AIDV Working Group
DELIVERABLE 3

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

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RATIONALE

Global Sociotechnological Landscape (3 Paragraphs)

- This section discusses how the impact of AI to human-technology relationship is bringing about changes in both existence of the individual himself and the present cognitive ecosystem. Particularly, this section highlights how AI is becoming an inseparable part of human cognition and biology, and how this phenomenon demonstrates the increasing influence of AI to the collective consciousness of humanity as well as its threat to the exercise of human autonomy. The aim of this section is to provide a picture of what challenges – and how entrenched those challenges are – that the conception and practice of informed consent will be up against.

Informed Consent Guidance (4-6 Paragraphs)

- This section is basically divided into two main parts: (1) discussion on sensitive data, particularly on psychographic and genomic data, and how the practice of informed consent provide protection to privacy and autonomy, and (2) case studies (i.e., human-computer interaction (HCI) and data visitation) demonstrating how AI is changing the game with regards to the collection, analysis and use of such data, and how this technology weakens the practice of informed consent, weaponizes sensitive data and compromises Open Science.

Ø *[Let us treat data visitation in the context of genomic data as a case study itself given the fact that DV is an AI-driven process essentially. This is the same with HCI, which is made sustainable and intimate via AI. In a sense, these two case studies are about how AI extract and make use of sensitive data, and the consequent challenges it brings to informed consent.]*

Recommendations (5 Paragraphs)

- This section has two parts: (1) general recommendations – these recommendations revolve on balancing research and innovation with regulation when it comes to AI and sensitive data with the objective of sustaining Open Science while ensuring a human-centered AI technology, and (2) specific recommendations – these recommendations are catered to specific stakeholders (i.e., states, companies and researchers) and are tailored to address particular issues such as global governance, big data, and HCI and clinical research in line with the main objective stated in (1).

PART I - GLOBAL SOCIOTECHNOLOGICAL LANDSCAPE

The deployment of the use of digital technology in all areas of society is illustrated in particular by the accelerated use of Artificial Intelligence (AI). This method, which takes several forms, including self-learning AI systems, requires the use or reuse of a very large amount of data: big data[1]. Therefore, access to and sharing of data is a major current issue, raising tensions for the deployment of innovation on one hand and risk to the privacy of individuals on the other hand. Thus, these legal, organizational and ethical barriers lead to a mistrust of data sharing[2]. It is in this context that reflections are developing around the technique of Data Visitation (DV). This method, which does not seem to be the primary consideration of official texts at national and international level[3] and which is not yet the subject of a clear and precise definition, brings a new way of considering access to data.

Access to large amounts of data and the deployment of AI are accompanied by legal and ethical considerations and questions.[4] Futhermore, the move towards the use of big data and AI and DV-based methods requires an articulation of legal and ethical considerations. In particular, the issues raised by the deployment of AI and data access require a re-examination of the effectiveness, applicability and form of informed consent.

I. AI and the Threat to Human Autonomy

A. AI and Human-Technology Fusion

Computational efficiency along with its self-learning capability has transformed AI from being a mere tool to an active 'extension of human cognition' as it becomes adept not only in providing whatever output that its human users expect, but also in discerning and delivering what they want.[5] As a result, AI is becoming a necessary part of how one understands the world and other people. This benefit that AI brings ensures its ever-increasing advancement as developers are more incentivized to build better AI technologies, exemplifying the so-called

[1] https://bmcmedethics.biomedcentral.com/articles/10.1186/s12910-022-00871-z

[2] https://jme.bmj.com/content/48/1/3

[3] Results of the literature review carried out by group 3 of the AIDV working group between December 2022 and March 2023.

[4] 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.

[5] *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).

"Law of Accelerated Returns".[6] But as AI becomes better cognitive extensions, it not only accelerates its own development, but also the consequent fusion of human and technology - human-technology relationship is becoming more inseparable. This means that AI is not only becoming reflective of whatever humans consider as 'intelligence' but also that humans are also becoming more driven by its algorithms through their own psychology and biology. Amidst the tremendous good that AI brings to humanity so far, this technology is already challenging the genuine exercise of human autonomy as choices and actions of the human individual become hackable through their underlying emotions that AI has become so good at knowing and manipulating.

