[63] Similarly, then, in the use case at hand, the legal basis for disclosing data to the pharma company could also be consent.

The guidance document also addresses the application of Articles 6 and 9 of the GDPR. In particular, it starts from the premise that under the GDPR, further processing can be considered compatible if Article 6(4) of the GDPR is fulfilled, and following Recital 50, a new legal basis is not required in that case. The compatibility of scientific research with RWD follows from Article 5(1)(b). The guidance considers that Articles 6 and 9 of the GDPR must be applied cumulatively, meaning that for re-use of RWD Article 9 must be complied with next to Article 6(4) of the GDPR. It specifies that 'Article 9 GDPR foresees that special category data, including health-related data, can, for example, be processed for scientific research in accordance with Article 89(1) based on Union or Member State law (art 9, 2. (j)) or other purposes of (substantial) public interest (art 9, 2. (g) and (j)).'[64]

62 Common position establishing a framework for secondary use of real-world data (routinely) collected in hospitals, adopted by RUZB-CHAB, Oct. 25, 2022, https://www.univ-hospitals.be/common-position-establishing-a-framework-for-secondary-use-of-real-world-data-routinely-collected-in-hospitals/.

63 *Id.*

64 *Id.*

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Q2. Belgian law distinguishes between informed consent as a legal basis for the processing of personal data, and informed consent as a legal and ethical requirement to participate in a study (ie, consent for participation in research).[65] For retrospective research with healthcare data, no research ethics consent would be required,[66] but the favorable opinion of an EC might be needed. For retrospective research with data collected for a previous research study, consent for participation in research will need to be collected again, unless the favorable opinion of an EC provides an exemption.

The right to information is of particular importance in the framework established by the Belgian university hospitals. Their advice is that transparency should be achieved by combining different stages and different levels of information: (i) general information about the secondary use of data (eg, provided in the hospital's privacy policy and information brochures), (ii) individually provided information on the specific projects that use data concerning patients (eg, ideally via digital solutions that allow patients to obtain direct access to their health records), and (iii) in the case of prospective (interventional) experiments, individually provided information about the processing of personal data should be provided together with the informed consent for participation in the study.

Q3. The guidance provided by the Belgian university hospitals does not support the implementation of broad consent for further use of real-world data due to the lack of specificity, explaining that: 'Even when limited to scientific research, the implementation of broad consent for further use of RWD is not considered valid. The false sense of security that might follow from obtaining broad consent risks creating wrong expectations in healthcare practitioners and researchers.'

Q4. With respect to the right to withdraw consent, a multidisciplinary team at the University Hospital Leuven has opined in the past that it is not possible to replace the consent with another legal basis upon withdrawal, and therefore the data controller would be obliged to cease to process the personal data.[67] In our view, the same logic would apply in the case where patients refuse to consent to the re-use in the first place: it would not be possible to legitimize the re-use on another legal basis.

Q5 and Q6. Non-interventional studies in Belgium must receive a favorable opinion from an ethics committee (EC). There is no official guidance about the role of ECs with respect to advice on the legal basis for the processing of personal data. In practice, different ECs may have different approaches and preferences towards different legal bases and special conditions, but no official mapping evidence exists about this. The DPA is not involved in these issues. However, if the processing operations present a high risk to the rights and freedoms of the data subjects (which will be the case for most research projects, eg, the processing on a large scale of special categories of personal data

65 Eg, informed consent for participation in prospective (both interventional and non-interventional) studies is required pursuant to Art. 5(7), Art. 6, and Art. 2(11) Belgian Law on experiments / *Loi relative aux expérimentations sur la personne humaine 7 Mai 2004*. Informed consent for participation is also required in the context of biobanking, pursuant to Art. 10(1) Law of Dec. 19, 2008 regarding the procurement and use of human body material destined for human medical applications or for scientific research purposes / Loi relative à l'obtention et à l'utilization de matériel corporel humain destiné à des applications médicales humaines ou à des fins de recherche scientifique.

66 This is because retrospective non-interventional research is outside the scope of the Belgian Law on experiments.

67 G. Verhenneman et al., *How GDPR Enhances Transparency and Fosters Pseudonymisation in Academic Medical Research*, 27 Eur. J. Health Law (2020).

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such as data related to health), controllers are obliged to carry out a DPIA prior to the start of the processing, the results of which may also lead to the conclusion that a prior consultation with the DPA is necessary.[68]

Q7. With respect to the newly adopted EHDS Regulation, Belgium has already established its national HDAB, ie, the Belgian Health Data Agency (HDA).[69] The HDA's mission is specified as: 'in collaboration with regional and federal data holders and users, [the HDA] will facilitate access to quality health (care) data and data related to health (care) in a simplified, and more uniform, reliable, transparent, and secure manner, through the development of a framework in which the re-use (secondary use) of quality health (care) data and data related to health (care) is optimally facilitated.[70]

The HDA is not a supervisory authority within the meaning of Article 51 of the GDPR and does not aim to replace or undermine the powers of the DPA.[71] The HDA will play a facilitating role in accessing health data for secondary use.[72] With respect to the HDA's relation to ethical committees, the HDA will examine how it can contribute to harmonizing the operations of existing ethical committees, in collaboration with hospitals, to ensure a consistent evaluation process.[73]

With respect to the current practices related to consent for re-use of personal data for scientific research, it is not yet clear whether and how these will change. The HDA addresses consent in its Frequently Asked Questions' section in lieu of the opt-out mechanism established under EHDS and in the following manner: 'The GDPR legislation states that personal data may be processed for scientific purposes. Member states may impose additional conditions to ensure that this processing is done safely and with respect for privacy. In Belgian law, it is stipulated that for use in scientific purposes, the data must be anonymized, and at least pseudonymized if a transversal approach is necessary, always with a full guarantee of privacy. If data have been collected for other purposes, Article 5, 4th point, states that further processing for scientific purposes is never incompatible, and compliance with the obligations in Article 5 must be met (...).[74]

Czech Republic

In the *Czech Republic*, the legal landscape in the area of conducting biomedical research is quite fragmented. The main legal acts containing rules on the conducting of biomedical research are the Oviedo Convention[75] and the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research

68 Art. 35, 36 GDPR, see also the advice provided by the Belgian Data Protection Authority, https://www.autoriteprotectiondonnees.be/professionnel/rgpd-/analyse-d-impact-relative-a-la-protection-des-donnees. Last accessed 17 April 2026.

69 The HDA was established by the law of Mar. 14, 2023 (hereafter the HDA Law) as an ASAA (administrative service with accounting autonomy) with enterprise number 0800309782. The law is available at https://www.ejustice.just.fgov.be/eli/wet/2023/03/14/2023041135/staatsblad.

70 HDA, *Mission*, https://www.hda.belgium.be/en/about_us#section-mission (accessed Aug. 13, 2025).

71 Article 4 and Explanatory memorandum of the HDA Law.

72 See also HDA, *Frequently Asked Questions*, https://www.hda.belgium.be/en/faqs/whats-relationship-between-dpa-ivc-and-hda (accessed Aug. 13, 2025).

73 See also HDA, *Frequently Asked Questions*, https://www.hda.belgium.be/en/faqs/how-does-hda-relate-ethical-committees (accessed Aug. 13, 2025).

74 See also HDA, Frequently Asked Questions, https://www.hda.belgium.be/en/faqs/do-citizens-need-consent-data-reuse (accessed Aug. 13, 2025).

75 Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, Apr. 4, 1997 ETS 164 (Oviedo Convention).

