



Review Article

Reassessing Informed Consent in the Era of Large-Scale Genomic Biobanking

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ABSTRACT

The consent model underlying most genomic biobanks was designed for discrete, time-limited studies, and it sits uneasily with an infrastructure built to store and reuse samples indefinitely.

This review surveys the major consent models now in use -- broad, tiered, dynamic, and meta-consent -- and the empirical evidence on how participants actually experience the trade-off between autonomy and practicality that each represents.

It then examines three unresolved fault lines that recent literature has sharpened rather than settled: the mismatch between data-protection law and bioethical consent norms, the operational and ethical difficulty of returning individual results, and the gap between individual consent and the collective interests of communities, particularly Indigenous communities, whose genomes are studied without a comparable mechanism for group consent.

We also examine the right to withdraw, which recent analyses describe as considerably weaker in practice than consent documents imply, since data and derived results already shared or published cannot be meaningfully recalled.

We conclude that no single consent model resolves these tensions on its own, and that defensible biobank governance likely requires combining broad consent with genuinely independent oversight, a narrow and honest disclosure policy for actionable findings, and, where warranted, a community-level governance layer that individual consent cannot substitute for.

Keywords: informed consent; biobanking; genomic research; data governance; research ethics

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INTRODUCTION

Informed consent has always rested on an assumption that is quietly breaking down in genomic research: that

a participant can be told, at the point of enrollment, roughly what will be done with their data. Large-scale biobanks make that assumption difficult to sustain. A blood sample given for one study today may end up, years later, feeding analyses its donor never anticipated and consent forms never described [1]. This is not a minor technical wrinkle in an otherwise settled ethical framework; it is a structural mismatch between a consent model built for discrete, time-limited studies and a research infrastructure built to be reused indefinitely.

The debate this has produced is not really about whether consent still matters -- almost no one argues that it does not -- but about what shape consent has to take to remain meaningful when the uses of a sample cannot be fully specified in advance [2]. Bioethicists, regulators, and biobank operators have converged on a handful of competing answers: broad consent, tiered consent, dynamic consent, and various hybrids described as meta-consent. Each represents a different compromise between participant autonomy and the practical reality that biobanks cannot function if every downstream use requires a fresh signature. This review surveys those models, the empirical evidence on how participants actually experience them, and the harder unresolved questions around withdrawal, return of results, and the interests of communities rather than individuals alone.

The stakes of getting this wrong are not hypothetical. The cell line derived from Henrietta Lacks's tissue in 1951, taken and distributed for research without her knowledge or consent, remains the field's starkest illustration of what happens when biospecimens outlive the circumstances under which they were obtained -- her genome was eventually published without her family's involvement, decades after her death [3]. That case predates modern biobanking by half a century, but the underlying problem it exposed, samples and data persisting and circulating far beyond what a donor could have anticipated, is precisely what today's consent models are trying, with only partial success, to manage [4]. Some commentators have argued plainly that despite two decades of proposed fixes, genomics still has not solved its consent problem so much as learned to live with it [5].

CONSENT MODELS IN PRACTICE

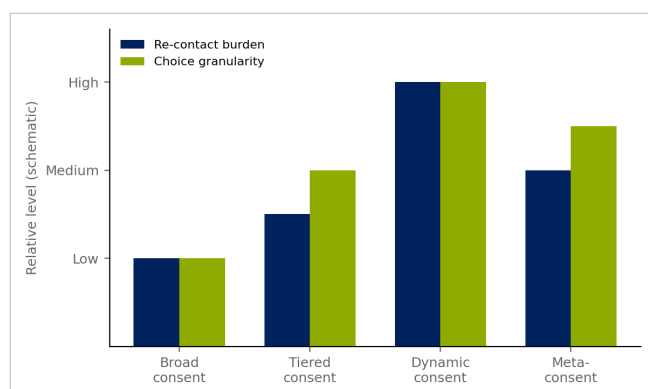
Broad consent asks a participant, once, to authorize a wide and largely unspecified range of future research uses, typically bounded only by an oversight committee's ongoing review; a widely cited multi-society workshop concluded that this model is ethically acceptable only when it is paired with credible, continuing oversight, not treated as a one-time substitute for it [6]. Its appeal is almost entirely practical: it lets a biobank operate at scale without re-contacting thousands of donors every time a new study is proposed. Critics have long argued that broad consent is barely consent at all, since a

participant cannot meaningfully weigh risks and benefits they have not been told about, and several commentators have proposed that broad consent only remains ethically defensible when paired with "deep" institutional safeguards -- transparent governance, meaningful ethics review, and a genuine option to withdraw -- rather than functioning as a substitute for those safeguards [7].