B. AI and the Global Cognitive Ecosystem

The capacity of AI to be the cognitive extension of human individuals rests on its capability to collect and process what is called "sensitive data", which is basically the psychographic and genomic information of the individual.[7] The former is about his/her personal beliefs and desires, while the latter is on his/her genetic constitution that drives biological functions and predispositions. The United Nations (UN) recognizes the importance of sensitive data, particularly in accessing services and facilitating transactions in today's digitalized world, but at the same time, it is also well aware that such information could be used by commercial companies and governments alike to manipulate human behavior via AI technologies.[8] The growing problem is that as AI systems become more entrenched to human existence in general, it also becomes the main driver of the global cognitive ecosystem, which is the environment – defined by human-technology relationship of the age - that shapes and enhances the cognitive or information-processing capabilities of individuals, institutions and cultures.[9] In short, this is the interrelated systems and infrastructures that help in determining how one thinks. But with the accelerating sophistication of AI, humanity is slowly losing control

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

[7] **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).

[8] Report of the High Commissioner for Human Rights A/HRC/39/29: The right to privacy in the digital age.

[9] Braden Allenby, 'World Wide Weird: Rise of Cognitive Ecosystem', Issues in Science and Technology, Vol. 37, No. 3 (Spring 2021), 36-37.

over the cognitive ecosystem that this technology is creating. In other words, the core of human-technology relationship is now shifting from human to non-human intelligence.[10]

PART II - INFORMED CONSENT GUIDANCE

The deployment of cutting-edge technologies such as Artificial Intelligence and Data Visitation systems is forcing 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 'automatic' consent would entail the risk of 'consent fatigue', while failing to consider the implementation of informed consent would risk creating blocking situations, 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. Yet AI, with its growing sophistication as a cognitive extension, poses significant risk to the genuine exercise of autonomy given the need for it to collect and analyze sensitive data in order to be effective in knowing, 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., black box problem). Thus, the way in which they are being used to exploit human users not only demonstrates the increasing lack of human control but more importantly human-centeredness of AI technologies.

This abuse of AI systems is most exemplified so far in online commercial and social media platforms 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 know the psychological disposition of the users, and make engagements more personalized in a way that appeals and uses their desires, fears and beliefs against them. One instance of this abuse is the 2018 Facebook-Cambridge Analytica Scandal wherein millions of personal information was

[10] Yuval Noah Harari, 'The Great Decoupling,' in *Homo Deus: A Brief History of Tomorrow* (New York: Harper Collins, 2015), 497-567.

clandestinely siphoned from Facebook, and used by Cambridge Analytica - a political consulting firm - in developing psychographic-based campaign strategies for its clients via political microtargeting techniques (PMTs).[11] Such an instance ultimately shows how almost it is becoming impossible to practice and even conceive informed consent in AI-driven HCIs in today's data-intensive cognitive ecosystem.

The study of informed consent in the context of HCI – particularly that of AI as cognitive extensions – is still nascent and in exploratory stage. Nonetheless, so far there are two intertwined models for informed consent being explored in the area of HCI – FRIES and TEASE:

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 utilized to signal that one party is becoming uncomfortable"

[11] 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.

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. 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 it likes to interact with.

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

More specifically, we study the case of the use or reuse of genetic data for clinical research in particular. In the European framework implemented, genetic data is considered personal data and more precisely health data by the GDPR[12], being directly associated with specific characteristics of an individual. By falling into this category of health data, genetic data is of a sensitive nature that may justify stricter supervision, depending on the wishes of each member state. That said, we are seeing a trend towards opening up the use of genetic data for research, as has been the case in France, for example, since the adoption of the bioethics law of August 2, 2021, which reinforces the already existing opt-out for a research project to a research program, an opt-out for a set of research projects[13]. This example of the French framework shows that the notion of consent has been superseded by non-opposition,

[12] 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 GDPR.
[13] Article L.1130-5 of the French legislation (Code de la santé publique).

presented as a sufficient tool to preserve patient autonomy on the one hand, and the development of innovation and medical research on the other[14]. However, this overlooks the fact that the processing of genetic data not only has consequences for 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 ethnic group. 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[15]. The issue of the purpose of processing is therefore essential. Data Visitation and AI technologies, by virtue of their opacity, can present considerable risks.