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(Additional Protocol);[76] the Act on Health Services;[77] the GDPR;[78] and the Czech Personal Data Processing Act.[79]

Q1. The determination of appropriate legal basis would require more complex consideration. Theoretically there are more legal bases available for conducting research (for example, legitimate interest Art. 6/1 f) and scientific research exemption (Art. 9/2 j) and Art. 16 of the Czech Data Processing Act), however, in this case explicit consent would probably be seen as the most appropriate legal basis for both health and research data reuse and providing them to the sponsor, taking into account that the sponsor (controller) is a private pharma company and intent of research is commercial.

Q2. Czech law does not require specific informed consent for the enrollment of participants in non-interventional research. However, from an ethical point of view (but also from a legal point of view, as informed consent may be seen as an appropriate safeguard to protect data subjects' rights and interests) specific informed consent may be required in use Case 1 as the sponsor is a private pharma company and the intent of the research is commercial, and we cannot presume a reasonable patients´ expectation of future use of their data for commercial research. Furthermore, consent for access to medical records for research is needed under the Act on Health Services[80] (which can also be broad).

In use Case 2 (re-use of research data), the interpretation of the initial consent is crucial. If it covers participation in further research studies and describes these studies [at least broadly by field of research, purpose, and nature (academic, commercial)] then it might be sufficient to also cover research data re-use and no re-consent is needed.

Information on processing of personal data must be provided to data subjects pursuant to Art. 14 of the GDPR except for cases stated in Art. 15/5 b) GDPR where the sponsor as data controller proves that providing information is impossible (for example there is no contact information on the data subject) or would involve a disproportionate effort (rec. 62—the number of data subjects, the age of the data and any appropriate safeguards adopted should be taken into consideration) or if providing information likely to render impossible or seriously impair the achievement of the objectives of that processing. But even in such a case there must be appropriate measures taken to protect the data subject's rights, freedoms, and legitimate interests, including making the information publicly available.

Q3. The term 'broad consent' is not legally defined, however, in practice it is used to describe consent given for research in certain fields (eg, oncology research) accompanied by the information mainly on possible purpose, nature, risks, or benefits of such future research. We assume that broad consent as a legal basis is not applicable. Czech national legislation does not impose any other conditions for the consent beyond the scope of Art. 7 of the GDPR. The Czech DPA also stresses that consent must be specific and does not provide further guidelines on consent besides referring to the

76 Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, Jan. 25, 2005, CETS 195.

77 Act No. 372/2011 Coll., on Health Services and Conditions of Their Provision, as amended (Act on Health Services).

78 European Parliament and Council Regulation 2016/679 of Apr. 27, 2016, Protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (GDPR), 2016 O.J. (L 119) 1

79 Act No. 110/2019 Coll., on Personal Data Processing, as amended (Czech Personal Data Processing Act).

80 Art. 65 of Act No. 372/2011 Coll., on Health Services and Conditions of their Provision, as amended.

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EDPB guidelines.[81] Broad consents for participation in non-interventional studies are generally admissible, but their admissibility in a particular research requires a more detailed assessment—such in this case of commercial research.

Q4. In the case of a refusal to give consent to participation in research or to data processing, the data should not be used by researchers, as there is a lack of a legal basis for data processing. Researchers have the right to find other appropriate legal bases; however, it must be a transparent process compliant with the GDPR principles (including informing research participants about such change). As the EDPB stresses in its guidelines, researchers cannot silently migrate from consent to this other lawful basis.[82]

In the case of a withdrawal of GDPR consent it is stated that data must be deleted in the absence of any other legal basis.[83] The EDPB also supports this view.[84] This could hamper research activities, especially when data have already been used. Hence, some authors question the strict obligation to erase data and suggest conducting a balancing exercise, considering thoroughly all fundamental rights at stake.[85]

The situation can be more complicated if a participant withdraws only the consent to participation in research. In cases where the processing of personal data is necessary for research (as is in our case), the separation of consent to data processing and consent to participation in research seems to be artificial. However, from a regulatory perspective, these two consents are two different requirements covered by different rules (ethics/medical law versus data protection law).[86] Contrary to the GDPR, the law does not state explicitly how to handle data in the case of a withdrawal of consent to participation in research. It is therefore unclear which (if any) processing operations are allowed. In our case, where research is dependent on data processing, we would recommend asking a patient explicitly about his/her will regarding data processing.

Q5. There is no legally defined authorization process for conducting non-interventional research in the Czech Republic.[87] Hence, the authorization process is up to internal rules of research institutions. In the case of non-interventional post-marketing research studies related to medicinal products, as described in the example above, the sponsor is obliged to report the start and end of the study to the medical regulatory authority—State Office for Drug Control—as well as submit a final report.[88]

In practice, researchers submit their retrospective non-interventional studies to 'ECs' established by their institutions for various non-legal reasons—for example fol-

81 Guidelines 05/2020 on consent under Regulation 2016/679, version 1, Adopted on May 4, 2020, edpb.europa.eu.

82 EDPB Guidelines 05/2020, p. 25.

83 Art. 17/1 (b) GDPR.

84 EDPB Guidelines 05/2020, p. 25

85 Marcu Florea, *Withdrawal of Consent for Processing Personal Data in Biomedical Research*, 13 Int. Data Privacy Law 107–123 (2023).

86 *Id.*

87 From Jan. 1, 2027 the situation will change slightly and EC assessment will be required also for certain types of 'non-interventional' research conducted by publicly funded research institutions. Specifically, Act No. 328/2025 Coll. on Research, Development, Innovation and Knowledge Transfer, § 6 par. 4 will set obligatory EC assessment for research on human, research on biological material of human origin, research involving animal testing or work with genetically modified organisms.

88 Art. 59a of Act No. 378/2007 Coll., on Pharmaceuticals, as amended.

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lowing internal policies, ensuring ethics integrity of research, fulfillment of grant agency requirements, or partner institutions´ requirements.

Q6. When it comes to the authorities' positions regarding consents, the DPA—Personal DPO—is established by the Czech Data Processing Act and its tasks and powers do not include any special roles in the area of the authorization of scientific research projects. It can be consulted by DPOs or researchers on an individual basis. ECs do not have an explicit legal mandate to suggest legal bases or require their changes. However, in practice, the review of legal bases is part of the overall project review, and we can identify situations where an EC finds appropriate different legal bases than the researchers. In such a case, researchers can decide not to follow the opinion of the EC, which can represent an obstacle for conducting a particular research project—either a legal obstacle (if there is a legal requirement for EC approval—eg, interventional studies), or a practical one (for example, if the EC approval is required by the grant agency, partner institution, or scientific journals as a prerequisite for publication). In the case that the submission of the research project to the EC was voluntary and approval is not required by law or the policy of some institutions, we assume that the data can be theoretically used for research in spite of the opinion of the EC, as the GDPR clearly states that it is the controller's responsibility to ensure the compliance of data processing with the GDPR. However, in practice, the EC's refusal to give approval is seen as a 'stop' sign for research.

Q7. The Regulation on the European Health Data Space (EHDS) is expected to influence the rules for electronic health data reuse significantly. In our use cases, the sponsor as a 'data user' will have the right to apply for pseudonymized or anonymized electronic health data from public hospitals in the EU under the mechanism established by the EHDS. Public hospitals, as 'data holders,' will have a legal obligation to provide their electronic health data to the sponsor for research in the case where a 'data permit' issued by the 'health data access body (HDAB)' has been obtained. In the case that health data would be protected under intellectual property laws (as may be in the use case of reuse of research data) they may be exempted from the obligation of their provision.

