
## AIDV Working Group
## DELIVERABLE 3

# GUIDANCE FOR INFORMED CONSENT IN THE CONTEXT OF ARTIFICIAL INTELLIGENCE AND DATA VISITATION

October 25th, 2024

**Co-leaders: Dr. Anne Cambon-Thomsen,** Emeritus Research Director at the Epidemiology and Population Unit of the French National Center for Scientific Research (CNRS), France; **Mr. Gauthier Chassang**, Lawyer, National Institute of Health and Medical Research (INSERM) CERPOP/UT3, Genotoul Societal Platform, France; **Dr. Kristy Hackett**, Assistant Professor and Assistant Director, Institute on Ethics & Policy for Innovation, McMaster University, Canada.

**Fellows: Mr. Luis Jacob Retanan**, Defense Research Officer for Cognitive Security and Artificial Intelligence, Department of National Defense, the Philippines; **Ms. Noémie Dubruel**, PhD Student in Health Law and Medical Research at INSERM and UT1 Capitole Maurice Hauriou Institute, France.

**Funding Acknowledgements:**

This work was developed by the EOSC-Future & RDA Artificial Intelligence and Data Visitation Working Group (AIDV-WG) with funding received from the European Commission under the Horizon2020 Programme with Grant Agreement Number 101017536 through the European Open Science Cloud – Future Project (EOSC-Future). The project was designed and coordinated by Francis P. Crawley as Principal Investigator with the Good Clinical Practice Alliance - Europe (GCPA). The AIDV-WG enjoys further support from the RDA TIGER programme funded under the Horizon Europe Grant agreement ID: 101094406.

**Relationship to other AIDV outputs/efforts:**

These recommendations proposed by the EOSC Future/AIDV Working Group's on Informed Consent team are meant to be informed by and responsive to the concurrent outputs of AIDV WG team deliverables particularly the AIDV WG AI Bill of Rights Recommendation[1] and the AIDV WG Guidance for Ethics Committees Reviewing AI and Data Visitation.[2]

[1] AIDV WG AI Bill of Rights Recommendation, **DOI**:10.15497/RDA00123
[2] AIDV WG Guidance for Ethics Committees Reviewing AI and DV, **DOI:**10.15497/RDA00122

## CONTENTS

**PART I - BACKGROUND: AI CHALLENGES FOR HUMAN AUTONOMY**

**PART II - INFORMED CONSENT GUIDANCE**

**I. Human-Centered AI and Informed Consent in Scientific Research**

A. *Psychographic Data and Human-Computer Interaction*

B. *Special Case of Genetic Research and the Impact of AI and DV*

**II. Challenges of AI and DV to the Conception and Practice of Informed Consent**

A. *Human Computer Interaction Implications on Informed Consent*

B. *Evolving Landscape of Informed Consent: Challenges and Opportunities*

**PART III - RECOMMENDATIONS ON INFORMED CONSENT IN AI, DV and OPEN SCIENCE**

**I. General Recommendations**

**II. Specific Recommendations**

A. *On Global Governance and Research and Development*

B. *On Specific Cases*

## PART I - BACKGROUND: AI CHALLENGES FOR HUMAN AUTONOMY

The accelerated use of digital technology in all areas of society is illustrated by the rapid development and deployment of Artificial Intelligence (AI). This technology, which can take many forms, including self-learning AI systems, requires the use or reuse of large datasets,: so-called 'big data', to perform a wide array of social and technical functions across many sectors including healthcare, education, manufacturing, and more[3]. Despite the many potential benefits of AI[4], concerns around access to and sharing of data persist, creating a tension between the deployment of innovation on one hand and risk to the privacy of individuals on the other. Thus, barriers to the ethical implementation of AI have been identified, such as a lack of coordination between personal data protection regulations and proposed AI regulations and the different frameworks applicable to specific fields (in health or research, for example). There are also concerns regarding the lack of harmonisation in the practices and methods used (i.e. inconsistencies in how AI models are built, which data goes into them, and the processing tools employed). Lastly, there are ethical concerns related to the lack of transparency of the means used to access data and the purposes for which it is used, and the potential for public distrust of data sharing as a result[5].

It is in this context that discussions around Data Visitation (DV) techniques have emerged[6]. This method, which is not yet concretely defined or adopted[7] involves a new way of providing temporary access to data wherein analyses can be 'brought to the data' in cloud-based environments with restrictions applied to data export.[8] Because AI tools may be used to facilitate the process of DV, the considerations outlined herein will be relevant to DV as the concept evolves.

---

[3] MÜLLER S., "Is there a civic duty to support medical AI development by sharing electronic health records?", *BMC Medical Ethics*, n°134, 2022.
[4] Council of Europe, "The Council of Europe & Artificial Intelligence", March 2023.
[5] KALKAM S., VAN DELDEN J., BANERJEE A., TYL B., MOSTERT M., VAN THIEL G., "Patients' and public views and atitudes towards the sharing oh health data for research: a narrative review of the empirical evidence", *Journal of Medical Ethic*, n°48, 2022.
[6] Data visitation refers to a process in which: i) data sets are subject to analysis within a host location without the data ever leaving the host location; ii) the analytical framework can be submitted by a third party external to the host location; and iii) the results can be returned to that third party.
[7] Results of the literature review carried out by group 3 of the AIDV working group between December 2022 and March 2023. See the Appendix.
[8] STARK Z., GLAZER D., HOFMANN O. *et al.* A call to action to scale up research and clinical genomic data sharing. *Nat Rev Genet* (2024). https://doi.org/10.1038/s41576-024-00776-0

The deployment of AI and DV methods and their requisite use of large volumes of data raise several important legal and ethical concerns related to privacy, data protection, and data sharing.[9] In particular, a re-examination of the effectiveness, applicability, and format of existing informed consent models is necessary.

