Essays

A value-sensitive approach to informed consent: insights from the WHO's Guidance for Human Genome Data Collection, Access, Use and Sharing

Tommaso Ropelato*

ABSTRACT: The growing complexity of clinical genomic research challenges existing informed consent models, demanding frameworks that reflect the collective, dynamic, and relational nature of genetic data. Drawing on six ethical principles from the recent WHO's Guidance for Human Genome Data Collection, Access, Use and Sharing — social justice, inclusivity, solidarity, responsible stewardship, transparency, and accountability — this paper proposes Value Sensitive Design as a methodological approach to translate normative aims into practice. It complements models like dynamic consent by integrating stakeholder values from the outset and enhancing ethical robustness, cultural sensitivity, and adaptability across diverse sociotechnical contexts. It also opens pathways for developing digital tools and speculative strategies for inclusive and forward-looking genomic data governance.

KEYWORDS: Genomics; informed consent; data governance; World Health Organization; value sensitive design

SUMMARY: 1. The shifting landscape of genomic research – 2. Introduction to Value Sensitive Design – 3. Reframing informed consent – 4. Intersecting the who's principles and value sensitive design – 5. Conclusion.

1. The shifting landscape of genomic research

In recent years, massive and rapidly expanding repositories of biomedical -omics data, combined with clinical data, have revolutionized health research and clinical practice, offering unprecedented insights into human biology, disease mechanisms, and therapeutic innovation.[1] This paradigm shift from reactive to proactive healthcare[2] has driven the development of computational tools and algorithms capable of navigating big data while accounting for individual variability in genetic and molecular profiles.[3] At the same time, increasing attention to patient engagement and empowerment

* Phd Student at the University of Turin; Phd Trainee at Bruno Kessler Foundation, Center for Religious Studies. Mail: Tommaso.ropelato@unito.it. *Contribution subject to double-blind peer review.*

[1] A. AHMED, R. XI, M. HOU, S. S. et al., *Harnessing Big Data Analytics for Healthcare: A Comprehensive Review of Frameworks, Implications, Applications, and Impacts*, in I*EEE Access,* 11, 1, 2023, 99.

[2] S. A. WALDMAN, A. TERZIC, *Health Care Evolves From Reactive to Proactive*, in *Clinical Pharmacology & Therapeutics*, 105, 1, 2019, 10.

[3] A. A. IMAM, A. O. BALOGUN, L. C. DE SILVA et al., *Recent Advancements in Emerging Technologies for Healthcare Management Systems: A Survey*, in *Healthcare*, 10, 10, 2022, 1940.

has reshaped the ethical and operational landscape of contemporary medicine, foregrounding the active role of individuals in health-related decision-making.[4] Taken together, these trends have laid the foundation for a more preventive, personalized, predictive, and participatory model of care:[5] a "4P" healthcare, effectively described by the Italian Committee for Bioethics under the broader concept of "precision medicine",[6] that enables tailored solutions with the potential to transform patient outcomes.

Since the publication of the first draft of the human genome sequence in 2001, which not only marked a significant scientific milestone but also catalysed political and cultural shifts heralding the so-called postgenomic era,[7] the World Health Organization (WHO) has been at the forefront of guiding international and institutional attention toward the transformative potential of this revolution in advancing global health.[8] Over the past decade, this focus has intensified, in part owing to the growing prominence of genome editing,[9] both in scientific discourse and in the public sphere, as well as the increasing feasibility, affordability, and even direct-to-consumer availability of genetic testing.[10]

In December 2018, the WHO established a global, multidisciplinary expert advisory committee, the *Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing*, to examine the scientific, ethical, social, and legal challenges associated with human genome editing. Two major publications from the Committee, *Human Genome Editing: A Framework for Governance*[11] and *Human Genome Editing: Position Paper,*[12] both released on July 12, 2021, represented the WHO's first structured attempt to provide guidance on governance mechanisms for human genome editing at institutional, national, regional, and global levels, emphasizing the importance of ethical frameworks in health policy and practice. The WHO reaffirmed its commitment to the responsible advancement of genomics in April 2021, when its *Science Council* chose genomics as the focus of its first report, *Accelerating Access to Genomics for Global Health.*[13] One of the report's key outcomes was the creation of a *Technical Advisory Group on Genomics* (TAG-G).[14]

---

[4] L. Palazzani, R. Halila, J. Dratwa, A. Górski et al., The ethical implications of new health technologies and citizen participation, in J. Dratwa, J. Parkin (eds.), *The ethical implications of new health technologies and citizen participation*, Luxembourg, 2016.

[5] O. Golubnitschaja, J. Kinkorova, V. Costigliola, *Predictive, Preventive and Personalized Medicine as the hardcore of 'Horizon 2020': EPMA position paper*, in *EPMA Journal*, 5, 1, 2014, 6.

[6] Comitato Nazionale per la Bioetica – Comitato Nazionale per la Biosicurezza, la Biomedicina e le Scienze della Vita, *Riflessioni bioetiche sulla medicina di precisione e sviluppi diagnostico-terapeutici*, Rome, 2020, www.bioetica.governo.it/media/4145/parere-congiunto-medicina-di-precisione-joint-opinion-precision-medicine.pdf (last visited 10/06/2025).

[7] C. Holmes, S.M. Carlson, F. Mcdonald et al., Exploring the postgenomic world: differing explanatory and manipulatory functions of postgenomic sciences, in *New Genetics and Society*, 35, 1, 2016.

[8] WHO's document Genomics and World Health: Report of the Advisory Committee on Health Research dates to 2002.

[9] D. Carroll, Genome Editing: Past, Present, and Future, in *Yale Journal of Biology and Medicine*, 90, 4, 2017, 653.

[10] B. Oh, Direct-to-consumer genetic testing: advantages and pitfalls, in *Genomics and Informatics*, 17, 3, 2019, 33.

[11] www.who.int/publications/i/item/9789240030060 (last visited 10/06/2025).

[12] www.who.int/publications/i/item/9789240030404 (last visited 10/06/2025).