Table 1. Major consent models used in genomic biobanking, compared by re-contact burden and granularity of participant choice.

Model	Re-contact required	Granularity of choice	Main ethical trade-off
Broad consent	None after enrollment	Single yes/no for all future ethically-approved research	Simple and scalable, but participants authorize uses they cannot foresee
Tiered consent	None after enrollment	Pre-defined categories chosen at enrollment (e.g. condition-specific vs. any research)	More specific than broad consent, but categories can still be too coarse for novel uses
Dynamic consent	Ongoing, per new use	Case-by-case authorization via an online interface	Closest to real-time autonomy, but depends on sustained participant engagement
Meta-consent	Chosen once, by preference	Participant sets how much future re-contact/choice they personally want	Shifts engagement burden to those who want it, but adds a layer of complexity up front

Figure 1. Schematic comparison of re-contact burden and choice granularity across the four consent models discussed in this review (illustrative, not derived from a single empirical study).



Dynamic consent moves in the opposite direction, using an online interface to let participants review and authorize (or decline) specific new uses of their data as they arise, effectively replacing a single moment of

authorization with an ongoing relationship [8]. It answers the autonomy objection to broad consent directly, but at a real operational cost: dynamic platforms require sustained participant engagement, technical infrastructure the average biobank was not built to support, and a workable answer to what happens when a participant simply stops responding. Tiered consent sits between the two, offering donors a menu of pre-defined categories of use (for example, "any ethically approved research" versus "research related to my condition only") that they can select from at enrollment without needing an ongoing digital relationship with the biobank.

Empirical comparisons between broad and dynamic consent have generally found that participants value the sense of control dynamic consent offers, but that this preference does not always translate into active engagement once the novelty wears off, raising the question of whether "passive participation" under a dynamic system is meaningfully different, ethically, from broad consent with good governance [9]. Meta-consent proposals attempt to resolve this by asking participants, at a single point, how much re-contact and choice they personally want going forward -- some opting for broad authorization, others for case-by-case review -- so that the burden of ongoing engagement falls only on those who actually want it [10]. A more recent formulation of this idea applies meta-consent specifically to the governance of population-level biobanks, letting the preference itself, rather than the biobank's default policy, determine how much say each participant retains over time [11].

Table 1 summarizes how the major models compare on the two dimensions that drive most of this literature: how much re-contact they require and how granular the participant's choice actually is. Figure 1 places the same four models on those two dimensions side by side; the pattern that stands out is not that any one model dominates, but that dynamic consent's advantage in choice granularity comes bundled with the highest re-contact burden of the four, which is exactly the operational cost critics point to.

DATA PROTECTION LAW AS A SECOND CONSENT REGIME

Since the Regulation took effect in 2018, the EU General Data Protection Regulation has effectively layered a second consent regime on top of the bioethical one, and the two frameworks do not map onto each other cleanly [12]. Guidance issued for research institutions on how to interpret the Regulation's provisions for genetic data has itself needed repeated revision as biobank practice has evolved, a sign of how unsettled the intersection between data-protection law and research ethics still is [13]. The GDPR's research exemption permits secondary use of health and genetic data under safeguards that do not always require fresh, specific consent, which sits awkwardly against a bioethics

literature that has spent two decades trying to make consent more specific and participant-controlled, not less [14]. Commentators have described the interaction between the GDPR and cross-border data sharing in biobank consortia as adding friction without necessarily adding protection -- multiplying legal bases and documentation requirements across jurisdictions while doing little to give participants clearer answers about what happens to their data [15].

Genomic data poses a particular problem for any consent-based privacy regime because it is not deletable in the way other personal data can be: a genome is identifying by nature, shared in part with blood relatives who never consented to anything, and cannot be meaningfully anonymized without destroying its research value [16]. Regulatory frameworks built around an individual's right to control their own data sit uneasily with a data type that is, by definition, also information about other people.

RETURN OF INDIVIDUAL RESULTS

A second major fault line concerns whether biobanks and researchers owe participants their individual results, particularly incidental findings with clinical significance discovered along the way. Early biobank practice generally treated samples as fully de-identified and research results as not clinically actionable, which made non-disclosure the ethically simpler default. That position has become harder to hold as genomic analysis has gotten cheaper and more clinically interpretable, and as participants have increasingly expressed an expectation that actionable findings will be shared with them [17].