Computational efficiency along with its self-learning capability is transforming AI from a mere tool to an increasingly viable component of human cognition as it becomes adept not only in providing whatever output that its human users expect, but also in anticipating what they want.[10] As a result, AI is becoming a necessary part of how one understands the world and other people. The augmentative potential of AI significantly contributes to its ever-increasing advancement as developers are more incentivised to build better AI technologies, exemplifying the so-called "Law of Accelerated Returns".[11] But as AI generates improved cognitive abilities, it not only accelerates its own development, but also the human-technology relationship. This means that AI is not only becoming reflective of whatever humans consider as 'intelligence' but also that humans are increasingly driven by its algorithms. This is brought about by its increasing capability to collect and process massive amounts of complex and heterogeneous data, notably "sensitive personal data", including psychographic and genomic information of individuals.[12] The former relates to their personal beliefs and desires, while the latter relates to their genetic characteristics, which drive biological functions and predispositions. Thus, despite the potential of AI to improve quality of life and facilitate human flourishing, it is also poised to challenge the exercise of human autonomy.[13] The growing sophistication of AI in shaping individual choices and actions is due

---

[9] Council of Europe, Study, "Toward regulation of AI systems. Global perspectives on the development of a legal framework on Artificial Intelligence (AI) systems based on the Council of Europe's standards on human rights, democracy and the rule of law", December 2020.

[10] *See* Peter Reiner and Saskia Nagel, 'Technologies of the Extended Mind: Defining the Issues,' in Judy Illes (ed), *Neuroethics: Anticipating the Future* (Oxford: Oxford University Press, 2017), 109-11; *See also* Jeff Orlowski (dir), *The Social Dilemma* (Netflix: Center for Humane Technology, 2021).

[11] *See* Ray Kurzweil, 'Law of Accelerating Returns', *Kurzweil Accelerating Intelligence*, last modified March 7, 2001, https://www.kurzweilai.net/the-law-of-accelerating-returns.

[12] **Sensitive data** should be considered as any data related to (i) racial or ethnic origin, (ii) political opinions, (iii) trade union association, (iv) religious beliefs or other beliefs of a similar nature, (v) physical or mental health or condition (or any genetic data), (vi) sexual orientation and other related activities, (vii) the commission or alleged commission of any offence, (viii) any information regarding judicial proceedings, (ix) any financial data, (x) children and (xi) an individual(s) or group(s) of individuals that face any risks of harm (e.g. physical, emotional, economic) (2017 Data Privacy, Ethics and Protection Guidance); **Psychographic data** - personal information highlighting the subjective expressions of the individual that features his/her belief systems, aspirations, and desires and aversions; **Genomic data** - personal information highlighting the objective yet unique genetic constitution of the individual that governs (or influence or contributes) determines his/her biological structure and processes (i.e., neural processes).

[13] The conception of autonomy being forwarded in this paper is the ability born out of the inherent human capacity of freewill that allows a person to discern and act in a manner that reflects (a) **rationality** – logical/ principled coherence of thought and action driven not by the fickleness of desires but rather a critical understanding of them, (b) **subjectivity** – self-expression that demonstrates control/ owning of desires towards building an authentic character,

to its ability not only to anticipate but also to harness human emotions, to deliver personalised and persuasive outputs thanks to natural language processing abilities (e.g. generative AI systems), making the technology increasingly addictive and the possibility of loss of human control greater.[14]

## PART II - INFORMED CONSENT GUIDANCE

The deployment of cutting-edge technologies such as Artificial Intelligence and Data Visitation systems is leading us to rethink the central concept of informed consent and its implementation. Specific examples illustrate the current limits of consent in an increasingly complex environment. Strictly applying implicit consent[15] would entail the risk of 'consent fatigue', while failing to consider the implementation of informed consent would risk creating blocking situations - where human autonomy is not respected and the individual's consent is required by law -, both for the protection of individuals and for the development of innovation.

### I. Human-Centered AI and Informed Consent in DV and Scientific Research

#### *A. Psychographic Data and Human-Computer Interaction*

Advancements in AI rendered intimate the interaction between human individuals and technology to such an extent that it is becoming an inseparable part of how people navigate today's data-intensive world. However, AI, with its increasing sophistication and the lack of transparency in its deployment, the training data used and the explicability of the resulting predictions, can present a risk to the exercise of autonomy. This risk may be reinforced by the fact that AI systems need to collect and analyse sensitive data in order to be effective in predicting, shaping (or manipulating) decision-making processes. What makes this risk more problematic is the nature of today's sophisticated AI systems whose algorithmic programs have become unexplainable and unpredictable (i.e., the 'black box' problem).

Some uses of AI systems may run counter to respect for autonomy and human rights. This is illustrated, for example, by the practices of online commercial and social media platforms

---

and (c) **empathy** – recognition of experiences of subjectivity and rationality of the person. The understanding of autonomy in this paper is grounded on its Kantian and Schopenhauerian conceptions.

[14] *See* Robert Mahari and Pat Pataranutaporn, 'We need to prepare for 'addictive intelligence'', MIT Technology Review (August 5, 2024), https://www.technologyreview.com/2024/08/05/1095600/we-need-to-prepare-for-addictive-intelligence.