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 health data, and in particular genetic data, to complement conventional clinical trials[16]. 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 force us to think about these considerations. In this context, broad and dynamic consent would appear to be a suitable solution to meet both protection and innovation challenges[17]. However, this form of consent requires sufficient and appropriate information to ensure that the individual is able to understand the various purposes and uses that will be made of the data[18].

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

[14] 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.
[15] 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.
[16] 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.
[17] 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.
[18] 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: 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].

A. HCI Implications on Informed Consent

The issues and risks identified justify the need to rethink the concept and practice of informed consent in order to adapt its implementation. Indeed, if we go back to the analysis of the TEASE models cited above, we note that they – even together with TRUST and CARE principles – would not be able to ensure practice of informed consent in HCI in line with FRIES. As discussed earlier, the nature of AI as a cognitive extension is a double-edge sword – its capability to act as part of human thinking comes from their effectiveness as tools for mind manipulation. This is demonstrated by the already prevalent use of AI as persuasive technologies for sustaining customer engagement and maximizing profit. 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;[19]
(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;[20]
(c) The fact that AI as smart persuasive technology manipulates users to primarily sustain engagement via appealing and amplifying their desires, it is therefore questionable whether users are genuinely enthusiastic in the course of their interaction with this technology.[21]

Accounting these three points, there is then a continuing need to explore technological innovations, which would be able to provide a kind of HCI with AI technologies that can facilitate ongoing affirmation – integrating consent for the entire duration of the interaction – while ensuring that manipulation will not result to a sustainable and irreversible mind control. In other words, innermost emotions will not be used to hack the user's autonomy nor will brain structures be reconstituted to totally destroy his or her autonomy. In this case, redesigning AI to fit TEASE will no longer be sufficient, there must be another technology that must be introduced in the interaction that would be able to provide users the means to mitigate (or even escape) AI manipulation throughout the interaction process.

[19] Strengers et.al, *What Can HCI Learn from Sexual Consent?*.
[20] Ibid.
[21] Ibid.

B. DV Implications on Informed Consent

We note that th deployment of new methods and techniques has led to a change in the very notion of Informed Consent, originally conceived -at both International and European level - as a tool for protecting fundamental rights.[22] 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).[23] 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[24] ; and consent in the context of data protection, which protects informational integrity[25], both fundamental to respect for the individual's right to privacy and requiring a balance to be struck with digital methods.[26] 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 between protection and innovation and the literature review sometimes highlights a criticism of strict consent as a barrier to data access and use.

Informed consent cannot therefore be presented as a strict and immutable concept. 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. The risk is that consent will be undermined in this 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, the deployment of AI transforms certain risks for privacy

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[22] 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.

[23] 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.

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

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

[26] 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.

and the preservation of human dignity and thus calls into question the effectiveness of certain fundamental rights. AI therefore calls into question not only the purposes for which consent is expressed, but also its content and the form it should take in order to avoid the automatic application of inappropriate consent as a meaningless shield.[27]

It must be a broad and evolving concept that can be adapted to today's challenges[28]. The classic concept of consent must be transformed by promoting information to go beyond consent to trust in professional organisations, giving individuals the possibility of controlling the use of their personal data. Consent is then no longer formalised as it traditionally was and adapted to the specific challenges of AI[29] and DV.