Professional guidance has moved toward a duty to disclose findings that are both analytically valid and clinically actionable, while leaving discretion around less clear-cut findings to the judgment of individual biobanks and their ethics oversight [18]. Even under this narrower duty, the operational burden is substantial: contacting participants years after donation, verifying findings in a clinically accredited setting before disclosure, and providing genetic counseling all require infrastructure many research biobanks were never funded to build. A 2025 mixed-methods study of return-of-results practice found that participants strongly favored being recontacted even for findings of uncertain significance, a preference that runs ahead of what most institutional policies currently promise [19]. Older ethical guidance on this question, developed originally for cardiovascular genetic cohorts, has aged reasonably well precisely because it tied disclosure to clinical actionability rather than to how interesting a finding might be to researchers [20]. International comparative work on the return of research results more broadly has reached a similar conclusion: the principles that hold up across jurisdictions are the narrow ones about clinical validity and actionability, not general statements about a right to "all" of one's data [21].

COMMUNITIES, INDIGENOUS DATA SOVEREIGNTY, AND THE LIMITS OF INDIVIDUAL CONSENT

Individual informed consent assumes that the relevant ethical unit is the person signing the form, but genomic data is also, unavoidably, data about the population that person belongs to. This becomes acute in research involving Indigenous communities, where historical experience includes cases of samples collected for one stated purpose being reused for research that communities later found offensive or harmful to their own understanding of ancestry and identity, without further consultation. Indigenous scholars have argued that individual consent, however rigorously obtained, cannot substitute for community-level governance over whether and how a population's genomic data is used at all [22].

Proposed responses include community-level research agreements negotiated before individual enrollment, tribal or community review boards with genuine veto power over specific analyses, and data sovereignty frameworks that keep genomic data under community control rather than in externally-held repositories [23]. A recent review of the cultural, ethical, legal, and social literature on Indigenous genomics research found that many of the frameworks proposed over the past decade remain more aspirational than implemented, with individual biobanks and funders often defaulting back to standard consent language once a project is underway [24]. This is arguably the sharpest current critique of the whole consent-model debate summarized above: broad, tiered, dynamic, and meta-consent are all still framed around what an individual authorizes, and none of them, on their own, resolve a claim about collective rather than individual harm.

WITHDRAWAL AND THE LIMITS OF WHAT CAN ACTUALLY BE UNDONE

Nearly every consent framework in genomic biobanking promises participants a right to withdraw, but the practical content of that right is thinner than it appears. Once a sample has been sequenced, the resulting genomic data may already be embedded in published datasets, shared with international consortia, or used to train downstream analytic models -- none of which can be meaningfully reversed by a withdrawal request submitted after the fact [25]. A 2025 analysis argued that the right to withdraw from biobank research is, in practice, "a weak right wrapped in empty promises," honored prospectively for future sample use but largely unable to claw back data and derived results already in circulation [26].

This has prompted renewed debate over whether open-ended, indefinite consent -- the norm at most large biobanks -- should give way to consent that expires or requires periodic renewal, forcing institutions to actually re-engage participants rather than treating

an initial signature as permanently sufficient authorization [27]. The UK Biobank's experience is often cited on both sides of this argument: it has operated for two decades under a broad-consent model without major scandal, which supporters take as evidence the model works at scale, while critics note that the absence of scandal is not the same as evidence that participants remain meaningfully informed about ongoing uses of their data two decades on [28].

CONCLUSION

None of the four consent models surveyed here -- broad, tiered, dynamic, or meta-consent -- resolves the underlying tension on its own; each simply relocates the trade-off between participant autonomy and biobank practicality to a different point in the process. What the recent literature adds is not a solution but a sharper sense of where the unresolved edges actually are: data protection law that does not track bioethical consent norms, a right to withdraw that cannot reach data already shared, and a persistent gap between individual consent and the collective interests of communities whose genomes are, in a real sense, also being studied without a comparable mechanism for their consent. A defensible governance model for any given biobank likely needs to combine elements deliberately -- broad consent backed by genuinely independent oversight, an honest and narrow disclosure policy for actionable findings, and, where the population involved calls for it, a community-level governance layer that sits above individual sign-off rather than being replaced by it.

DECLARATIONS

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Conflict of Interest

The authors declare no conflicts of interest relevant to this work.

Author Contributions

Kasper Zielinska conceived the review and drafted the initial manuscript. Eszter Virtanen performed the literature synthesis on data-protection law and return-of-results policy and critically revised the manuscript. Sylvie Greco contributed the sections on community governance and Indigenous data sovereignty and provided final approval of the submitted version. All authors read and approved the final manuscript.

Ethics Statement

As a literature review synthesizing previously published, publicly available research and policy analysis, this article did not involve new data collection from human participants and did not require institutional ethics committee approval.

Data Availability

No new data were generated or analyzed for this review. All sources discussed are cited in the reference list and are publicly available through their respective publishers.

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