[15] See page 12 for definitions.

whose marketing strategy depends on ensuring continued engagement from their users through collecting psychographic data based on these users' online activities. The algorithms essentially leverage human-computer interaction (HCI) to exhibit the psychological disposition of users, and make engagements more personalised in a way that exploits their desires, fears and beliefs. One instance of this abuse is the 2018 Facebook-Cambridge Analytica Scandal wherein millions of people's personal information were collected from Facebook (without their informed consent), and used by Cambridge Analytica - a political consulting firm - to develop psychographic-based campaign strategies for its clients via political microtargeting techniques (PMTs).[16] Such an instance ultimately shows how difficult it is to practise and even conceive informed consent in today's data-intensive AI ecosystem. This example illustrates how the deployment of AI to exploit massive, complex data sets can lead to abuses such as failing to comply with data privacy regulations. Furthermore, the practice of informed consent requires that subjects receive, and understand sufficient information on the matter at stake. The emergence of AI therefore makes the traditional conception and practice of informed consent obsolete. It is no longer sufficient to merely ask users for their consent at a certain point because AI systems are increasingly contributing to the cognitive process itself. Moreover, as much as algorithmic transparency can help address issues of informed consent in the use of AI systems, it must not be taken to be the solution to ensure human autonomy, especially if the trajectory of AI development leads to a more entrenched role in human cognitive processes. If we are to respect and secure the autonomy of human users, then consent must be accompanied by educational programs and become an ongoing and dynamic process wherein users are given the opportunity to be involved from the beginning up to the end of their use of the AI system. This would enable users to determine the direction and manner in which the AI will collect, process and use the data they provide. The challenge is making this practicable and appropriate given the tension between freedom of consent and the possible influence of AI on human cognition.

The study of informed consent in the context of HCI – particularly that of AI as a cognitive extension – is still nascent and in an exploratory stage. Nonetheless, there are two related models of processual informed consent being explored in the area of HCI – FRIES and TEASE:

[16] Nicholas Confessore, 'Cambridge Analytica and Facebook: The Scandal and the Fallout So Far,' The New York Times (April 4, 2018), Retrieved from https://www.nytimes.com/2018/04/04/us/politics/cambridge-analytica-scandal-fallout.html.

| FRIES Model of Informed Consent | TEASE Model of Informed Consent |
|---|---|
| **Freely given** – "consenting is a choice you make without pressure or manipulation" | **Traffic Lights** – a "traffic lights system" denoting "stop", "slow down", and "continue" |
| **Reversible** – "anyone can change their mind about what they feel like doing, anytime" | **Establish ongoing dialogue** – "dialogue between participants around consent, boundaries and desire" |
| **Informed** – "You can only consent to something if you have the full story" | **Aftercare** – "participants check in after play, discussing how the 'scene' [interaction] met their expectation of consent and desire, or where limits may have been reached or breached" |
| **Enthusiastic** – "You should only do stuff you want to do, not things that you're expected to do" | **Safewords** – "safewords are used to immediately withdraw consent; they can also be utilised to signal that one party is becoming uncomfortable" |
| **Specific** – "saying yes to one thing doesn't mean you've said yes to others" | **Explicate soft and hard limits** – "hard limits are absolute prohibitions against certain activities, while soft limits denote something that is currently not allowed in the interaction but may be revisited and permitted under specific circumstances" |

Source: Yolande Strengers et.al, 'What Can HCI Learn from Sexual Consent?: A Feminist Process of Embodied Consent for Interactions with Emerging Technologies,' *Association for Computing Machinery* (2021).

Scholars of HCI are of the view that the TEASE model is especially crucial in ensuring interaction of individuals and smart technologies would bring about a relationship wherein practice of informed consent based on the FRIES model could be exercised, thereby enhancing

their sense of privacy and autonomy.[17] However, in order to apply the TEASE model effectively, it would require innovations in the design of the smart technologies themselves. The primary design innovation must enable seamless exercise of "ongoing affirmation", which means that consent is not just a requirement but rather an integral part of the entire interaction itself, which helps enhance user experience, and prevents coercing the user into consenting just to avail the services of the technology they interact with.

### *B. Special Case of Genetic Research and the Impact of AI and DV*

In the European GDPR[18]genetic data being directly associated with specific inherited or acquired characteristics of an individual is considered personal data and potentially as health data. Genetic data, like health data and other types of very personal information[19], is of a sensitive nature that may justify stricter supervision and individual control, depending on the wishes of each member state which can enact specific and eventually stricter provisions than those laid down by the GDPR[20] to process such data. That said, we are seeing a trend towards opening up the use of genetic data for research, as it has been the case in France, for example, since the adoption of the bioethics law of August 2, 2021, which reinforces the opt-out mechanisms to provide access to genetic data for research on somatic genetic characteristics, and open possibilities to perform somatic but also constitutional genetic research as a secondary use of existing materials such as biological samples procured during healthcare.[21] This regulatory update limits the consent practice to activities presenting higher informational risks for individuals and their relatives (namely constitutional genetic research likely to involve information of interest for relatives). Furthermore, French law allows now to plan broader processing purposes in the context of a research program, allowing to practice opt-out for a set of research projects[22]. This example of the French framework shows that the notion of consent has been superseded by opt-out (as non-opposition), presented as a sufficient tool to preserve patient autonomy on the one hand, and the development of