[13] www.who.int/publications/i/item/9789240052857 (last visited 10/06/2025).

[14] E. Ambrosino, A.N. Abou Tayoun, M. Abramowicz et al., The WHO genomics program of work for equitable implementation of human genomics for global health, in Nature Medicine, 30, 2024, 2711.

The *Technical Advisory Group on Genomics*' most recent publication, *Guidance for Human Genome Data Collection, Access, Use, and Sharing,*[15] published on November 20, 2024, holds significant importance and further reflects the WHO's growing recognition of its leadership role not only in the normative domain[16] but also in the sociopolitical aspects of genomic technology development. By outlining a set of globally applicable principles, the WHO's document underscores its commitment to promoting transparency, safeguarding both individual and collective rights, and addressing the growing involvement of new actors, including digital and AI technologies. However, this paper contends that the *Guidance*'s relevance lies not merely in its articulation of updated ethical standards, but in its attempt to shape actionable, context-sensitive practices for genomic data collection and use. Its practical orientation is particularly evident in its emphasis on informed consent, which is placed at the centre of its governance model. Indeed, the very first principle — *to affirm the rights of individuals and communities to make decisions* (3.1., 4 ff), reflects a dual commitment: to uphold the autonomy of individuals capable of informed choice, and to recognize the broader familial and communal implications of genomic data. As the *Guidance* makes clear, genomic information cannot be treated as purely individual: it resonates across generations, kinship networks, and social groups, and thus demands context-sensitive governance structures. This recognition is anything but straightforward. It challenges the conventional, individual-centric models of consent and demands a rethinking of both the conceptual foundations and technical infrastructures that support consent practices in genomic research and clinical contexts.[17]

In response to this challenge, this paper explores the potential of Value Sensitive Design as both a conceptual and methodological lens through which to operationalize the WHO's call for ethically grounded, context-sensitive, and stakeholder-informed consent practices. Indeed, Value Sensitive Design, with its emphasis on embedding human values into the design of sociotechnical systems, is especially well-suited to rethinking informed consent considering the complex ethical terrain of clinical genomic research. Developed in the late 1990s by Batya Friedman[18] and subsequently expanded by scholars such as Jeroen van den Hoven[19] — particularly within the broader discourse of Responsible Innovation — and more recently by Sarah Spiekermann-Hoff[20] through her framework of Value Based Engineering, Value Sensitive Design is a methodology that aims to systematically integrate human values into the earliest phases of technology development. As van den Hoven (2013) argues, it is especially suited to addressing situations of moral overload, by redesigning contexts in ways that allow for the simultaneous realization of multiple, and sometimes conflicting, values. Rather than simply adding new functionalities, Value Sensitive Design makes it possible to, in his words, "grab the bull by both horns": that is, to proactively transform systems to anticipate ethical tensions, navigate value conflicts, and foster inclusive, accountable, and agency-enhancing practices. Over the past three decades, Value Sensitive Design has demon-

[15] www.who.int/publications/i/item/9789240102149 (last visited 10/06/2025).

[16] C. Regis, M. Cohen, J.L. Denis et al., Understanding the normative leadership of the World Health Organization (WHO): a mixed-method approach, in Population Medicine, 5, Supplement A1807, 2023.

[17] A.J. Andreotta, *Rethinking Informed Consent in the Big Data Age*, London, 2024.

[18] B. Friedman, D.G. Hendry, *Value Sensitive Design: Shaping Technology with Moral Imagination*, Boston, 2019.

[19] J. van den Hoven, Value Sensitive Design and Responsible Innovation, in R. Owen, J. Bessant, M. Heintz (eds.), *Responsible Innovation: Managing the Responsible Emergence of Science and Innovation in Society*, Hoboken, 2013.

[20] S. Spiekermann-Hoff, *Value-Based Engineering: A Guide to Building Ethical Technology for Humanity*, Berlin, 2023.

strated remarkable versatility across a wide range of domains. While remaining grounded in a consistent normative vision, it has evolved into a robust methodological toolkit with interdisciplinary reach and enduring relevance — not only as a conceptual framework, but as a practical approach to designing ethically informed technologies and policies.[21]

This paper aligns itself with this evolving body of literature and aims to further extend the scope of Value Sensitive Design by opening its field of application to a domain still largely unexplored within its corpus: genomic data governance and informed consent. To date, Value Sensitive Design has had only marginal engagement with biotechnological contexts — most notably through Steven Umbrello's work on reproductive technologies[22] — while remaining virtually absent from discussions on genome research and global policy frameworks such as those articulated by the WHO. Curiously, however, one of the earliest applications of VSD by Friedman herself focused precisely on informed consent — in the context of web navigation and cookie management.[23] This early study explored values such as efficiency, privacy, autonomy, and safety, which remain highly pertinent to today's debates on the governance of genomic data. Yet the ethical terrain has evolved: consent in the genomic domain involves not just individual decisions but also relational, communal, and intergenerational dimensions that demand renewed conceptual and methodological attention.

2. Introduction to Value Sensitive Design

Value Sensitive Design, in contrast to approaches focused primarily on efficiency or usability, centres the normative dimensions of design by ensuring that technologies reflect the values and interests of those they impact. Although Van den Hoven (2007) situated it within a broader "design turn" in applied ethics[24] — an approach that aims to front-load moral reflection into the earliest stages of technological development —Friedman and Kahn (2002) emphasized that Value Sensitive Design distinguishes itself from adjacent fields such as computer ethics, social informatics, Computer Supported Cooperative Work, and participatory design by offering a structured and replicable methodological framework.[25] It will be briefly presented shortly. Value Sensitive Design has however not remained immune to critique, particularly concerning the scope and foundations of its normative commitments. Scholars such as Manders-Huits (2011)[26] have questioned the universality and cross-cultural applicability of the values VSD seeks to promote, raising important concerns about the risk of implicit moral bias and normative parochialism. Others, including Le Dantec et al. (2009)[27] and Jacobs and Huldtgren (2021)[28], have critically examined