The EHDS introduces an 'opt-out' principle for the secondary use of health data,[89] which means that an explicit data subject's consent would not be required as a legal basis in the EU anymore. It is therefore expected that the process of reuse of electronic health data will be simplified on both the national and international levels.

THe EHDS explicitly states in Art. 71 that after a person has opted out, and where personal electronic health data relating to them can be identified in a dataset, personal electronic health data relating to them shall not be made available or otherwise processed pursuant to data permits granted after the person has opted out. Opt-out shall not however affect the processing of personal data pursuant to data permits that were granted before the person has opted out.

It is, however, not clear how to proceed in the case of a withdrawal of consent to participation in research (if required by national laws, ECs, or the HDAB in our case) or the withdrawal of GDPR consent. Such a withdrawal cannot be considered an opt-out from secondary processing and should be assessed separately. Since the EHDS does not regulate the interplay between its own mechanism for secondary use and existing

89 Art. 71 of the Regulation on the European Health Data Space.

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frameworks, we see important to carefully assess the practical implications arising from their coexistence. For example, an examination of the conditions for application, as well as the consequences of the application of the right to opt-out under the EHDS, consent withdrawal (either 'ethics consent' or 'GDPR consent'), and the right to object to data processing. The relevance of ethics assessment for assessing data applications under the EHDS represents other important ethico-legal topic which deserves further discussion during the national implementation process. Ethics assessment is obligatory for data requests under the EHDS only if required by national laws (Art. 67/2 j) EHDS). Czech legal norms do not require an obligatory ethics assessment for the secondary use of health data per se in research; hence, it would not be an automatic part of the assessment of data applications under the EHDS. This implicates that the HDAB would not have empowerment to request ethics safeguards (such as 'ethics consent') nor to reject a data application based solely on ethical grounds. If the HDAB would do so without an explicit basis in national law, its administrative decision[90] could be appealed by the applicant and subsequently changed or canceled for unlawfullness.

The Czech adaptation legislation will be prepared by the Ministry of Health, and its proposal is expected to be published in 2026. Currently, a national analysis is being conducted by the Ministry of Health with the aim to examine and describe current conditions for the secondary use of health data in the Czech Republic and analyze the needs and opinions of all involved stakeholders. Further details are not known yet.

Finland

Q1. The legal basis is for the data controller to decide, but for scientific research public interest is supported in national legislation.

Sponsors of a study are typically considered the data controllers of the study data. To get data from public registers there are the biobanks (disclosure regulated by the Biobank Act) and health and social care registers (disclosure regulated by the Secondary Use of Social and Health Care Data Act).

The legal bases are for the data controller to identify and choose. Based on the Data Protection Act § 4 (1050/2018), scientific research can be based on public interest under the GDPR Article 6.1(e). Consent and other legal bases are available. For the processing of special categories of data, a derogation from the GDPR Article 9.1 is available in the Data Protection Act § 6: Article 9 paragraph 1 will not be applicable to scientific research. Based on the *travaux preparatoires*, this derogation is based on Article 9.2(j) (Government Bill 9/2019). For invasive/interventional research (medical research, as defined in the Medical Research Act), and for clinical trials under the EU Clinical Trials Regulation, regardless of whether scientific or not, research can be based on the GDPR Article 6.1(e) and 9.2(i) (Medical Research Act § 21, the Clinical Trials Act § 33 (983/2021)).

The Medical Research Act (488/1999) applies to 'medical research,' which in the Act means 'research involving intervention in the integrity of a person, human embryo or human foetus for the purpose of increasing knowledge of health, the causes, symptoms, diagnosis, treatment and prevention of diseases or the nature of diseases in general.' In the Biobank Act (688/2012), 'biobank research' means 'research utilising the samples contained in a biobank or information associated with them for the purposes of promoting health, understanding the mechanisms of disease or developing the products and treatment practices used in healthcare and medical care.' 'Biobank'

90 See definition of 'data permit' as administrative decision in Art. 2(2) letter (v) of EHDS regulation.

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in the Biobank Act means a unit specifically established to manage sample and data collections for future research purposes. Under the Biobank Act, a biobank needs to be approved by the national medical research EC and approved for registration with the national competent authority Fimea. Diagnostic samples outside of biobanks are available for research under the Act on the Medical Use of Human Organs, Tissues and Cells (101/2001) with (i) consent, or (ii) ethical committee approval and Fimea's permission, or in the case of deceased patients (iii) with EC approval.

Q2. No, providing data for reuse is based on legislation, not consent (but see Q3 for assent). Researchers typically do not get identifiers, so can only inform on a general level. GDPR exemptions can be invoked. No national legal requirement for consent for patient enrolment in a non-interventional study.

Q3. Yes, but there is no definition of how broad. The biobank consent is now considered to cover only the collection of samples, nothing to do with data, but the biobank sample donor needs to assent to the use of their personal data for the purposes of biobanking. Research use must be covered by other means than biobank consent. Consent is seldom used as a legal base in health research, even if an ethical consent is required (for interventional research).

Q4. Secondary use is normally not based on consent. GDPR right to object applies.

Q5. Under the Secondary Use Act, for access to multiple data controller's registers, a national authority Findata can provides the permissions. It also collects the data, pseudonymizes it, and provides it to a secure processing environment. From May 1, 2026 onwards, separate permissions can also be applied from individual public data controllers, even when data from several sources are required. No EC approval is required. For biobank data, biobanks make access decisions, which can be appealed in administrative courts. The Finnish medicines agency Fimea supervises the biobanks. EC approval is typically a prerequisite for getting samples/data from biobanks. For biobank research (as defined in the Biobank Act, see question 1 above), the applicant applying for access to biobank samples and/or data must present a positive statement from a statutory regional EC (established based on the Medical Research Act) or other statement by which the biobank can assess the viability of the application. The biobank will decide on access to their samples/data, and the decision can be appealed in the public administrative courts of law. The biobanks also hold a wealth of clinical and other health related data that they can provide for research in addition to their samples and sample-originating data. Access to other social or health care services register data requires a permission either from the national permissions authority Findata (www.findata.fi) or from the particular social or health care providers. Some non-interventional research can fall eg, under the EU Medical Devices Regulation requirements and need to be approved by the Finnish Medicines Agency Fimea (www.fimea.fi). Hospitals and research institutions may require their researchers to apply for internal research permits, but these are not statutory. Personal data processing in general is supervised by the data protection ombudsman's office.

Q6. I don't think so. An EC could insist on specific legal bases for a research project where their statement is required by law. Consent is generally not considered to be the preferred legal basis especially in health care context, where based on for example the EDPB guidelines obtaining a GDPR compatible consent could be challenging due to a power imbalance. DPA has no authority to grant processing permissions. The Finnish

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DPA would seem to follow the EDPB guidelines. It is not the DPA's role to decide on legal bases, but they can take a stand on whether or not the controller has identified and chosen appropriate bases. They could for example evaluate the validity of consent, or the actual existence of a legitimate interest.

Q7. The impact of EHDS remains to be seen.

France

Q1. For both use cases, the legal basis is the public interest when the controller is a public entity (eg, an hospital) and the legitimate interest when the controller is a private company. The French lawmaker allowed the processing of health data without GDPR consent based on national legislation, as permitted under the GDPR Art. 9(2)j.