[17] We are trying to extract the fundamental characteristics of a sexual consent explicated in the FRIES and TEASE models. Studying such kind of consent in the context of HCI presents value in developing a processual consent beyond people towards a more general one applicable particularly as to how people interact with AI.
[18] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation), recitals 34 and 35, Art.4(13) and 4(15) GDPR.
[19] Art.9(1) GDPR.
[20] Art.9(4) GDPR.
[21] Art.16-10 French Civil Code.
[22] Article L.1130-5 of the French legislation (Code de la santé publique).

innovation and medical research on the other[23]. However, this is conditioned by the respect of ethical imperatives, including the need to get ethics approval of the program, and other regulatory obligations fixed under the GDPR and the French data protection law. This approach considers existing regulatory safeguards and considers the fact that the processing of genetic data not only requires steps for ensuring individual patient autonomy, but also has possible implications for members of the individual's family, for a group of individuals or even for an entire community. Thinking of the issues involved in genetic data processing as a whole means considering the notion of a group rather than just an individual. Moreover, the processing of genetic data can lead to the emergence of incidental data not originally envisaged.[24] The issue of the definition of the purpose of processing is therefore essential, also in the context of the use of data visitation and AI, in particular where highly informational data are processed.

It should also be noted that the evolution of research methods is leading to the use of a large amount of health data, particularly genetic data, to implement current clinical trials. Take, for example, the technique of digital twins, which makes it possible to create virtual patient cohorts from real-life health data, and in particular genetic data, to complement conventional clinical trials[25]. This large-scale data processing illustrates the difficult balance between, on the one hand, a desire for greater protection of individuals, which would lead to the need for strict consent for a specific purpose, and, on the other hand, the blatant risk of limiting innovation and the deployment of these methods by preventing access to data.

DV and AI methods accentuate the possibilities of data access and lead us to consider such issues. In this context, broad and dynamic consent[26] would appear to be a suitable solution to meet both protection and innovation challenges[27]. However, this form of consent requires sufficient and appropriate information to ensure that the individual is able to understand the various purposes and uses of the data[28]. A definition of what constitutes

[23] Olivier JM., et al. " Balancing the Risks and Benefits of Genomic Data Sharing: Genome Research Participants' Perspectives", Public Health Genomics 2012, 15, pp. 106-114.
[24] Mathaiyan J, Chandrasekaran A, Davis S. Ethics of genomic research. Perspect Clin Res. 2013 Jan;4(1):100-4. doi: 10.4103/2229-3485.106405. PMID: 23533991; PMCID: PMC3601693.
[25] Benson Mikael, 'Digital Twins for Predictive, Preventive Personalized, and Participatory Treatment of Immune-Mediated Diseases', Arteriosclerosis, Thrombosis, and Vascular Biology. 26/01/2023; 43:410-416, https://doi.org/10.1161/ATVBAHA.122.318331.
[26] See pages 11 and 12 for definitions.
[27] Budin-Ljøsne, I., Teare, H.J.A., Kaye, J. *et al.* Dynamic Consent: a potential solution to some of the challenges of modern biomedical research. *BMC Med Ethics* 18, 4 (2017). https://doi.org/10.1186/s12910-016-0162-9.
[28] Wedow R, Researchers can learn a lot with your genetic information, even when you skip survey questions-yesterday's mode of informed consent doesn't quite fit today's biobank studies", The conversation, 29/06/2023 ,[Article on line:

appropriate and sufficient information, adapted to the requirements of clarity and completeness is also required.

## II. Challenges of AI and DV in the Conception and Practice of Informed Consent

### *A. Human Computer Interaction Implications on Informed Consent*

The analysis of the TEASE models cited above, shows that they – even together with TRUST and CARE principles[29] – would not be able to ensure a relevant practice of informed consent in HCI in line with FRIES. AI as a cognitive extension is a double-edge sword – its capability to act as part of human thinking comes from its effectiveness as a tool for mind manipulation. This is demonstrated by the already prevalent use of AI as persuasive technologies for sustaining customer engagement.

Thus, there will always be an element of persuasion and deception in the interaction that compromises FRIES in three ways:

(a) Considering that there is deception to begin with – shaping the mind of the user to think in a certain way – then it is questionable whether consent could be freely given;[30]

(b) Given that the AI in this case – in order to perform what it is programmed to do – must obscure certain facts or functions, which then prevents the user from being informed of the whole picture as well as the opportunity to reverse any decision he or she might take, and to choose what specific interaction he or she would want to have;[31]

(c) Given that AI can effectively manipulate users[32] to sustain engagement via appealing to and amplifying their desires, it is questionable whether users are genuinely enthusiastic in the course of their interaction with this technology.[33]

Considering these three points, there is a continuing need to explore technological innovations that could provide a kind of HCI with AI technologies that can facilitate ongoing

---

https://theconversation.com/researchers-can-learn-a-lot-with-your-genetic-information-even-when-you-skip-survey-questions-yesterdays-mode-of-informed-consent-doesnt-quite-fit-todays-biobank-studies-208416].

[29] "These principles complement the existing FAIR principles (www.go-fair.org) encouraging open and other data movements to consider both people and purpose in their advocacy and pursuits. Collective benefit Authority to control Responsibility Ethics" (RDA).

[30] Strengers et.al, *What Can HCI Learn from Sexual Consent?*.

[31] Ibid.