[21] A. Gerdes, T.F. Frandsen, A Systematic Review of Almost Three Decades of Value Sensitive Design (VSD): What Happened to the Technical Investigations?, in *Ethics and Information Technology*, 25, 26, 2023.
[22] S. Umbrello, Designing Genetic Engineering Technologies for Human Values, in *Etica e Politica*, 2, 2022, 481.
[23] B. Friedman, D. Howe, E. Felten, Informed Consent in the Mozilla Browser: Implementing Value Sensitive Design, in *Hawaii International Conference on System Sciences*, 8, 2002, 247.
[24] J. Van Den Hoven, ICT and Value Sensitive Design, in P. Goossenaerts, R. Jacquet, J. Berleur (eds.), *The Information Society: Innovation, Legitimacy, Ethics and Democracy in Honor of Professor Jacques Berleur S.J.*, Boston, 2007, 67.
[25] B. Friedman, P.H. Kahn Jr., Human Values, Ethics, and Design, in J.A. Jacko, A. Sears (eds.), *The Human-Computer Interaction Handbook: Fundamentals, Evolving Technologies and Emerging Applications*, Mahwah, 2002, 1177.
[26] N. Manders-Huits, What Values in Design? The Challenge of Incorporating Moral Values into Design, in *Science and Engineering Ethics*, 17, 2, 2011, 271.
[27] C.A. Le Dantec, E. Poole, S. Wyche, Values as Lived Experience: Evolving Value Sensitive Design in Support of Value Discovery, in *Conference on Human Factors in Computing Systems - Proceedings*, 2009, 1141.

the original list of "human values with ethical import" proposed by Friedman and colleagues,[29] arguing that it may lack the flexibility to accommodate the pluralism of moral perspectives found in different sociocultural contexts. Nevertheless, Value Sensitive Design has proven resilient as a methodological framework. Over time, it has evolved through a combination of empirical adaptation and theoretical refinement, extending its application across a wide range of technological and institutional domains.

At the core of this evolution lies what is arguably the most distinctive feature of the Value Sensitive Design approach: its commitment to the early and systematic identification of stakeholders, along with the explicit articulation and integration of the values at stake in each sociotechnical context. This normative orientation is made actionable through its well-established tripartite methodology — comprising conceptual, empirical, and technical investigations.[30] Thus, before examining its application to informed consent in genomic data governance, it is worth briefly outlining the structure and rationale of Value Sensitive Design's tripartite framework, whose components operate in a mutually reinforcing and iterative manner:

> Conceptual investigation involves the identification of relevant stakeholders and the articulation of the values most pertinent to the system or technology under development. This phase typically includes stakeholder mapping, the definition of guiding values, and the analysis of potential value tensions or conflicts that may arise between different actors or within institutional settings. Positioned as the initial step in the Value Sensitive Design methodology, this investigation is crucial not only for clarifying ethical priorities but also for embedding them structurally into the design process. Its placement underscores the inherently interdisciplinary nature of Value Sensitive Design, where philosophical reflection, bioethical analysis, and legal reasoning are not supplementary but foundational.
>
> Empirical investigation seeks to understand how stakeholders interpret and prioritize these values in practice. Using methods such as interviews, focus groups, and surveys, this phase grounds the design in lived experiences and social realities.
>
> Technical investigation explores how design features, technological affordances, and governance mechanisms can embody, support, or balance the values identified in the earlier phases. It links ethical reflection with concrete implementation.

As noted on the VSDLab website,[31] this methodology starts from the recognition that tools, policies, and technologies are never neutral: they co-construct what is perceived as fair, intimate, or trustworthy within communities. It aims to make these normative dimensions visible and actionable from the beginning of the design process, thereby increasing the likelihood that resulting infrastructures will enable all stakeholders to participate meaningfully and flourish. It is within this broader methodological orienta-

[28] N. JACOBS, A. HULDTGREN, Why value sensitive design needs ethical commitments, in *Ethics and Information Technology*, 23, 2021, 23.

[29] B. FRIEDMAN, P. H. KAHN JR., A. BORNING, Value sensitive design and information systems, in *Human-Computer Interaction and Management Information Systems: Foundations*, New York, 2006, 348.

[30] D. YOO, Stakeholder Tokens: a constructive method for value sensitive design stakeholder analysis, in *Ethics and Information Technology*, 23, 2021, 63.

[31] www.vsdesign.org (last visited 16/06/2025).

tion that the following sections explore how Value Sensitive Design can be employed to scaffold informed consent as a dynamic, inclusive, and ethically responsive practice in the context of genomic research and data governance.

3. Reframing informed consent

The growing centrality of translational genomic research — driven by high-throughput sequencing technologies, global data sharing initiatives, and the long-term storage of biospecimens — has profoundly challenged the conventional paradigm of informed consent.[32] In this evolving landscape, the conventional model of study-specific, one-time authorization — rooted in the primacy of individual autonomy — is increasingly viewed as insufficient to meet the demands of contemporary genomic research.[33] The shift toward digital infrastructures and the growing reliance on large-scale data integration have further complicated the ethical terrain, introducing new challenges related to privacy, power asymmetries, and the potential for misuse.[34] Consent in this context is no longer a discrete act, but a complex, temporally extended process entangled with ethical questions concerning the return of individual results, the management of incidental and secondary findings, and the moral acceptability of downstream uses of genomic data. The scale and interpretive uncertainty of genomic datasets exacerbate these challenges, rendering it difficult to determine what participants can meaningfully be informed about, what they may wish not to know, and how their data should be governed over time. While open data practices are often justified by appeals to scientific transparency and efficiency, they simultaneously expose fundamental questions of legitimacy, accountability, and trust[35] — especially where governance mechanisms remain opaque or disconnected from the expectations of data contributors and the public.