In this respect, the analysis of the literature carried out prior to 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[30]. 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 forces us to reconsider the other forms of consent that could be applied[31].[32] Informed consent for data collection, storage and use can take several forms, listed below:

- **Explicit consent**: This form of consent requires people to give their consent actively and explicitly, for example by ticking a box or clicking on a button.[33]
- **Negative consent**: With this form of consent, individuals must express their opposition explicitly.[34]
- **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

[27] 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.
[28] HEIKKILÄ Melissa, The Algorithm, MIT Technology Review, new letter dated 5.01.2023.
[29] EU, Independent High Level Expert Group on Artificial Intelligence set up by the European Commission, "Ethics Guidelines for Trustworthy AI", guidelines, 2019.
[30] Poster published to mark the 20th anniversary of the GDR Alliance.
[31] 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.
[32] UNESCO, Recommendation on the Ethics of Artificial Intelligence, 24 November 2021.
[33] https://bigid.com/blog/opt-in-vs-opt-out-consent/
[34] https://bigid.com/blog/opt-in-vs-opt-out-consent/

provided to individuals so that they can freely consent to the processing of their data for a specific purpose, via a specific form.[35]

- **Layered or multi-layered consent**: This form of consent is made up of different layers of information, recipients or purposes[36]. Essential information can be highlighted (layer 1), then other optional information (layer 2) can be made accessible, for example.[37]
- **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.[38] 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.[39]
- **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.[40]

Other less traditional conceptions of the form of consent may be mentioned here, such as that of "**Community** consent".[41] This concept, developed in particular in genomics research, highlights the possibility of grouped consent, i.e. an entire community consenting together to the same purpose.

In addition to the form of consent used, it can also be formalised in different ways, for example on paper or in electronic form.

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[35] 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.

[36] 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.

[37] 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.

[38] 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.

[39] 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.

[40] Antonio Sandu, Ana Frunza , Ethics in research practice and innovation, Chapter 9 "Informed consent in research involving human subjects", 2019, 21p.

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

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.[42]

AI and Big Data thus open up the question of the most appropriate form of consent. In this sense, some authors agree that broad and dynamic forms of consent could be more appropriate in the face of the challenges of AI and Big Data.[43]

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 even the methods used to achieve specific objectives, and in accordance with the various national requirements.

Finally, we show that informed consent must therefore be considered through a gold standard based on the values of governance, explicability and transparency.[44] Such a reflection requires us to highlight the genuinely 'informed' dimension of consent by raising the question of the distinction between informed and enlightened consent. Information is therefore 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[45]. However, the opaque nature and lack of explicability of AI systems, the way they operate, the way in which data is analysed, and the explanation of the results obtained, considerably limit the information transmitted. In fact, it seems complicated to provide individuals with sufficient and clear information to enable them to consent in complete freedom. This is particularly true in the doctor-patient relationship.[46] This observation calls for a reconsideration of the role and importance of information in the light of the need for

[42] 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), Reciptal 50.
[43] 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.
[44] Human Rights Council, "Report of the High Commissioner for Human Rights A/HRC/48/31: The right to privacy in the digital age" (2021).
[45] UN, Report of the High Commissioner for Human Rights A/HRC/39/29 / *The right to privacy in the digital age, 3 August 2018.*
[46] Council of Europe, "The impact of artificial intelligence on the doctor-patient relationship", CDBIO report by Brent Mittelstadt, June 2022.

transparency and explicability, both in terms of AI methods and aims, in order to give individuals a genuine capacity to express their true autonomy.[47]

The principles of explicability and transparency then emerge as the foundations of a human rights-based approach to the global governance of AI, as the development of "explainable AI" aims to ensure transparency about how AI algorithms process data and arrive at the solutions they provide.[48] This consideration requires privacy-based 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.

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

I. General Recommendations

In general, the possible solutions seem to be a reconsideration of the classic form of informed consent to move towards a more flexible notion of trustful governance of self-determination, perhaps through a dynamic consent approach, but with greater emphasis on the obligations concerning information and privacy-friendly governance of data access. More specifically, in the following section, recommendations have been identified for various actors and stakeholders, and even for specific areas.

II. Specific Recommendations

A. On Global Governance

<u>For States</u>

1. Consider the existing issues regarding the articulation of the frameworks in order to avoid the accumulation of regulations which leads to legal uncertainty and increased risk of non-compliance
2. Facilitate conducive international political environment for establishment of the "Digital Geneva Convention" that will provide a common global governance framework for cybersecurity.