[32] Council of Europe CM Declaration Decl(13/02/2019)1 on the manipulative capabilities of algorithmic processes, adopted by the Committee of Ministers on 13 February 2019 at the 1337th meeting of the Ministers' Deputies.

[33] Strengers et.al, *What Can HCI Learn from Sexual Consent?*.

affirmation – integrating consent for the entire duration of the interaction – while preventing harmful manipulation in a way that the users' innermost emotions cannot be used to disrupt his/her autonomy. In this case, redesigning AI to fit TEASE will no longer be sufficient, there must be another technology developed that could provide users the means to mitigate (or even escape) AI manipulation throughout the interaction process.

While there are ways of combating the manipulation that can be carried out via AI systems, both legally and technically, the preservation of individual autonomy is an essential principle that must be remembered at every stage in the deployment and use of AI.

### *B. Evolving Landscape of Informed Consent: Challenges and Opportunities*

The deployment of new AI methods and digital techniques has led to a change in the very notion of Informed Consent, originally conceived - at both the International and European level - as a tool for protecting fundamental rights.[34] In the field of health research, for example, informed consent is affirmed in the form of a legal obligation, which must be strictly formalised, attesting to the autonomy and even self-determination of the individual (essential consistency in the application of fundamental rights).[35] The widespread use of personal data has led to the articulation of two distinct types of consent: consent in the context of interventional research, which protects bodily integrity[36] ; and consent in the context of data protection, which protects informational integrity[37], both fundamental to respect for the individual's right to privacy and requiring a balance to be struck with digital methods.[38] This intermingling of types of consent makes the application of informed consent complex and can lead to consent being seen as a limit on access to data, and this limit is also highlighted in relation to the deployment of AI. There is a balance to establish between ensuring protection and fostering innovation. The available literature does not always highlight such a balance.

---

[34] P. du Bois, Pierre, L'Union européenne et les droits de l'homme, Relations internationales, vol. 132, no. 4, 2007, pp. 33-39, available at: https://www.cairn.info/revue-relations-internationales-2007-4-page-33.htm.
UN, Report of the High Commissioner for Human Rights A/HRC/39/29: The right to privacy in the digital age, 3 August 2018.

[35] Declaration of Helsinki, World Medical Association, June 1964; Note: However, consent is not the only standard allowing access to data in the context of research activities. In the GDPR, consent is presented as one of the possible legal bases for the access and use of data implemented when there is an increased risk to the protection of individuals and their privacy. However, consent within the meaning of the GDPR is understood as a legal basis and should not be confused with the concept of informed consent analysed here.

[36] Shuster E. The Nuremberg Code: hippocratic ethics and human rights. Lancet 1998;351(9107):974-7.

[37] EDPB, Consent Guidelines 05/2020 under Regulation 2016/679, Version 1.1.

[38] O CATHAOIR Katharina, "The evolution of human rights in the European Union and its impact on consent for genetics/genomics research", oral presentation in session GA4GH 2023 "Consent for the sharing of biological materials and data in genetics/genomics research. L'impact de l'évolution des normes européennes dans les cadres de la science ouverte". 20 April 2023.

Informed consent cannot therefore be presented as a strict and immutable concept, because in practice it is a tool and tools need to be adapted. The risk would be to empty this principle of all its essence with the emergence of consent fatigue due to the very large number of uses of data via the Internet, which a single person cannot control, for example. Consent could be undermined in a digital world where consent must be given for each data processing operation, identified according to purpose, by ticking boxes without really grasping all the information.

Consequently, a third dimension of the implementation of informed consent must be considered in the context of AI. Indeed, AI questions not only the purposes for which consent is expressed but also its content and the form it should take to avoid the automatic application of inappropriate consent as a meaningless shield.[39]

It must be a broad and evolving concept that can be adapted to today's challenges[40]. The classic concept of consent must be transformed by promoting information to go beyond consent to trust professional organisations, giving individuals the possibility of controlling the use of their personal data. Consent should then no longer be formalised as it traditionally was and should be adapted to the specific challenges of AI[41] and DV.

In this respect, the analysis of the literature carried out before the drafting of this document highlighted a point of convergence on the need to develop consent by promoting information, trust and proactive consideration of individuals[42]. The literature review showed that the most commonly used form of informed consent is specific consent, which is most often written. However, this form of informed consent does not appear to be adapted to the challenges of AI and DV and leads us to reconsider the other forms of consent that could be applied.[43,44] Informed consent for data collection, storage and use can take several forms, listed below:

[39] Council of Europe, "Toward regulation of AI systems. Global perspectives on the development of a legal framework for artificial intelligence (AI) systems based on Council of Europe standards of human rights, democracy and the rule of law", study, December 2020.
[40] HEIKKILÄ Melissa, The Algorithm, MIT Technology Review, new letter dated 5.01.2023.
[41] EU, Independent High Level Expert Group on Artificial Intelligence set up by the European Commission, "Ethics Guidelines for Trustworthy AI", guidelines, 2019.
[42] Poster published to mark the 20th anniversary of the GDR Alliance.
[43] European Economic and Social Committee, Opinion of the European Economic and Social Committee on the European Health Data Space, Communication from the Commission to the European Parliament and the Council. A European Health Data Space: harnessing the potential of health data for people, patients and innovation. [COM(2022) 196 final, 3 May 2022.
[44] UNESCO, Recommendation on the Ethics of Artificial Intelligence, 24 November 2021.