These concerns are also reflected in the evolving regulatory landscape. Most notably, the European General Data Protection Regulation (GDPR) has introduced a robust legal framework for the processing of personal data,[36] including genomic information,[37] which it classifies as a special category (Art.9 (1)) due to its inherently sensitive and identifiable nature. However, the challenge of governing genomic data ethically and legally does not lie solely in its personal character. Genomic data are, by nature, relational: they extend beyond the individual, carrying potential implications for biological relatives, social groups, and even entire communities. This inherent entanglement challenges conventional understandings of informational self-determination — still foundational to most legal frameworks and bioethical discourse — and becomes particularly salient when translating consent requirements into practice. While the GDPR mandates that consent be "freely given, specific, informed and unambiguous" (Art.

[32] W. Burke, L.M. Beskow, S.B. Trinidad, S.M. Fullerton, K. Brelsford, Informed Consent in Translational Genomics: Insufficient Without Trustworthy Governance, in Journal of Law and Medicine Ethics, 46, 1, 2018, 79.

[33] K.C. O'Doherty, M. Shabani, E.S. Dove, H.B. Bentzen et al., Toward better governance of human genomic data, in Nature Genetics, 53, 1, 2021, 2.

[34] E. Vayena, T. Haeusermann, A. Adjekum, A. Blasimme, Digital health: meeting the ethical and policy challenges, in Swiss Medical Weekly, 148, 2018.

[35] M.A. Majumder, R. Cook-Deegan, A.L. Mcguire, Beyond Our Borders? Public Resistance to Global Genomic Data Sharing, in PLOS Biology, 14, 11, 2016.

[36] www.gdpr-info.eu (last visited 16/06/2025)

[37] *The GDPR and genomic data: The impact of the GDPR and DPA 2018 on genomic healthcare and research*, PHG Foundation report funded by the Information Commissioner's Office, 2020.

4(11)), such conditions are increasingly difficult to fulfil in the context of genomic research. The open-ended, longitudinal, and often transnational character of genomic inquiry — where data may be reused, integrated with external datasets, or subjected to secondary analysis across jurisdictions — undermines the possibility of providing participants with the granularity and foreseeability that truly informed consent would demand. Among the most debated instruments in this regard is the notion of broad consent, widely used in biobanking and longitudinal studies. Broad consent — which authorizes the future use of data for unspecified research purposes — has become a legally contested and ethically ambivalent mechanism. While it offers a pragmatic response to the evolving nature of scientific inquiry, its legitimacy under the GDPR remains disputed. Its ethical robustness is also increasingly questioned, especially given its limited responsiveness to shifting values, risks, and expectations over time. Additional complications arise from the GDPR's principle of data minimization (Art. 5(1)(c)), which requires that data collection be "adequate, relevant and limited to what is necessary". While this principle may appear structurally at odds with the epistemic logic of genomic research — which depends on the large-scale aggregation, long-term storage, and probabilistic interpretation of complex datasets — close attention to the specific definition of the research purpose has become, as Becker et al. have shown, a critical step in establishing the legal basis for data processing, particularly when datasets are repurposed or linked to new sources.[38]

Although such issues have been addressed in the legal literature, they are seldom examined from an ethical perspective that fully engages with their conceptual stakes. This gap is further compounded by the fact that existing ethical models — largely developed in the context of project-specific, investigator-driven studies — often struggle to keep pace with the social, technical, and epistemic transformations introduced by digital genomics.[39] It has become increasingly evident that fundamental bioethical concerns — such as therapeutic misconception, the porous boundary between care and research, and the delegation of decision-making authority — are significantly amplified both by the nature of next-generation sequencing technologies, which produce results that are probabilistic, uncertain, and potentially relevant across generations, and by the broader structural transformation of the research landscape. In particular, the growing involvement of private actors in genomic research and the increasing commercial value of biospecimens and datasets raise critical issues. As Cozzi (2021) observes,[40] the alliance between legal and ethical domains in genomic research often proves fragile, with the two dimensions operating in parallel rather than in concert. Although various national and international guidelines address the return of incidental or secondary findings — including the ACMG recommendations, European and French regulatory frameworks, and the Italian Bioethics Committee — they frequently reduce informed consent to a procedural formality, rather than recognizing it as a dynamic and context-sensitive ethical practice.

Considering these challenges, this paper argues that the central problem is no longer technical or procedural, but conceptual: how can informed consent remain meaningful in research environments shaped

[38] R. Becker, D. Chokoshvili, A. Thorogood et al., Purpose definition as a crucial step for determining the legal basis under the GDPR: implications for scientific research, in Journal of Law and the Biosciences, 11, 1, 2024.

[39] E. Vayena, A. Blasimme, Health Research with Big Data: Time for Systemic Oversight, in Journal of Law and Medicine Ethics, 46, 1, 2018, 119.

[40] A.O. Cozzi, Incidental findings and the right not to know in clinical setting: constitutional perspectives, in BioLaw, 1S, 2021, 79.

by temporal uncertainty, social entanglement, and epistemic complexity? What normative conditions are required for consent frameworks that not only safeguard rights but also resonate with participants' values and support responsible scientific progress? These questions expose the limits of a compliance-driven approach and underscore a key insight: legal adequacy does not guarantee ethical sufficiency. What is needed is not just a rethinking of how consent is obtained, but a reframing of what consent is — what it affirms, enables, and expresses within morally complex and relationally embedded research practices.

As Gerald Dworkin has observed, the traditional doctrine of consent is "a creature of law",[41] "developed within legal domains where one party grants another the authority to perform some course of action to which the consented-to party would otherwise have no moral right".[42] The fundamental idea underpinning the *moral magic*[43] of consent is that the permissibility of one party (A) performing an action (x) on another party (B) depends, at least in part, on meeting these specific conditions:

> Sufficient information: B must be adequately informed about the relevant facts concerning x to understand its nature and likely consequences.
>
> Voluntary agreement: B must freely agree to x without undue influence or coercion.
>
> Decision-making capacity: B must possess the cognitive and emotional capacity to comprehend the information and make an informed decision.