Q2. For both use cases, consent will not be required by law (none of the consents). However, patients must be informed about the research project prior to its start, and can object at any time. In practice, there are two categories of information to be provided:

- information related to the research study (provision related to the observational studies
- information related to the processing of (health related) personal data as provided for in the GDPR, Articles 13/14

Q3. The broad consent is not explicitly mentioned under the French legislation. However, in practice, the French DPA tolerates its use according to Cnil Guidance MR-004 and provided that:

- the broad scope of research has been explicitly foreseen in the information notice
- a specific information notice is provided for each project on an information portal known by the patients
- the project is being registered on the central public French Health Data Hub website (LINK)

Q4. If a patient does not want his data to be used for the study, they can object before the start of the study (ie, study must give the patients a reasonable time frame after information to allow them to exercise their right to object).

In case patients object to the use of their data after the start of the study, no further data can be transferred to the sponsor.

It is not clear under the legislation if the data already acquired by the sponsor can or not be further processed. The common practice is to restrict the use of objected patients data collected before the objection for the statistical analysis of the project to not bias the analysis, provided that it is already foreseen in the information notice.

Q5. The DPA is not directly involved (no authorization required) provided the study is conducted in compliance with Cnil guidance MR-004 and the sponsor is registered with the Cnil.

French ECs (CPP) are only dealing with 'RIPH' ('research involving human persons'), whether interventional or non-interventional studies. The studies based on the use/reuse of data only 'without involving human persons' ('retrospective studies' and studies reusing health or research data, etc.) are to be submitted to another committee (CESREES) and Cnil if not compliant with Cnil MR-004.

Q6. It happens that ECs require to collect written consent whereas data is allowed to be processed on the basis of the public or legitimate interest. A guidance from Cnil has

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been shared with ECs to clarify that they are not responsible for challenging the legal basis selected by the controller.

Q7. We don't know yet. What we see at the moment is that the French model is being considered by other countries or European bodies as a potential solution for implementing the EHDS opt-out process.

Germany

Germany has not adopted a general law for research involving humans on a federal level and thus has not used the opening clause of Art. 9 (2) (j) of the GDPR in order to introduce a general national legal basis or regime for biomedical research. Instead, the GDPR remains directly applicable. There are legal acts on the State level allowing hospitals to use patient data from the routine care context for internal research projects without the consent of the included patients. But sharing these data beyond the sphere of medical secrecy—ie, within the hospital or within a network of hospitals and only to medical staff—is not allowed. Recently, the 'Gesundheitsdatennutzungsgesetz' has been adopted, but it has limited impact, since its primary purpose is to streamline the use of patient data for internal purposes across the nation. Consent is still a requirement for data usage for research purposes outside the boundaries of professional secrecy. There are some exceptions in specific laws, eg, in social security law, and a more general exception has been introduced into the Federal data Protection law. But there is quite a debate about the scope and the mode of balancing the interests of research against privacy. Therefore, it cannot be used for regular data using or sharing for research purposes. One requirement would be that it is hardly possible or at least very difficult to obtain consent. A conflict with an assumed ethical requirement to collect consent is therefore not very likely.

Q1 and Q2. As soon as data are captured beyond the care context in order to conduct a study of whatever form, the consent of the respective patient is needed. There is only one consent, and no distinction is made between 'Helsinki' or 'ethical' consent and 'GDPR' consent. From the German perspective, it is the horizon of the patient that counts. A 'yes' means 'I agree' to the use of my data through inclusion into the study under all applicable laws. If the law does not require consent, ethical principles do not either. Ethical concerns, to which the Helsinki Declaration, for example, is a response to, are fully incorporated into German law. The remit of an EC is to ensure that a researcher respects all legal obligations. If a researcher is at the same time a clinician, they have to obey special law for the conduct of clinicians, in addition to the GDPR, of course. Therefore, ECs apply—in addition to the GDPR—all rules stemming from professional law (e.g no harm for the patient, no ethically questionable research questions, and respect the professional secrecy). But there are no rules to require consent for the use of data beyond the GDPR and national law, especially professional secrecy for medical staff, based on GDPR opening clauses such as Art. 9 (2) (j), being for example the recently adopted Gesundheitsdatennutzungsgesetz.

If the study data are to be used after the study was finished (secondary use), this must be in line with the initial consent. Many studies ask for the option of secondary use in the study consent form in order to ensure that the data can be re-used. The latter additional—and optional—consent is the only way to ensure that the patient/research participant does not have to be contacted for re-consent. The latter is only possible if

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the initial consent form provided at least for this option. If not, then secondary use is excluded.

In addition to the information requirements on an individual level in the GDPR, a core principle of the recently adopted Gesundheitsdatennutzungsgesetz is the requirement for research projects in a specific register to be published via an information portal. This seems to become a standard requirement of transparency to make sure that patients are informed at all times about the ongoing research on the basis of their data, in order to enable them to take an informed decision to (not) opt out or withdraw their (broad) consent.

Q3. The so-called broad consent has been the standard for many years for biobanking and beyond, for example to access routine patient data from a network of all University hospitals in Germany. This consent has been agreed within a 2-year process with all participating sites and with all DPAs and ECs in Germany. The purpose is equally defined as 'research to improve prevention, diagnosis, and treatment.' There are some choices for individuals signing up, but industry exclusion is not an option.

The solution is debated from time to time, but it has become the standard. It is seen by the vast majority of those involved as preferable to an opt-out or a legal basis for processing without the decision of the research participant. The transparency requirements are high, in order to balance the broadness of the consent, and to make sure that research participants can decide at any time, if they are still in agreement with the conducted research or if they wish to withdraw.

Q4. Data of individuals expressing their will to not be included in any research activity are blocked for research with very minor exceptions (urgencies as deadly pandemics). After withdrawal the data has to be deleted. If they have already been used for research, they can be archived in order to prove research results. But they are excluded from future research.

A 'no' as a response to a consent request that is submitted to research participants, although there is already an applicable legal basis for the intended use, would have to be analyzed under the GDPR and could be interpreted as exercising the right to object according to Art. 21 of the GDPR. Again, the label 'consent' is not the leading argument, if there is legally no room for consent. The will of the patient to block the processing of their personal data is the only thing that counts and it has to be interpreted according to all applicable laws.

Moreover, consent in Germany is never considered a 'safeguard.' It might be the researcher who is safeguarded in cases where the legal allowance is fuzzy. This situation has been addressed by the EDPB: legal basis hopping is not allowed, since it would hinder transparency for the patient.[63] As soon as a researcher asks for consent although there already is a legal basis for the intended data use, he/she needs to respect the negative response and cannot process the data. This would override the legal regulation providing the allowance to process, and thus violate law, and give ECs requiring such a 'safeguard' a kind of power they do not have under German jurisdiction. Of course, there are cases where a local EC disagrees with the submitting researcher about the scope of a legal basis and requires consent for what it assumes not to be covered. But these are usual debates about the interpretation of law, and not a different approach.

Q5. The first responsible person in a research institution is the local DPO. They have to ensure that all data are being handled according to the law and put in place

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the appropriate safeguards (TOMs). Research data can only be collected, if such secure systems exist.

The DPO can be part of the local EC. In any case, there should be a data protection expert. The EC will, among other topics, check whether all GDPR rules have been taken into account and if research participants are appropriately informed.

The DPA is normally not involved in single research applications. But they might be involved by DPOs, especially where major projects or infrastructures are planned requiring considerable investments. The normal way to be on the safe side, however, is to involve the TMF, a nationwide research umbrella organization to provide advice. It offers its members to present upcoming projects to be discussed within the data protection working group and to even seek approval, which is normally not contested by the DPA. This is possible due to the constant dialog the TMF is maintaining with all DPAs in Germany.