- **Explicit consent (opt-in)**: This form of consent requires people to give their consent actively and explicitly, for example by ticking a box or clicking on a button.[45]
- **Implicit consent (opt-out)**: With this form of consent, individuals must express their opposition explicitly.[46]
- **Specific consent**: This is, for example, the form of consent required by the European Data Protection Regulation (GDPR), which requires clear and precise information to be provided to individuals so that they can freely consent to the processing of their data for a specific purpose, via a specific form.[47]
- **Layered or multi-layered consent**: This form of consent is made up of different layers of information, recipients or purposes[48]. Essential information can be highlighted (layer 1), then other optional information (layer 2) can be made accessible, for example.[49]
- **Dynamic consent**: This form of consent is characterised by the desire to make consent mutable and to adapt it as techniques and knowledge evolve, with the same aim in mind.[50] It can take the form of personalised consent and communication platforms, enabling ongoing communication and information. Different forms of consent can thus converge towards the broader form of dynamic consent, enabling individuals to evolve their decision-making.[51]
- **Broad consent**: This is a form of consent that allows an individual to give general consent to the use and re-use of their data for further research, for example, without any further explicit consent from them.[52]

[45] https://bigid.com/blog/opt-in-vs-opt-out-consent/
[46] https://bigid.com/blog/opt-in-vs-opt-out-consent/
[47] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation), Articles 4 and 7.
[48] Bunnik EM, Janssens AC, Schermer MH. A tiered-layered-staged model for informed consent in personal genome testing. Eur J Hum Genet. 2013 Jun;21(6):596-601. doi: 10.1038/ejhg.2012.237. Epub 2012 Nov 21. PMID: 23169494; PMCID: PMC3658183.
[49] Symons, TJ, Straiton, N., Gagnon, R. et al. Consumer perspectives on simplified multilevel consent for a pragmatic low-risk but complex trial. Trials 23 , 1055 (2022). https://doi.org/10.1186/s13063-022-07023-z.
[50] Budin-Ljøsne, I., Teare, HJA, Kaye, J. *et al.* Dynamic consent: a potential solution to some of the challenges of modern biomedical research. *BMC Med Ethics* 18, 4 (2017). https://doi.org/10.1186/s12910-016-0162-9.
[51] Kaye J, Whitley EA, Lund D, Morrison M, Teare H, Melham K. Dynamic consent: a patient interface for 21st century research networks. Eur J Hum Genet. 2015;23(2):141-6.
[52] Antonio Sandu, Ana Frunza , Ethics in research practice and innovation, Chapter 9 "Informed consent in research involving human subjects", 2019, 21p.

Other less traditional conceptions of consent , such as "**Community-based** consent"[53] are worth considering. This concept, developed primarily in health and genomics research[54,55,56], highlights the possibility of grouped consent, wherein an entire community consents together to the same purpose. Crucial in this regard is the consideration of indigenous cultures and their respective notions of informed consent as embodied in the principle of Free, Prior and Informed Consent (FPIC) under the UN Declaration on the Rights of Indigenous Peoples.[57] Cultural preferences, beliefs and values influence individuals' conception and practice of informed consent, therefore considering these factors in the development of AI models will help discern appropriate thresholds or limitations in how they interact with human users, and facilitate the development of culturally sensitive processual forms of informed consent. Community engagement and assent can promote valid informed consent of individual community-members.[58] The exercise of collective autonomy comes into play if the exercise of individual autonomy has proved impossible or unsuitable for the pursuit of a specific research objective (for example, genomic research), but it must guarantee that it will not produce results that undermine the cognitive well-being of the individual. At the same time, it is important to distinguish between community consent and community engagement, which may be necessary for the researcher to understand a community's own expectations and functioning with regard to individual consent processes[59]. Thus, the processes of obtaining free, prior and informed consent on a collective basis can complement the individual basis in pursuing a specific research purpose (i.e., genomics research), but without substituting for it. Ethical review processes at the community level may be appropriate as AIDV develops.Therefore, community-based ethical review[60] processes may be appropriate as AIDV is further developed.

---

[53] Developed countries should not impose ethics on other countries, *BMJ* 2002; 325:796: https://doi.org/10.1136/bmj.325.7368.796/a.

[54] CIOMS, International Ethical Guidelines for Health-related Research Involving Humans, 2016, Guideline 7.

[55] CIOMS Working Group report on Clinical research in resource-limited settings, 2021.

[56] Participants in the Community Engagement and Consent Workshop , Kilifi, Kenya , March 2011. Consent and community engagement in diverse research contexts. J Empir Res Hum Res Ethics. 2013 Oct;8(4):1-18. doi: 10.1525/jer.2013.8.4.1. PMID: 24169417; PMCID: PMC4836561.

[57] UN General Assembly, "UN Declaration on the Rights of Indigenous Peoples," September 2007, https://www.un.org/development/desa/indigenouspeoples/wp-content/uploads/sites/19/2018/11/UNDRIP_E_web.pdf.

[58] Adhikari, B., Pell, C., & Cheah, P. Y. (2019). Community engagement and ethical global health research. *Global Bioethics*, *31*(1), 1–12. https://doi.org/10.1080/11287462.2019.1703504

[59] Hayward A, Sjoblom E, Sinclair S, Cidro J., "A New Era of Indigenous Research: Community-based Indigenous Research Ethics Protocols in Canada", *Journal of Empirical Research on Human Research Ethics*, n°16, Vol 4, 2021, pp. 403-417.