Among the various domains where such a conceptualization of informed consent has proven particularly significant, healthcare stands out as especially prominent. Its legal foundation within the medical sphere first gained explicit recognition on October 22, 1957, in the California Court of Appeals decision Salgo v. Leland Stanford Jr. The University Board of Trustees, a landmark malpractice case, that helped shape the doctrine's subsequent interpretation and application. In this case, the court concluded that "a physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment […] in discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent".[44] Since then, the ethical and legal significance of informed consent in medicine and research has progressively become a cornerstone of both theory and practice.[45] When the previously discussed principles are applied to the medical framework, informed consent occurs when a patient or research participant (B) voluntarily agrees to allow a physician or researcher (A) to perform a specific action (x), such as conducting a medical test or procedure. For consent to be considered informed, B must be provided with comprehensive and relevant information about x,

[41] G. Dworkin, Autonomy and informed consent, in G. Dworkin, The Theory and Practice of Autonomy, Cambridge, 1988, 100.

[42] J. Kleinig, The Nature of Consent, in F. Miller, A. Wertheimer (eds.), The Ethics of Consent: Theory and Practice, New York, 2009.

[43] H.M. Hurd, The Moral Magic of Consent, in Legal Theory, 2, 2, 1996, 121.

[44] D. Robert, History of the Use of the Term "Informed Consent" Up To Salgo, Madison, 2020.

[45] For a reconstruction of the evolution of the concept of informed consent with regard to both the practice of medicine and research conducted with human volunteers see L.A. Bazzano, J. Durant, P.R. Brantley, A Modern History of Informed Consent and the Role of Key Information, in Ochsner Journal, 21, 1, 2021, 81.

including its potential risks, benefits, and alternatives, to make an autonomous decision. We may further specify that B is deemed autonomous with respect to x if it is carried out:

> Intentionally,
>
> With understanding, and
>
> Without control influences determining the decision to undertake action x.

Reflecting the observations of other scholars,[46] this paper stresses that achieving the ethical standard of fully informed, autonomous consent is particularly challenging — if not inherently limited — in the context of clinical genomic research. One central difficulty lies in the variable clinical significance and interpretive complexity of genomic results, which poses significant barriers to ensuring participant or patient understanding.[47] While some findings — such as pathogenic variants in genes associated with well-characterized monogenic disorders — have clear diagnostic and therapeutic implications, many others remain ambiguous or context-dependent. A subset of results may offer actionable insights for treatment or disease prevention; some provide probabilistic information or open pathways for further investigation; others generate uncertainty or raise sensitive ethical issues, including incidental, unsolicited, or secondary findings; and still others may yield no clear meaning at the time of sequencing, such as variants of uncertain significance, which may become interpretable only through future advances in genomic knowledge. This temporal and epistemic instability poses a unique challenge to consent processes that are structured around a single transactional moment of decision-making. In genomic research, where data reuse and reanalysis are integral to the research logic, the initial act of consent often cannot account for future uses, new interpretations, or unforeseen findings.[48] Yet, re-engaging participants to revisit their consent remains logistically and normatively complex, particularly in large-scale studies or international consortia.[49]

To address these limitations, dynamic consent has emerged as a promising and technologically attuned model, leveraging digital infrastructures to enable real-time, participant-driven governance of data use. One of the most compelling implementations of this approach is the CHRIS initiative (Cooperative Health Research in South Tyrol), which since 2011 has integrated a dynamic consent system into its biobank platform.[50] Built into a digital infrastructure, CHRIS allows participants to express and update granular preferences, access relevant study information, and maintain continuous, tailored communication with

[46] J.J. Koplin, C. Gyngell, J. Savulescu, D.F. Vears, Moving from 'fully' to 'appropriately' informed consent in genomics: The PROMICE framework, in Bioethics, 36, 2022, 655.

[47] J.S. Roberts, Patient understanding of, satisfaction with, and perceived utility of whole-genome sequencing: findings from the MedSeq Project, in Genetics in Medicine, 20, 2018, 1069.

[48] D. Lorenzo, M. Esquerda, M. Bofarull et al., The reuse of genetic information in research and informed consent, in European Journal of Human Genetics, 31, 12, 2023, 1393.

[49] Z. Fehlberg, Z. Stark, S. Best, Reanalysis of genomic data, how do we do it now and what if we automate it? A qualitative study, in European Journal of Human Genetics, 32, 2024, 521.

[50] D. Mascalzoni, R. Melotti, C. Pattaro, P.P. Pramstaller, M. Gögele, A. De Grandi, R. Biasiotto, Ten years of dynamic consent in the CHRIS study: informed consent as a dynamic process, in European Journal of Human Genetics, 30, 2022, 1391.

researchers. Yet the CHRIS experience also illustrates the critical dependencies of its dynamic consent model: its success is deeply embedded in a specific regional, institutional, and linguistic ecosystem; it requires substantial infrastructural investment and long-term commitment to digital literacy. While CHRIS exemplifies the potential of dynamic consent to realign ethical and operational demands, it also highlights the model's limitations when deployed in less favourable or more heterogeneous contexts. Crucially, dynamic consent in its current instantiations often focuses on procedural flexibility without offering a structured methodology for identifying, negotiating, and embedding competing values into the architecture of consent systems. This is where Value Sensitive Design enters as a conceptual and procedural complement. It does not replace dynamic consent models but rather informs their design from the ground up by shifting the ethical focus: from discrete moments of consent to the sociotechnical and institutional conditions that make consent meaningful, responsive, and just. It interrogates the value-laden nature of design choices and foregrounds key questions often sidelined in implementation: which normative assumptions shape the design of platforms? Who has the authority to define consent parameters? How are conflicts between transparency, equity, efficiency, and autonomy identified and resolved? And, crucially, how can these processes remain attuned to contextual variation, stakeholder plurality, and evolving normative expectations? In alignment with the WHO's call for informed consent models that are inclusive, adaptive, and sensitive to local sociotechnical contexts, Value Sensitive Design offers a robust methodological scaffold for reimagining consent within a broader, dynamic framework of socially responsive governance in genomic research.