[47] Andreotta, Kirkham and Rizzi, *AI, big data, and the future of consent,* p. 1721.
[48] 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.

3. Incentivise and implement mechanisms to ensure accessible and sufficient information about the functioning, challenges and risks of the use of AI in order to allow for an improvement of knowledge in this area
4. Establish clear data access governance rules and guidelines for research activities in consultation with professional stakeholders and representatives of the civil society.
5. Incentivise and implement mechanisms to ensure accessible and sufficient information about the functioning, challenges and risks of the use of AI in order to allow for an improvement of knowledge in this area.

For International Organizations

6. Clarify the requirements for the use, the form and required content of consent for the deployment of AI and DV
7. Develop harmonised strategies for data governance, AI and informed consent frameworks that are sustainable, future-proof, and sufficiently flexible
8. Develop an ethical approach to the use of AI in line with internationally and European recognised fundamental rights and principles
9. Develop standards for data sharing, data reuse and even data visitation
10. Provide an adapted and harmonised framework for the implementation of AI for the deployment of Data Visitation methods

For Grassroot Movements

11. Promote a human-centered approach of AI and DV
12. Promote a risk-based approach to AI and DV developments based on technological and privacy risks assessments
13. Encourage interdisciplinary discussion and exchanges on AI and DV, and their implications on informed consent in the digital and research areas (i.e., SINNA project)
14. Initiate public information campaigns and educational programs for empowering and awareness people.
15. Assess existing legal frameworks applicable to AI and DV and enhance their provisions where relevant to protect autonomy of individuals
16. Seize the challenges of AI deployment and DV methods by taking into account the risks but also the benefits for society (especially in the field of research)

17. Affirm the expression of a common and citizen will on the identification of the purposes of AI use that citizens wish to see developed and the limits to be respected

B. On the Commercial Use of Big Data

For Social Media Companies

1. Raising awareness of the public and ensuring respect for the fundamental rights of individuals, including privacy, through accessible policies.
2. Inculcate core tenets of humane technology of respect for the user's time, attention and personal data into business practices, particularly marketing strategies.
3. Training personnel performing DV or developing AI with humane technology courses that help highlight ethical issues regarding informed consent of data subjects and the respect of privacy of individuals concerned.
4. Ensure that social media companies discloses third parties and engages users as to what data and how much could be reused (or even if it can be reused) by these third parties.
5. Integrate innovative design (e.g., privacy or anti-persuasive technologies) in user interface based on TEASE and FRIES model of informed consent so as to protect human attention, agency and privacy while using the platforms.

For Data Analytics Firms

1. Find means to ensure that the deployment of big data analytics does not lead to violation of human agency and dignity by reducing the individual into a mere statistics but rather incorporate innovative conception and practice of informed consent.
2. Inculcate transparency 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.

C. On HCI, Clinical and Non-Clinical Research

For Human-Computer Interaction Research

1. Integrate TEASE and FRIES model in accessing health or biological data via smart devices so as to ensure that the individual contributing such intimate information has a

say over what could be accessed and processed by these devices, and given to other third party users.

2. Explore the development of alternative technologies to AI that can facilitate (or enhance) the practice of TEASE and FRIES in HCI, preferably that which can mitigate the power of AI as cognitive extensions - a form of delimiting technology with a nature in contrast to AI (i.e., virtual reality technologies).

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

3. Adapt the modalities and form of access to information and consent according to the technique, the regulatory requirements and the purposes pursued.
4. Identify the most relevant form of informed consent according to the purposes pursued and adapt the information accordingly by providing details on the method, the issues and the risks.
5. Work in collaboration with AI specialists to allow sufficient explicability of AI systems.
6. Take into account vulnerable groups of people with a potential evolution of this consideration: in relation to the respect of informational integrity/privacy, we are not all equally vulnerable.
7. Strive to implement the EU-like personal data minimisation approach, based on an assessment of the necessity of processing such data.
8. 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).

D. Specificity of genetic research

For sensitive research, in particular that using genetic data, we recommend the following the broad form of dynamic consent. Dynamic consent gives patients 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.