[60] Shore N, Brazauskas R, Drew E, Wong KA, Moy L, Baden AC, Cyr K, Ulevicus J, Seifer SD. Understanding community-based processes for research ethics review: a national study. Am J Public Health. 2011 Dec;101 Suppl 1(Suppl 1):S359-64. doi: 10.2105/AJPH.2010.194340. Epub 2010 Dec 16. PMID: 21164086; PMCID: PMC3222468.

Existing forms of consent can be applied in the context of data consultation. However, if informed consent is to be used in a way that is truly relevant and protective, the ways in which consent is implemented need to be adapted to the purposes for which the data is consulted. This consideration is in line with the arrangements established by the GDPR, which creates a compatibility of the purposes of consent.[61]

AI and Big Data thus open up the question of the most appropriate form of consent. Some authors agree that broad and dynamic forms of consent could be more appropriate to face the challenges of AI and Big Data.[62] Consequently, the choice of the extent and form of consent must be made in accordance with the legal and/or ethical framework applicable to the research, or the methods used to achieve specific objectives, in accordance with the various national requirements, and in consultation with local communities where appropriate.

On the basis of the literature review presented in **Appendix** of this document, we argue that informed consent should not be considered solely as a gold standard. Indeed, principles and values such as explicability and transparency[63], implemented as part of an appropriate and sufficient governance process, go beyond the notion of "consent" alone, in our view. In other words, the strict application of informed consent in the form of an express signature by each individual does not appear to be appropriate. Sufficient, clear and exhaustive information and providing individuals with the tools to express themselves should be preferred.

The genuinely 'informed' dimension of consent raises the question of the distinction between informed and enlightened consent. Information regarding the potential risks and benefits of data use by AI and DV applications is of considerable importance, both in terms of its form and its level of accessibility. In order to retain the full conceptual value of informed consent, it is important to provide clear, fair and appropriate information to individuals[64] according to criteria which must be determined by regulation, legislation or at the very least by a harmonised standard.

---

[61] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation), Recital 50.
[62] Henri-Corto Stoeklé et al., Data Medicine : 'Broad' or 'Dynamic' Consent ?, *Public Health Ethics* , Volume 15, Issue 2, July 2022, Pages 181-185, https://doi.org/10.1093/phe/ phac014.
[63] Human Rights Council, "Report of the High Commissioner for Human Rights A/HRC/48/31: The right to privacy in the digital age" (2021).
[64] UN, Report of the High Commissioner for Human Rights A/HRC/39/29 / *The right to privacy in the digital age, 3 August 2018.*

However, the opaque nature and lack of explicability of AI systems, the way they operate, and the way in which data are analysed and interpreted, make it difficult for consent to be truly 'informed'. In fact, it seems complicated to provide individuals with sufficient and clear information to enable them to consent freely, i.e. in a sufficiently informed manner, without being forced in any way and with the possibility of withdrawing their consent at any time and without deleterious effects. In light of the need for transparency and explicability, both in terms of AI methods and aims, information should aim to give individuals a genuine capacity to express their true autonomy with sufficient consideration of the individuals' literacy, values, personalities, constraints, interests and their rights.[65]

The principles of explicability and transparency then emerge as the foundations of a human rights-based approach to the global governance of AI and related data sources. The development of "explainable AI" aims to ensure transparency about how AI algorithms process data and reach the solutions they provide.[66] This consideration requires specific design of AI models from the outset, in order to affirm key ethical principles that must also be at the heart of the content of information and consent depending on the level of explainability and risks.

## PART III - RECOMMENDATIONS ON INFORMED CONSENT IN AI, DV and OPEN SCIENCE

### I. General Recommendations

In general, a reconsideration of the classic form of informed consent - most commonly a written signature following receipt of sufficient information - seems necessary in order to move towards a more flexible notion. These changes should be considered with a view to promoting self-determination and enabling the implementation of a trust-based governance process[67].

The dynamic approach to consent therefore seems to us to be the most appropriate, provided that the emphasis is placed on obligations concerning information and privacy-friendly governance of data access. We therefore emphasise the multifaceted nature of informed

[65] Andreotta, Kirkham and Rizzi, *AI, big data, and the future of consent,* p. 1721.
[66] Report A/HRC/43/29 of the Secretary-General: Report on the role of new technologies in the realization of economic, social and cultural rights, 5 March 2020.
[67] KALKMAN S. , VAN DELBEN J. , BANERJEE A. *, et al, "Patients' and public views and attitudes towards the sharing of health data for research: a narrative review of the empirical evidence", Journal of Medical Ethics 2022;48:3-13.*

consent. The proposal would therefore be to have multiple and flexible forms of consent, adapted to the multiple areas of activity concerned, allowing modulation of the content, which remains fixed, according to the essential principles of respect for autonomy and human dignity.

In the following section, recommendations have been identified for various actors and stakeholders.