Q6. There are no fundamentally different positions, just some different opinions concerning details. No EC has ever required consent on top of a clearly existing legal basis. ECs are organized in an association and issue aligned positions and templates. They maintain a constant dialog with the research departments of the DPAs throughout Germany.

Even if an EC requires the consent of patients for certain data processing, despite the fact that the processing is already legally allowed and maybe even required, then the 'yes' of the patient lacks any practical effect, since an allowance cannot be duplicated. The doctrine of 'falsa demonstratio non nocet' is widely accepted in German jurisdiction. It means that whatever the headline or label of a legal document—be it a contract or an ICF—would be, content is the only criteria to legally analyze it. If consent is given in relation to the processing of data, the GDPR is applicable, even if the ICF expressly states 'this is not consent under GDPR.' Thus, the consent fully underlies GDPR requirements and GDPR consequences in any instance. Ethics might fill the gap, especially if the law provides for a respective decision by an EC, but it never derogates nor circumvents the law. The GDPR is clearly applicable to any processing of personal data, so any national law has to be based on a valid GDPR derogation including the introduction of high standards as professional secrecy might introduce; the latter is based on Art. 9 (4) of the GDPR. The GDPR is not made to prevent researchers as much as possible from the use of data, but also to define, when the use is allowed. Art. 9 (4) of the GDPR allows national legislators to impose additional constraints. But it is the legislator who is in charge, not a single EC. There is no room for circumventing applicable laws by ethical instruments. Thus, in Germany, no EC can allow the use of data without a legal basis, but it cannot prohibit it either.

Q7. The EHDS will introduce opt-out instead of consent for all applications to access data through the EHDS infrastructure.

Italy

Observational studies are not regulated by *ad hoc* legislation, but only by a circular (Circular of the Ministry of Health, n. 6 of September 2, 2002[91]) and by a Determination from the Italian Medicines Agency (AIFA Resolution of March 20, 2008,

91 Gazzetta Ufficiale, MINISTERO DELLA SALUTE CIRCOLARE 2 settembre 2002, n. 6, https://www.gazzettaufficiale.it/atto/vediMenuHTML?atto.dataPubblicazioneGazzetta=2002-09-12&atto.codiceRedazionale=02A11274&tipoSerie=serie_generale&tipoVigenza=originario (accessed Aug. 13, 2025).

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Guidelines for the classification and conduct of observational studies on drugs[92]), in particular related to drug studies.

Italian Health Ministerial Circular n. 6 of September 2, 2002 provides the following definition of non-interventional clinical studies (observational): 'study centered on problems or pathologies in which medicines are prescribed in the usual way in accordance with the stipulated conditions in the marketing authorisation. The inclusion of the patient in a specific therapeutic strategy is not decided in advance by the trial protocol but falls within the normal clinical practice and the decision to prescribe the drug is completely independent of that to include the patient in the study.'

Italian Medicines Agency (AIFA) determination March 20, 2008, 'Guidelines for the classification and conduct of studies drug observations,' states that in the case of observational studies, the sponsor should declare that: (i) the drug has been prescribed according to the indications for use authorized for release in trade; (ii) the prescription of the drug must be part of normal clinical practice; (iii) the decision to prescribe the drug to the individual subject is completely independent of that to include the subject themselves in the study; and (iv) diagnostic and evaluation procedures correspond to current clinical practice.

Q1. In both the case of reusing healthcare data and reusing research data, the rules provided by the GDPR and its Italian implementation (ie, Legislative Decree 101/2018) apply. The Decree states that for processing data used for observational studies, a legal basis is needed, and it should be one of those identified in Art. 110 of the Decree.

Art. 110 (on 'Medical, Biomedical and Epidemiological Research') expressly mentions that consent is the required legal basis for processing health data for the purposes of scientific research.

Under Art. 110, par. 1, Decree 101/2018, consent is not necessary when:

- the research is carried out on the basis of legal or regulatory provisions or EU law (Art. 9, 2, letter j GDPR), including the case of a research for which a DPIA is conducted.
- informing the research subjects results is impossible or entails a disproportionate effort or risks seriously jeopardizing the research purposes.

In these cases, the processing can disregard consent if the research program, once the favorable opinion of the competent EC has been obtained, is submitted to the prior consultation of the Italian DPA pursuant to Art. 36 of the GDPR and obtains a favorable opinion. Therefore, when it is difficult to obtain consent, a preventive consultation of the DPA is needed. Moreover, a DPIA is required, and many research ECs also require additional documents, such as Material or Data Transfer Agreements. It should be noted that, according to the DPA, the impossibility to inform subjects should be clearly proved and demonstrable.

92 Gazzetta Ufficiale, *DETERMINAZIONE 20 marzo 2008 Linee guida per la classificazione e conduzione degli studi osservazionali sui farmaci,* https://www.gazzettaufficiale.it/eli/id/2008/03/31/08A02109/sg (accessed Aug. 13, 2025).

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In addition, Provision n. 146, June 5, 2019[93] from the Italian DPA (Garante) regulates the case of studies carried out with previously collected data, for health care purposes or for the execution of previous research projects. In these cases, the research must be carried out on the basis of a project, subject to a reasoned favorable opinion from the competent EC at the local level, and on the basis of consent as the legal basis for data processing.

A specific exception for re-use of data previously collected for routine healthcare purposes refers to 52 research hospitals accredited with the Ministry of Health (ie, the so-called 'IRCCS'): they are the only ones allowed to re-purpose the data for research originally collected for routine healthcare purposes, or collected and stored within the hospitals' biobanks (D.lgs 101/2018, Art. 110-bis comma 4).

In general, thus, the re-use of data for observational studies is based on consent as a legal basis. The re-use of data originally collected for research purposes needs the reconsenting of the participant. There is an ongoing discussion that includes the relevant stakeholders with the Authority (IRCCS, University, Industry, BBMRI IT and others) in order to write a code of conduct for scientific research. The goal is to simplify the way forward with broader consent as a basis as foreseen in Preamble 33 given specific safeguards to be defined within the code of conduct. There is also a parallel, not structured, ongoing discussion on the possibility to introduce different legal bases for the processing of data.

Q2. In Italy, the collection of informed consent from research participants is fundamental as a guarantee of the protection of the right to the integrity and dignity of the person, and in line with the provisions from the Nuremberg Code (1947), the Declaration of Helsinki (1964), Belmont Reports (1979), and Articles 2, 13, and 32 of the Constitution. So, consent to participate in research is provided by Italian adherence to international and EU standards and principles. In practice, in Italy, there are usually four distinct documents provided to participants:

- information on the research project: information should contain an indication of the investigator, their insurance, their financial basis for conducting the research, the purpose of research, methodology of research, risks, benefits, incidental findings, the possibility of withdrawal of consent, and its consequences.
- Informed Consent Form (consent to participate in research). Research centers usually provide a Declaration in lieu of informed consent in the case of retrospective observational studies in which it is not considered possible to inform the interested parties and obtain from them the consent to the processing of personal data.
- Information regarding data processing (privacy notice): it indicates legal basis, Data controller, DPO, to whom to communicate the withdrawal of consent to data processing.
- Form on consent to data processing.