As underscored during the Third International Summit on Human Genome Editing (London, March 6–8, 2023), there is indeed an urgent need to reconceptualize governance mechanisms in terms of redistributed ethical responsibility.[51] This shift aligns with Boers and Bredenoord's argument (2018) that ethical legitimacy in genomic research cannot rest solely on discrete acts of consent but must instead be embedded in the evolving architecture of systems, protocols, and institutional arrangements[52]. Value Sensitive Design might contribute to make this shift actionable — not by proposing a single model, but by embedding value deliberation into the infrastructures, policies, and practices through which consent is enacted and sustained. It provides a way to set the "rules of the game" in research environments where the nature, scope, and implications of data use are open-ended. By integrating technical design with moral imagination, Value Sensitive Design helps ensure that genomic data governance can evolve alongside research practices — without compromising on the ethical imperatives of autonomy, justice, and respect.

This capacity for forward-looking, ethically grounded design becomes especially relevant when we consider what the WHO's *Guidelines* most effectively bring to the forefront: the recognition that traditional approaches to informed consent have consistently failed to account for the fundamentally social character of genomic data. While this has been introduced through legal categories (e.g., genomic data as "special" under Art. 9 GDPR), it acquires real normative traction only when reframed through a concep-

[51] https://royalsociety.org/news/2023/03/statement-third-international-summit-human-genome-editing/ (last visited 06/06/2025).

[52] S.N. Boers, A.L. Bredenoord, Consent for governance in the ethical use of organoids, in *Nature Cell Biology*, 20, 6, 2018, 642.

tual lens — as Value Sensitive Design prescribes. As underlined by Rehmann-Sutter,[53] while genomic information should primarily be regarded as private,[54] genetic agency and knowledge extend beyond the individual, encompassing a broader social dimension in three significant ways: backwards, as it reveals information about ancestors; forward, as it anticipates traits in future descendants; and laterally, as it impacts other family members. Furthermore, genomic data are not neutral inputs, but are embedded within symbolic orders, cultural narratives, and bioethical imaginaries that shape how they are understood and acted upon.[55] This hermeneutic dimension reinforces the importance of designing consent as a value-sensitive and culturally mediated process, rather than as a static legal mechanism.

A further, closely related shortcoming of traditional consent models lies in their limited capacity to build and sustain trust. This is particularly critical among communities with low scientific literacy,[56] individuals affected by rare diseases, those with specific impairments or disabilities,[57] and ethnically diverse populations.[58] Indeed, what conventional consent and data governance frameworks often fail to grasp is that trust is not built merely on information disclosure or regulatory compliance. As explicitly articulated in the WHO's *Guidance*, trustworthy genomic data practices must be context-sensitive, inclusive, and grounded in normative commitments to equity, solidarity, and participant empowerment (Sections 3.1–3.5). This requires recognizing participants not merely as data contributors, but as moral agents with epistemic authority and legitimate stakes in how their data are used and governed. By drawing from these normative principles, the WHO document implicitly challenges narrow, proceduralist models of consent and invites the development of frameworks that are more dialogical, adaptable, and responsive to different social realities.

4. Intersecting the who's principles and Value Sensitive Design

This final section offers a conceptual exploration of how the normative vision articulated in the WHO's *Guidance* can be meaningfully operationalized through the methodological lens of Value Sensitive Design. Rather than presenting a fully developed case study or prescribing a fixed model of informed consent — an endeavour that would be both methodologically and normatively inappropriate — the section embraces Value Sensitive Design as a flexible approach better suited to guide inquiry and design within ethically complex domains. Framed as a methodological orientation rather than a blueprint, Value Sensitive Design is here considered for its potential to complement existing models such as dynamic consent, enriching them with context-sensitive, value-aware strategies. The aim is to outline how Value Sensitive Design can translate abstract principles into actionable practices — fostering consent processes that are

[53] C. Rehmann-Sutter, Why Non-Directiveness is Insufficient: Ethics of Genetic Decision Making and a Model of Agency, in *Medicine Studies*, 1, 2009, 113.

[54] I. Brassington, *The Private Life of the Genome: Genetic Information and the Right to Privacy*, London, 2023.

[55] E. Postan, *Attending to Identity*, in *Embodied Narratives: Protecting Identity Interests through Ethical Governance of Bioinformation*, Cambridge, 2022.

[56] K. Jayasinghe, W.A.S. Chamika, K. Jayaweera et al., *All you Need is Trust? Public Perspectives on Consenting to Participate in Genomic Research in the Sri Lankan District of Colombo*, in *Asian Bioethics Review*, 16, 2024, 281.

[57] D.N. Bryen, *Ethical Issues in Conducting Research Involving Persons with Disability: A View from the Past and Some New Challenges*, in *Humanities and Social Sciences*, 4, 2-1, 2016, 53.

[58] M. Shete, M. Kocher, R. Pratt, H. Lee, H. Zierhut, *Genetic counselling processes and strategies for racially and ethnically diverse populations: A systematic review*, in *Journal of Genetic Counseling*, 33, 4, 2024, 842.

inclusive, transparent, and attuned to the distributed, relational, and evolving nature of genomic data governance.

First and foremost, as previously established, the process should begin with a systematic identification of relevant stakeholders and a careful mapping of their values, expectations, and vulnerabilities. In the context of clinical genomic research — particularly within the global, data-intensive, and socially complex landscape envisioned by the WHO — this stakeholder map must extend well beyond the conventional triad of researchers, clinicians, and individual participants providing their genomic data.

More obviously, it must include biological family members who may be directly affected by secondary or incidental findings, especially in cases involving heritable conditions. Less intuitively, it should also encompass representatives of communities whose collective identities, ancestries, or health vulnerabilities are implicated in genomic sampling or data interpretation — such as Indigenous groups or population isolates. One illustrative case is the controversy surrounding the Havasupai Tribe in the United States, where DNA samples collected for diabetes research were later used, without consent, for studies on mental illness and population migration, sparking accusations of cultural harm and mistrust.[59] Equally essential are institutional actors such as bioethics committees, institutional review boards (IRBs), and data access committees, which play a pivotal role in mediating between ethical norms, legal standards, and research imperatives.