## II. Specific Recommendations

### *A. On Global Governance and Research and Development*

| | **Global Governance**<br><br>(Regulatory Measures)<br><br>*Vertical – working within the hierarchy of the international system* | **Research and Development**<br><br>(Driving Innovation and Progress)<br><br>*Horizontal – working together with other groups/ stakeholders across the international landscape.* |
|---|---|---|
| Governments | Facilitate enabling international conditions, such as transparency, trust and standardisation, in the establishment of a normative regime necessary for regulation in the area of AIDV for research, emphasising measures guaranteeing appropriate human autonomy, notably through informed consent.<br><br>Streamline national legislation to enhance readability and strengthen efficient mechanisms for protecting data confidentiality and informational self-determination in AIDV, in line with human rights and sectoral ethical and regulatory needs. | Establish clear standardised data access policies, affirm the importance of respecting human autonomy and transfer guidelines for research activities in consultation with representatives of civil society, industry and academe.<br><br>Incentivise Open Science to provide avenues for discussion and collaboration to tackle the risks and challenges of the use of AI. |

| | | |
|---|---|---|
| | Raise awareness among the various public and private stakeholders of the challenges of open science, AI and DV techniques and the importance of informed consent. | |
| International Organisations | Develop harmonised regulatory frameworks for AI, access to data and open science, encouraging dialogue between States and other stakeholders on the role and importance of human autonomy to help render the global normative conditions conducive for the establishment and follow-up of implementation of such frameworks.<br><br>Develop an ethical approach to the use of AI, the use of data and respect for informed consent, in line with internationally recognised fundamental rights and principles. | Encourage innovative initiatives from various stakeholders that will further drive deeper discussion of the ethical implications of AI developments, for the design, conception and practice of informed consent. |
| Social Movements / Civil Society | Engage further with regulators on data protection and data sharing within states and the international community to raise awareness and build tools to raise awareness of the impact of AI, the importance of human rights and democratic participation to affirm a win-win orientation of the purposes of AI use for DV and the limits to be respected, all of which are essential points for the development of truly appropriate informed consent. | Help foster participatory and interdisciplinary research communities anchored on the core principles of Open Science across the globe to develop AI and informed consent frameworks that are sustainable, future-proof and sufficiently flexible.<br><br>Anticipate a participatory approach to enable individuals to grasp the issues of AI and DV to understand how their data is being used and for what purposes. And be aware of the limits of informed consent |

| | | |
|---|---|---|
| | | when faced with methods that cannot guarantee total transparency. Informed consent must therefore take account of the limits of transparency and explicability of certain methods, and these limits must be specified in the information provided to individuals. |
| Academy | Identify the most relevant form of informed consent according to the purposes of the research or experiment, and in consideration of varying vulnerabilities of different groups of people. For instance, in genetic research, broad and dynamic consent is recommended, while for research and application concerning human-computer interaction (HCI), it is recommended to adapt the TEASE and FRIES Model. | Work in collaboration with AI and data visitation (DV) specialists to sufficiently and proactively ensure the explainability of these methods in research, and to gain technical know-how in creating synthetic data (i.e., extract specific characteristics from certain data to create non-identifying data to train AI models used in research or to fill gaps and limitations in access to certain data (e.g., rare diseases)). All with the aim of contributing to the design and implementation of informed consent adapted to these new practices. |
| Industry | Participate in better information by instilling transparency and trust in data collection and processing of its AI systems, promoting a white box model for its algorithms that could be reviewed by policy-makers, stakeholders and the public, most especially if they engage in the development of political strategies. | Uphold core tenets of humane technology, including respect for the user's time, attention to the use of personal data and how it is used in business practices, particularly marketing strategies. This can be achieved by ensuring personnel training in humane technology, and innovative design in user interface based on the TEASE and FRIES models of informed consent (e.g., privacy enhancing technologies or anti-persuasive technologies). |

| | | |
|---|---|---|
| Data professionals across all stakeholder groups | Recognise and uphold the importance of protecting sensitive data of AI users through confidence-building and safety mechanisms for cross-border data exchange in line with TEASE and FRIES models of informed consent. | Exercise discretion and transparency in engaging with endeavours that commercialise data by ensuring that personal or sensitive data will not be leveraged to create addictive or otherwise harmful HCI, and embedding the principles of TEASE and FRIES in the training as well as technical development of AI models for businesses. |

### *B. On Specific Cases*

<u>For Clinical and Non-Clinical Research</u>

For specific fields such as clinical research, the general recommendations set out above, whether vertical or horizontal, apply. In this particular case, however, we would stress the importance of identifying the most appropriate form of informed consent in advance of the research, depending on the risks and objectives pursued, in order to adapt the information accordingly, providing details of the methods, issues and risks involved.

In addition, in this particular case it may be appropriate to consider using DV and AI methods to create 'synthetic data', i.e. extract specific characteristics from certain data to create non-identifying data to train AI models used in research or to fill gaps and limitations in access to certain data (e.g. rare diseases).

<u>For genetic research</u>

For sensitive research, in particular that using genetic data, we recommend that researchers use the broad form of dynamic consent. Dynamic consent gives research participants more control over their involvement in research and opens up a partnership between the participant and the research team. This form of consent for the most sensitive research, particularly in the field of genetic data, can help to remove barriers to access to data by fostering trust between individuals and researchers with the aim of creating a genuine research collaboration.

However, we also note examples of initiatives that go beyond the simple implementation of consent by implementing specific governance methods that meet the ethical and regulatory requirements applicable to each context. This is notably the case with the Beacon project, an initiative led by the GA4HG Global Alliance for Genomics and Health, which enables genomic and clinical data to be shared via federated networks within a responsible sharing framework[68].

[68] FIUME M., CUPAK M., KEENAN S. *et al.*, "Federated discovery and sharing of genomic data using Beacons", *Nat. Biotechnol.* 37, 220–224 (2019). https://doi.org/10.1038/s41587-019-0046-x

## APPENDIX

Literature review

https://docs.google.com/spreadsheets/d/1IwnisFwv7as9WPdLgLCjlD0iI6wTc9t_Kmt5v_KdAjE/edit#gid=1506423627