The Italian Medicines Agency (AIFA) determination of March 20, 2008, 'Guidelines for the classification and conduct of studies drug observations' affirms that a sponsor

93 Provvedimento n. 146, June 5, 2019, (doc. web n. 9124510) annex 4 on genetic data and annex 5 on data processing for research purposes.

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should provide a privacy notice to the data subject and collect their consent to data processing, together with the research protocol which describes the procedures put in place to ensure the confidentiality of information.

The Ministerial Decree of November 30, 2021 states that prospective pharmacological observational studies can be started only after receiving a favorable opinion from the competent EC, which is valid for all the centers in which the study will be carried out. Documents to be submitted to ECs include an informed consent form relating to the study (in which there are two sections: the information on the protocol research, risks, benefits, etc, and the section dedicated to the expression of consent), and authorization to process personal and sensitive data (usually, also divided into two sections: information on data and samples processing, and the section dedicated to the expression of consent).

The Italian DPA with the resolution no. 52 (guidelines for the processing of personal data in the context of clinical trials of medicinal products—July 24, 2008) has reiterated the need to provide a privacy notice to the data subjects and to collect consent for the processing of personal data. The DPA has insisted on the fact that data processing can occur only with the consent of the patient and with the prior opinion of the relevant EC (territorially competent). The patient can express their consent only when being fully informed of the purpose and objectives of the study.

Q3. The use of broad consent represents a still contentious and unsettled issue in the Italian context. A number of research institutions have adopted broad consent models, though the Italian DPA maintains a restrictive position vis-à-vis the use of broad consent, as exemplified for instance by the Opinion of June 30, 2022. Here, the DPA states that, when data already collected for a specific research purpose are re-purposed for a different research project, subject to approval by the local competent EC, the data controller is required to obtain the re-consent of participants. In constructing its legal argument, the DPA makes reference to the equally restrictive position of the EDPB vis-à-vis the interpretation of Recital 33 of the GDPR (cf. Guidelines 5/2020 on consent, pt. 7.2).

In general, Italy adopts a 'dualist' approach to consent, making an explicit distinction between informed consent as a legal basis for the processing of personal data, and informed consent as a legal and ethical requirement to participate in a study (ie, consent for participation in research). These two types of consent are *de facto* conflated, even though, in practice, participants receive two different templates, a privacy notice and a 'GDPR consent,' on the one hand, and information about the study and consent to participate in research, on the other hand. However, while broad consent has been generally considered admissible by ECs, the national DPA has traditionally argued against its use not allowing broad consent as a valid legal basis for re-using data in observational research, despite mostly in light of the EDPB guidelines on consent that have enforced a strict interpretation of Recital 33 of the GDPR. ECs and the authority authorize the collection of data under broad consent, provided there is further consent or the use of Art. 110 in case it is impossible to obtain consent.

Q4. When individuals decline to participate in research or refuse consent for data processing, their personal data cannot be used for the intended research purposes. Without such consent, processing personal data for research is generally prohibited unless another legal basis applies.

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In the case of a withdrawal of GDPR consent, researchers must cease processing the individual's data for the purposes initially agreed upon. However, the withdrawal does not affect the lawfulness of processing conducted prior to the withdrawal. Interactive forms of consent allow opting out of specific projects avoiding complete withdrawal. However, as the legal basis will no longer be valid, there is an obligation to cancel data or completely anonymize them (which in most realities means canceling them) within one month. Additionally, appropriate safeguards, like data minimization and pseudonymization, must be implemented to protect individuals' rights and freedoms.

Q5. ECs and DPA are involved. The prior approval from the EC is needed. In the case of impossibility of obtaining consent, their approval is required, in alignment with the authority directions in the interpretation of Art. 110 of the GDPR as it is seen as a necessary oversight measure where, for instance, research can be carried out without consent (only possible in specific cases and if DPIA shows low risk). Moreover, there is an obligation to publish the DPIA on the DPA site. The approval by ECs is very complicated at the moment, as they were born to evaluate clinical trials. There is a growing need for more specialized bodies that can take into account specific aspects of data handling.

Q6. The Italian DPA shows an extremely strict approach to observational studies, and scientific research more broadly. It always requires grounding health research on consent as a legal basis, and only when not possible for the reasons indicated in Art. 110 Privacy Code (people died, or impossible to collect consent, or disproportionate effort to do so), it is required to obtain a favorable opinion from the EC and to carry out prior consultation with the DPA.

As regards the DPA's position it is interesting to consider the General Authorization on data processing for research purposes (June 5, 2019) issued by the DPA, stating that health data can be processed without consent for health research purposes provided that:

- Research is pursued on the basis of a national or EU law
- It is impossible to contact the research participants (ie, informing them would create a material or psychological damage to them; or there is an organizational impossibility to contact them because it would entail a disproportionate effort: or research participants are dead persons, or people affected by serious illnesses).

Moreover, in the already mentioned DPA's Opinion of June 30, 2022 [doc. web n. 9791886], the DPA affirms that, for building a database for research purposes, consent is needed for prospective research, while the procedure pursuant to Art. 110 of the Privacy Code should be followed for retrospectives (being impossible to collect consent for many dead people). Then, further studies taking data from the database cannot be considered compatible with the initial processing and therefore will require specific consent. It means that the Italian DPA requires 'general' consent (or procedure pursuant to Art. 110) for the establishment of the database and specific 'progressive' consent (or procedure pursuant to Art. 110) for the individual studies that will follow.

Italian legislation, as well as the orientation of the Italian DPA, is very much 'consent-centric' (an argument often heard by functionaries within the DPA is that 'in order to change this approach, there is not much that the DPA can do, you have to change the law'). Hence, ECs tend to follow this general approach, although it should be noted

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that eg, the Italian national coordination center of ECs (CCNCE, 2023)[94] has insisted on adopting other legal bases for secondary use and observational research, such as legitimate interest (even if this is highly debatable, since it would lead to a situation in which each institution could have a different and highly subjective legitimate interest for justifying research).

Q.7 The impact of the EHDS is still unclear, especially since the country shows a low level of preparedness as to EHDS implementation.

Poland

In Poland, there is no act comprehensively regulating biomedical research or biobanking. The Polish constitution directly protects two values: freedom of scientific research and the right to privacy. Both of these freedoms can only be limited by law. With regard to the right to privacy, Art. 51 of the Constitution, no one may be obliged, other than pursuant to statute, to disclose information relating to their person. In the field of biomedical research in Poland, such regulations are included in three acts: (i) Act on the professions of doctor and dentist—in the field of medical experiments; (ii) Act on clinical trials of medicinal products for human use, Pharmaceutical Law Act regarding clinical trials; and (iii) Act on patients' rights and the patients' rights ombudsman regarding conducting research on data from medical records.

Q1. In the first described case, the basis for the research will be the patient's consent in accordance with Art. 9(2)(a) of the GDPR and Art. 26(1) of the Act on Patient Rights and the Patient Ombudsman (the entity providing health services makes medical documentation available to the patient or his legal representative, or a person authorized by the patient). If the documentation is kept in electronic form, entities have access to it with the patient's consent in accordance with Art. 35 of the Act on the health care information system. In the second case, it may consider the patient's consent or Art. 26(4) of the Act on Patient Rights and the Patient Ombudsman, according to which medical documentation may also be made available to a university or research institute for use for scientific purposes, without disclosing the name and other data enabling the identification of the person to whom the documentation relates. If the company does not have the status of a research institute or university, the basis is the patient's consent in accordance with Art. 9(2)(a) of the GDPR and Art. 26(1) of the Act on Patient Rights and the Patient Ombudsman. Consent to the disclosure of data is also consent to the violation of personal rights in the form of the right to privacy in accordance with Art. 23 of the Civil Code.