Yet what sets Value Sensitive Design apart is its methodological insistence on also including non-traditional stakeholders — actors who may not formally participate in the research process but whose influence and epistemic authority is nonetheless substantial. These may include religious or spiritual leaders, cultural representatives, or civil society organizations capable of articulating local moral imaginaries, community norms, or historical traumas that bear on participation in genomic research. Similarly, the use of Community Advisory Boards (CABs) has proven instrumental in surfacing communal concerns and guiding research priorities in underserved or historically exploited populations. By foregrounding this plurality, Value Sensitive Design does not dilute the ethical significance of individual autonomy; rather, it re-situates it within a relational, systemic, and culturally informed ethical framework.

Second, building on the WHO's *Guidance*, the values to be integrated into this framework include:

> Social Justice: addressing structural inequities in the representation of populations within genomic databases and ensuring a fair distribution of research benefits across different social and geographical contexts.
>
> Inclusivity: actively engaging underrepresented communities, marginalized groups, and individuals with diverse cultural, linguistic, and health backgrounds, ensuring that research priorities and outcomes are co-shaped by those historically excluded.
>
> Solidarity: fostering shared commitments and collective responsibility, recognizing that the benefits and risks of genomic research extend beyond individuals to broader social networks and future generations.

[59] N.A. GARRISON, *Genomic Justice for Native Americans: Impact of the Havasupai Case on Genetic Research*, in *Science Technology and Human Values*, 38, 2, 2013, 201.

Trustworthiness: promoting ethical data stewardship, transparent governance, and responsiveness to participant concerns as conditions for sustaining trust in genomic infrastructures.

Transparency: ensuring clarity and accountability regarding data access, sharing agreements, commercial partnerships, and the scope of future research applications.

Before any empirical or technical implementation, a Value Sensitive approach requires a deeper articulation of the normative content of the values identified and a concrete exploration of their operational translation into the design of consent processes and governance infrastructures. This phase must go beyond abstract declarations and move toward institutional and procedural experimentation.

A priority is the identification and rectification of power asymmetries in the governance of genomic data. Underrepresented and historically marginalized communities — whether defined by geography, socio-economic status, ethnicity, or health condition — must not only be consulted but meaningfully integrated into the processes by which consent models and data use policies are designed, evaluated, and revised. One viable mechanism is the institutionalization of Community Advisory Boards (CABs), composed of community-nominated members who hold consultative and, where appropriate, deliberative or even co-decisional authority.[60] They should be empowered to review research protocols, assess potential harms or stigmatizing outcomes, and contribute to the formulation of communication strategies and data sharing policies. Their role should be formally embedded within ethics review and data governance procedures, not treated as auxiliary or optional.

Second, capacity-building initiatives are essential to enable genuine participation.[61] A Value Sensitive approach should include structured educational modules tailored to the epistemic, cultural, and technological background of the target communities. These could be delivered through workshops, multilingual digital platforms, or community-located facilitators and should cover core themes such as the goals of genomic research, the nature of data collection and storage, potential benefits and risks, and the rights and roles of participants. Such initiatives not only enhance informed participation but foster a sense of epistemic agency and co-ownership over research trajectories. The CHRIS initiative offers a compelling example of how a dynamic consent infrastructure can operationalize these principles at a technical and communicative level. Value Sensitive Design might offer a complementary layer. By interrogating which values are embedded in the model, which voices are structurally excluded or underrepresented, and how system design could evolve in response to changing social expectations, it transforms stakeholder engagement from a function of usability into a moral and political practice. These strategies are particularly critical in low- and middle-income countries[62] or contexts with limited digital literacy, conditions that differ markedly from the technologically advanced and institutionally stable environment of South Tyrol, where traditional models of consent are often misaligned with local ethical frameworks or practical realities. In these settings, a Value Sensitive approach can inform the co-development of culturally

[60] Y. Zhao, T. Fitzpatrick, B. Wan et al., *Forming and implementing community advisory boards in low- and middle-income countries: a scoping review*, in *BMC Medical Ethics*, 20, 2019, 73.

[61] E.G. Cohn, M. Husamudeen, E.L. Larson et al., *Increasing Participation in Genomic Research and Biobanking Through Community-Based Capacity Building*, in *Journal of Genetic Counseling*, 24, 2015, 491

[62] M. Hetu, K. Koutouki, Y. Joly, *Genomics for All: International Open Science Genomics Projects and Capacity Building in the Developing World*, in *Frontiers in Genetics*, 10, 2019, 95.

adapted tools — such as visual consent aids, story-based consent formats, or mobile-compatible dynamic consent platforms — which facilitate communication while preserving local moral imaginaries. In this regard, Value Sensitive Design proves particularly valuable both for articulating the normative architecture of consent itself and developing technical artifacts. It can be employed especially to design culturally tailored consent mechanisms to reflect the decision-making practices, values, and linguistic needs of the populations involved.[63] This entails moving beyond standardized, text-heavy forms and toward multimodal, context-specific strategies that address variations in literacy, conceptual understanding, and trust in medical or research institutions. For example, in rural Uganda, researchers have employed community drama performances and audio-recorded scripts in local languages to convey research objectives, risks, and procedures. Qualitative and quantitative assessments revealed that these participatory methods significantly improved comprehension, trust, and community engagement, with follow-up surveys indicating strong information retention and positive behavioural outcomes.[64] Similarly, one promising avenue for future research and design is the development of envisioning tools — such as pictorial flip charts or multilingual consent videos — to support genomic studies among linguistically diverse and low-literacy communities, particularly in initiatives like H3Africa.[65] While such communication aids have been discussed or informally employed in various settings, they have not yet been systematically designed or evaluated through the Value Sensitive Design methodology. Furthermore, in Indigenous contexts, such as among First Nations, Inuit, and Métis communities in Canada, traditional written consent procedures may be supplemented — or even replaced — by oral consent processes mediated through tribal councils or elders' committees.[66] These mechanisms reflect culturally embedded understandings of collective responsibility, relational autonomy, and intergenerational decision-making, challenging the individualist assumptions that often underpin standard consent models. Value Sensitive Design enables these adaptations by offering a structured framework for the integration of stakeholder perspectives into the design and governance of consent processes, aligning ethical aspirations with technological feasibility.

This paradigm shift also supports the integration of a solidarity-based ethos into consent design. As emphasized in the WHO *Guidelines*, genomic research implicates not only individual participants but also families, communities, and society at large. By embedding the principle of collective responsibility into consent frameworks — an approach endorsed by recent literature on genomic justice[67] [68] — researchers can acknowledge and address the broader social implications of data sharing and scientific advancement. For example, participant-led initiatives and community-based governance structures have proven

[63] M. Colom, P. Rohloff, *Cultural considerations for informed consent in pediatric research in low/middle-income countries: a scoping review*, in *BMJ Paediatrics*, 2018, 298.

[64] J. O'Donovan, A. Thompson, C. Stiles, J.A. Opintan et al., *Participatory approaches, local stakeholders and cultural relevance facilitate an impactful community-based project in Uganda*, in *Health Promotion International*, 35, 6, 2020, 1353.

[65] *H3Africa Revised Informed Consent Guideline for SC* (2017), accessed via h3africa.org (last visited 16/06/2025).

[66] C. Peltier, S. Dickson, V. Grandpierre et al., Culturally appropriate consent processes for community-driven indigenous child health research: a scoping review, in BMC Medical Ethics, 25, 3, 2024.

[67] A.J. Clarke, C.G. Van El, Genomics and justice: mitigating the potential harms and inequities that arise from the implementation of genomics in medicine, in Human Genetics, 141, 5, 2022, 1099.

[68] M. Gaille, R. Horn, The ethics of genomic medicine: redefining values and norms in the UK and France, in European Journal of Human Genetics, 29, 2021, 780.

effective in empowering minority and marginalized groups to articulate their own notions of public good and to play an active role in shaping research priorities and oversight mechanisms.[69]

Ongoing engagement and sustained communication are equally vital for building trust. Digital tools such as mobile apps, interactive dashboards, and secure participant portals can facilitate longitudinal interaction and reinforce agency by enabling participants to monitor, modify, or withdraw their consent over time.[70] Again, the CHRIS study exemplifies this potential by demonstrating how digital platforms can operationalize dynamic consent in ways that are both ethically and legally compliant. However, as noted, CHRIS operates within a highly specific sociotechnical environment — its success relies on stable infrastructures, digital literacy, and localized governance — which may not be easily replicable elsewhere. Here, Value Sensitive Design offers a complementary and generalizable approach by embedding ethical reflection into the early stages of design and by fostering deliberation around future scenarios. Of particular interest is its compatibility with speculative design strategies, such as scenario-based simulations, interactive decision trees, and AI-driven consent assistants.[71] These tools enable participants to anticipate downstream uses of their data, visualize potential impacts, and engage in informed deliberation around complex trade-offs. For instance, prototype interfaces can simulate various data governance models — e.g., federated access, decentralized control, or public data commons — allowing stakeholders to co-evaluate ethical implications and practical outcomes before implementation. Such anticipatory design work is not merely technical; it is fundamentally philosophical. It calls for a design ethic that is attuned to uncertainty, plurality, and contextual nuance. By adapting consent architectures to local epistemologies, narrative frameworks, and relational dynamics, Value Sensitive Design bridges the gap between universal ethical principles and culturally responsive implementation. It allows us to think not only about how to protect participants, but about how to co-create systems in which they can act, reflect, and trust — thus transforming consent from a procedural safeguard into a dynamic site of democratic co-production.

These reflections, although preliminary, outline the distinctive contribution that Value Sensitive Design may offer: a methodology that integrates ethical analysis with design practice, enabling the creation of consent infrastructures that are not only technically robust but also normatively responsive. By embedding moral reflection into the architecture of consent tools and governance systems, Value Sensitive Design paves a way to engage with the evolving ethical demands of genomic research — anticipating conflicts, supporting inclusive participation, and aligning research practices with diverse stakeholder values across cultural and institutional contexts.

5. Conclusion

The rapid advancements in genomic research and its growing integration into healthcare call for a fundamental rethinking of how informed consent is both conceptualized and operationalized. The World

[69] I. Galasso, S. Geiger, Genetic research and the collective good: participants as leaders to reconcile individual and public interests, in Journal of Medical Ethics, 2023.

[70] T. Tamuhla, N. Tiffin, T. Allie, An e-consent framework for tiered informed consent for human genomic research in the global south, implemented as a REDCap template, in BMC Medical Ethics, 23, 2022, 119.

[71] R. Bendor, M. L. Lupetti, Teaching speculative design, in International Journal of Technology and Design Education, 2024.

Health Organization's *Guidance for Human Genome Data Collection, Access, Use and Sharing* underscores the urgent need for ethical frameworks capable of addressing the complex, transnational, and evolving nature of genomic data governance. This paper has argued that Value Sensitive Design offers a compelling methodological contribution to this effort. By embedding values such as equity, transparency, and trust directly into the design of digital tools, governance infrastructures, and consent practices, it helps reframe informed consent not as a static legal requirement but as an ongoing, participatory process. In this light, Value Sensitive Design is proposed not merely as an ethical lens but as a practical design methodology for developing and integrating consent tools and infrastructures that are culturally attuned, digitally accessible, and ethically resilient.

Though the discussion here remains largely conceptual, it supports the case for reinforcing the "fourth P" of precision medicine: participation. Crucially, participation must be understood not as a procedural formality, but as a normative imperative — an ethical stance that affirms the need for communities, particularly those historically marginalized, to be actively and meaningfully involved in shaping consent processes from the outset. When co-produced in this way, informed consent mechanisms become not only more robust and inclusive but better aligned with the lived realities and moral expectations of those most directly affected by genomic research.

Such alignment is not a matter of ethical idealism alone, but of practical necessity. It is a condition for fostering trust, legitimacy, and long-term engagement in an increasingly globalized and data-driven research ecosystem.