Q2. The Act on Patient Rights and the Patient Ombudsman does not indicate how detailed the information must be provided to a patient who may authorize access to their medical records. In practice, therefore, the patient's declaration does not even have to indicate the purpose of such disclosure—it is sufficient to indicate the entity to which the documentation is to be made available. Before the entry into force of the GDPR, the Supreme Administrative Court in its judgment of September 17, 2013 II OSK 1539/13 ruled that the patient may now prepare a declaration of consent to the disclosure of documentation both within and outside the medical documentation, and the content and scope of authorization of this declaration will depend only on their will. Article 26

94 Centro di Coordinamento nazionale dei comitati etici (CCNCE), *Criticità etiche e normative nel trattamento dei dati personali sanitari nella ricerca osservazionale, Apr. 6, 2023*, https://www.aifa.gov.it/documents/20142/1808580/Criticita_etiche_ricerca_osservazionale_06.04.2023.pdf (accessed Aug. 13, 2025).

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of the Act on Patient Rights allows access to medical records, but further processing is possible on the basis of the GDPR.

However, consent issued pursuant to Art. 9(2)(a) of the GDPR should be preceded by an information obligation, so it is indicated that the patient should be informed in accordance with Art. 13 and 14 of the GDPR. The information obligation may be limited if the hospital providing the data provides it to the company in an anonymized manner. Then the hospital will have to obtain the patient's consent to such data transfer and anonymization, and a company that does not process personal data will not have an information obligation.

According to Art. 26(4) of the Act on Patient Rights and the Patient Ombudsman, medical documentation without consent and special information obligation may be made available to a university or research institute for the use for scientific purposes but only without disclosing the name and other data enabling the identification of the person to whom the documentation relates.

Q3. Consent must be specific under the GDPR. In practice, however, the purpose of processing does not have to be related to a single test, but be related to, for example, the scope of operation of the biobank (eg, cardiological diseases).

Particular attention must be paid to terminology. Indeed, what is called 'broad consent' in Germany, is termed 'specific consent' in Poland. It is true that until the development of biobanks in Poland, consents were collected for a very narrow purpose. Now, if this purpose is, for example, research on civilization diseases (which is most often related to the specificity of a given biobank), it is difficult to call this consent specific, although it is sometimes referred to as such on the forms.

Q4. If the patient does not provide access to medical records or withdraws consent, the medical data cannot be processed. Withdrawal of consent takes effect from the moment of withdrawal—this means that test results obtained before such withdrawal of consent may be used. In practice, two methods are used to secure research data. The first is that the hospital transmits data encoded in such a way that the company does not have access to personal data. Then, withdrawal of consent means that the hospital cannot provide new data, but the company can conduct research on the anonymized data that it previously received. The second solution used when the data cannot be anonymized is to provide information about the withdrawal of consent to the company and exclude the patient's data from further research.

Q5. The approval of the bioethics committee is not required to conduct research on data. The requirement to obtain approval from the bioethics committee applies only to clinical research and medical experiments on humans, within the meaning of the Act on the professions of physicians and dentists. According to the Act on the Professions of Doctors and Dentists, a medical experiment is research carried out on a human being or biological material collected from them. To conduct an experiment on a human being, the consent of the person and the opinion of the bioethics committee are always required (Article 39 of the Constitution of the Republic of Poland). A medical experiment is not conducting research on medical data. An observational study is not an experiment within the meaning of the Constitution or any other act; therefore, it does not require the approval of the bioethics committee.

In practice, however, the requirement to obtain the opinion of the bioethics committee may result from internal regulations, eg, the status of the university or hospital or the

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financing institution. When such a requirement exists, opinions are issued by the unit's internal ECs or the bioethics committees located at the District Medical Chambers. Such opinions are only ethical guidelines, and they do not create an independent legal basis for conducting research on data from medical records.

Conducting research despite a negative opinion of the bioethics committee or EC (in the case of conducting research on data from medical records) may result in employee liability (if the requirement to obtain such an opinion resulted from, for example, the status of the employer), make it impossible to obtain financing (if such a requirement resulted from the requirements of the institution financing), or the inability to publish research results if such a requirement resulted from the publisher's requirements. The lack of an opinion in this regard does not make such research illegal.

Q6. In Poland, there are no major differences between legal regulations and practice. The only existing discrepancy is that some bioethics committees also issue opinions on personal data research. However, such opinions do not then become a legal basis for data processing and do not repeal any GDPR regulations.

The obligation to issue such an opinion does not result from legal regulations. According to the Polish Act on the professions of physician and dentist, the bioethics commission issues opinions only in the scope of medical experiments and clinical research, and therefore not scientific research on data. In practice, therefore, if the bioethics committee issues such an opinion, it is treated as an opinion confirming the ethicality of the indicated research and confirming the appropriate protection of the rights of the person whose data is processed, but not as a legal basis for processing. Hospitals often also apply for such an opinion from the bioethics committee in the case of sharing data from medical records without the patient's consent. In such a case, the opinion is also not an independent basis for processing, but Art. Art. 26(4) of the Act on Patients' Rights and the Patient's Advocate is.

Q7. The Polish Ministry of Health is working on legal regulations to implement the EHDS. At the time of preparation of the article, the drafts of these regulations have not been made public. It can be observed that, until the GDPR came into force, consent was not at all the most important basis for processing personal data for scientific purposes. It became so as a result of the GDPR repealing the national regulation on the protection of personal data. Now, with EHDS, it seems that we are returning to the stage in which consent is not an independent legal basis for data processing but can be treated as a substantive treatment of research participants and building trust between researchers and citizens. For years, it has been said that consent to the processing of personal data has been reduced to a formal requirement only and does not guarantee the protection of the rights of data subject. Additionally, it seems that an ethical argument can be raised here: if the only basis for processing data for scientific purposes is the patient's consent, then *de facto* we are transferring a quite significant element of responsibility for data processing to the data subject who does not know anything about research.

Spain

Q1 and Q2. If it concerns clinical trials or pharmacovigilance studies, the legal basis for data processing should be a legal obligation: once the subject agrees to participate in the research (clinical trial), there is an obligation to process the data. The Farmaindustria code of conduct, approved by the Spanish Data Protection Agency, determines this. It is true that there is no legal obligation to conduct a clinical trial, but if it takes

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place, there is a legal obligation to register the data. Otherwise, Spanish legislation implementing the GDPR does not specify a particular legal basis. It could be any in Article 6 of the GDPR.

In general, the law does not foresee the need for consent for non-interventional studies (but consent is needed for collection and analysis of biospecimens), but ECs usually require it.

The proposed cases could fit the definition of an observational study with medicines as per Royal Decree 957/2020, of November 3, which regulates observational studies with human-use medicines (Article 2.1 a):

> Observational study with medicines': any research that involves the collection of individual health data, as long as it does not meet any of the conditions required to be considered a clinical trial as established in Article 2.1.i) of Royal Decree 1090/2015, of December 4, which regulates clinical trials with medicines, and is conducted for one of the following purposes: To determine the beneficial effects of the medicines, as well as their modifying factors, including patients' perspectives, and their relationship with the resources used to achieve them; To identify, characterize, or quantify the adverse reactions of the medicines and other patient safety risks related to their use, including possible risk factors or effect modifiers, as well as to measure the effectiveness of risk management measures; To obtain information on the patterns of medicines use in the population. Observational studies with medicines must aim to complement the existing information about the medication without interfering with regular clinical practice.

When it comes to observational studies with medicines, Article 5 of Royal Decree 957/2020 stipulates: 'Observational studies with medicines that involve interviewing the participating subject will require their informed consent. However, following the applicable provisions of the current regulations and the ethical principles for medical research involving humans, it may be possible to waive the requirement for informed consent, provided that the ethics committee for Research with Medications (CEIm) considers that the observational research has significant social value, that its conduct would not be feasible or viable without such a waiver, and that it entails minimal risk to the participants. (...) When requesting informed consent, the norms and ethical principles related to the collection, storage, and possible future use of the subjects' biological samples will be taken into account, if applicable.'

Regarding consent as the legal basis for data processing, Article 5 of this Royal Decree states: 3 (...) c) Notwithstanding the provisions of paragraph 1, the consent of the participating subject will be necessary unless another legitimate basis for the processing of their personal data, as referred to in Articles 6.1 and 9.2 of Regulation (EU) 2016/679 of the European Parliament and of the Council, of April 27, 2016, is applicable. Additionally, the sponsor and researchers must apply the criteria governing data processing in health research in accordance with the seventeenth additional provision of Organic Law 3/2018, of December 5. (...)

Therefore, we could conclude that the legal basis for data processing could be found in Article 6.1 (a), 6.1 (e), or 6.1 (f). Spanish legislation has developed what is provided in Article 9.2 (j) of the GDPR (Additional provision 17ª of Organic Law 3/2018, of December 5).

There is no specific development regarding the content of the information that must be provided, beyond what is stipulated in the GDPR. There are also no provisions

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regarding exceptions to the duty of information, although what is provided in Art. 14.5 of the GDPR could be applicable.

A guide has been developed for the correct preparation of a model participant information sheet and informed consent (HIP/CI) for observational studies with medicines (EOM): https://www.aemps.gob.es/medicamentos-de-uso-humano/investigacion_medicamentos/estudiospostautorizacion/#nor2021

Regarding the second case, it seems that the researcher could rely on the 17ª Additional Provision of Organic Law 3/2018 (if the 'new' research purpose is related to the former one) that states:

> c) The reuse of personal data for research purposes in health and biomedical fields will be considered lawful and compatible when, having obtained consent for a specific purpose, the data is used for purposes or areas of research related to the area in which the initial study is scientifically integrated. In such cases, the data controllers must publish the information established by Article 13 of Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, in an easily accessible place on the corporate website of the center where the research or clinical study is conducted and, if applicable, on the sponsor's website. Additionally, they must notify the existence of this information by electronic means to the affected individuals. If these individuals lack the means to access such information, they may request its provision in another format. For the data processing activities outlined in this paragraph, a prior favorable report from the ethics committee of the research will be required.

This provision underscores the legality and compatibility of reusing personal data for related research purposes once consent has been obtained, provided that proper notification and transparency measures are followed, including publishing the necessary information online and obtaining prior approval from the EC.

Q3. In the case of the legal basis for data processing for scientific research, consent can be given for research areas (ie, broad consent):

> a) The data subject or, where applicable, their legal representative may give consent for the use of their data for health research purposes and, in particular, biomedical research. Such purposes may include categories related to general areas linked to a medical or research specialty (17ª Additional Provision of Organic Law 3/2018).

This means that individuals or their legal representatives can consent to the use of their personal data for health and biomedical research. The scope of the consent can cover broad categories related to specific medical or research specialties. This provision allows for a wider application of the data, facilitating research within related fields without needing to obtain separate consents for each specific study within the same specialty.

Q4. As the studies cases are stated, if the subject refuses to participate in the research, data processing could not be carried out on any legal basis, since the subject would not be involved in the research, which is conceived as a prerequisite.

In the case of consent withdrawal, the necessary prerequisite for data processing has been met.

In this second scenario, the subject will leave the study after withdrawing consent to participate and may request the erasure of the data (Art. 17.1 b, or 17.1 c).

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However, it should be recalled that the withdrawal will not affect the lawfulness of the processing based on the consent prior to its withdrawal. Before giving consent, the data subject shall be informed thereof.

Furthermore, erasure shall not apply where the 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), insofar as the right referred to in paragraph 1 would make impossible or seriously impede the achievement of the purposes of such processing (...). (Art. 17.3).

Concerning Spanish legislation, mention should be made to the provisions of Art. 59.1 e) of the Law 14/2007 on Biomedical research in the framework of research with biological samples, according to which the effects of the withdrawal of consent shall not extend to the data resulting from research that has already been carried out. Royal Decree 1090/2015, which regulates clinical trials with medicinal products, states that:

> (...) The withdrawal of consent shall not affect the activities carried out on the basis of consent before it was withdrawn, guaranteeing in turn that neither the data nor the samples obtained on the basis of said consent may be used in analyses or studies after the date of withdrawal (...).

In addition, the obligation to maintain trial documentation is established, both for the RECs for a minimum of three years (Art. 16.7), and for the sponsor and the investigator for a minimum of 25 years (Art. 43). The Law 14/2007 also contains some provisions regarding the obligation to maintain data for 30 years for specific cases in which it is necessary to ensure the traceability of cells and tissues that have been applied to humans for research purposes (Art. 8).

Ultimately, if the maintenance of the data is necessary for the purposes of the research to which consent was given, revocation has a limited effect since the data will continue to be recorded and form part of the results of the study. Anonymization should be assessed as the best option that can reconcile the interests at stake.

Q5. Observational studies with medicines are regulated by specific legislation, and detailed information about the requirements and practical application can be found on the Spanish Agency of Medicines and Medical Devices (AEMPS) website: https://www.aemps.gob.es/medicamentos-de-uso-humano/investigacion_medicamentos/estudiospostautorizacion/?lang=en. The research EC should be involved. If there is a commercial interest in a prospective study, the authority of the corresponding autonomous community should also be involved.

Q6. The difference between consent as a legal basis for data processing and consent as an expression of the subject's autonomy to participate in research is being assumed. There is no conflict between institutions in this perception, although there has been some confusion. A good example is that this perspective is assumed in the first code of conduct in Europe, approved by the Spanish DPA: https://www.aepd.es/es/documento/farmaindustria-code-conduct-regulating-processing-personal-clinical-en.pdf.

Q7. In Spain, the Ministry for Digital Transformation and the Civil Service is coordinating the strategy for integration into the EHDS, which also requires the involvement of the Autonomous Communities. As a starting point, there is the Digital Health

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Strategy of 2021 (https://www.sanidad.gob.es/areas/saludDigital/doc/Estrategia_de_Salud_Digital_del_SNS.pdf).

Work is being done on the construction of data lakes, high pseudonymization and anonymization capabilities, medical imaging, predictive artificial intelligence, and the development of infrastructures. There is also a high degree of digitization at every level of healthcare. However, this ecosystem needs to build its governance for the purposes of integration into the EEDS (for example, with regard to the DAB and the development of the accreditation system at the national level for research ECs).

On the other hand, the data protection legal framework developed in Spain (Organic Law 3/2018, of December 5, on Personal Data Protection and guarantee of digital rights) facilitates the secondary use of data for research purposes, while maintaining adequate safeguards (Additional Provision 17th: Health data processing). Consent is a possible legal basis for processing, but not the only one, so that the system conceived by the EHDS is not unknown in our legal system.

A major challenge will be the integration of the private sector into the system, as well as the management of the economic interests of the agents involved.

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