



From Tissue to Data to Commercial Value: Transformation-Triggered Governance for Human Biospecimens Beyond Informed Consent

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Abstract

Background: Human biospecimens undergo continuous transformation after collection. Tumor fragments may become immortalized cell lines, genomic sequences, research datasets, artificial intelligence inputs, and commercially valuable products. However, research governance often treats informed consent as the primary normative event and focuses primarily on whether the initial authorization was sufficiently broad.

Objective: This article develops *Transformation-Triggered Governance* (TTG), a conceptual and doctrinal legal-bioethical framework for addressing governance challenges that emerge when scientific transformations alter the risk, identifiability, relational scope, purpose, or economic significance of biospecimens.

Methods: Using conceptual legal-bioethical analysis, TTG identifies five transformation triggers: biological, informational, purposive, relational, and commercial. Each trigger corresponds to proportional governance responses, including traceability, ethics review, controlled access, transparency, representation, renewed consent where appropriate, and benefit-sharing conditions when justified. The framework is examined through the HeLa cell case as a diagnostic illustration and compared with United States human subjects regulations, European data protection law, biobank fiduciary theory, genomic data governance, and community-engaged research.

Results: The analysis indicates that TTG provides an intermediate approach between one-time authorization and impractical perpetual consent by shifting attention from ownership of biospecimens to circumstances that require governance adaptation.

Conclusion: TTG offers an event-sensitive model for addressing downstream biospecimen transformations while distinguishing existing legal obligations from additional institutional safeguards.

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INTRODUCTION

Modern biospecimen research is built on a quiet instability. The object that enters a laboratory is often not the object that later matters ethically or legally. A piece of tissue may be collected during clinical care, stored for research, immortalized, sequenced, linked with phenotypic records, shared across institutions, aggregated into a database, analyzed through computational models, and incorporated into a commercial development program. Each step may be scientifically continuous with the one before it. Normatively, however, the sequence is not continuous in the same way. What changes is not only the form of the material but also the kind

of power that can be exercised through it.

The history of HeLa cells exposes this instability with unusual clarity. Cells taken from Henrietta Lacks's cervical tumor in 1951 became the first widely used immortal human cell line and eventually a foundational infrastructure for biomedical science. Decades later, whole-genome sequencing of HeLa cells created a different category of concern because sequence data could reveal information not only about the cell line but, probabilistically, about living relatives. In 2013, the National Institutes of Health and members of the Lacks family created a controlled-access arrangement for HeLa whole-genome sequence data, which the NIH later reaffirmed and updated. The episode is often narrated as a story about the historical absence of informed consent. That is correct, but incomplete. The more difficult lesson is that the ethical object itself kept changing ([National Institutes of Health, 2024](#)).

HeLa's transformation from tissue to cell line, from cell line to genomic data, and from research resource to source of downstream commercial value illustrates a general feature of contemporary bioscience. Landry and colleagues' genomic and transcriptomic characterization of HeLa, and Adey and colleagues' haplotype-resolved HeLa genome, demonstrated the scientific value of treating an established cell line as a genomic resource. At the same time, publishing HeLa genomic information exposed the familial dimension of genetic identifiability and prompted a governance response that was not contemplated when the original tissue was obtained (Clayton & King, 2020). This dynamic is not confined to a single historical case. As living tissue models such as organoids acquire increasingly complex functional characteristics, the same instability recurs at the point where biological material becomes a durable, reproducible research resource in its own right ([Bredenoord et al., 2017](#)).

Contemporary law has moved far beyond the regulatory world of 1951. The revised United States Common Rule expressly addresses secondary research, broad consent, possible commercial profit from biospecimens, and whole-genome sequencing. European data protection law treats genetic data as a special category of personal data and subjects scientific research processing to principles of lawfulness, purpose limitation, accountability, and appropriate safeguards. International ethical guidance similarly recognizes that stored biological materials and related data require governance over time, not merely a signature at collection. Yet these regimes still tend to organize the problem around identifiable information, consent categories, institutional responsibility, or the legal status of repositories. They are less explicit about a recurring operational question: when is a downstream scientific change substantial enough that governance itself should be reconsidered ([Council for International Organizations of Medical Sciences \(CIOMS\), 2016](#); 45 C.F.R. § 46.116, 2026; Regulation (EU) 2016/679, 2016;).

That question matters because neither of the two familiar poles is satisfactory. One pole is transactional consent. It treats the initial authorization as the decisive event and evaluates later use primarily by asking whether the original consent was broad enough. The other pole is continuous control. It imagines that participants must repeatedly authorize each new use or each downstream development. The first can underreact to transformations that were not reasonably imaginable at collection. The second can make long-term, data-intensive research impracticable and can confuse respect for persons with perpetual veto power over every derivative act of science.

This article proposes a third approach: Transformation-Triggered Governance (TTG). TTG does not make every change legally significant. It asks whether a downstream transformation materially changes the normative profile of a biospecimen or its derivatives. Five categories are proposed: biological transformation, informational transformation, purposive transformation, relational transformation, and commercial transformation. When a trigger is crossed, the appropriate response is not automatically renewed consent. Instead, the response is proportionate to the transformation and may include enhanced traceability, renewed research-ethics review, controlled access, participant or community representation, expanded transparency, renewed consent where feasible and warranted, or benefit-sharing and commercialization conditions. The literature mapping distinguishes consent and its temporal limits Sheehan et al. (2019), continuing institutional stewardship Milne et al. (2021), informational safeguards Mostert et al. (2016), and the limits of proprietary remedies ([Nielsen & Nicol, 2024](#)). TTG adds a decision rule for when these existing forms of oversight should be

reconsidered, rather than proposing a further form of consent.

The central claim is deliberately narrower than a theory of tissue ownership. The article does not argue that a donor owns every cell line, data point, invention, patent, or product causally traced to a biological contribution. Nor does it argue that commercialization necessarily creates a right to profits. Rather, it argues that downstream scientific transformation can create new governance obligations even where property doctrine does not give the source individual continuing ownership. This distinction matters because the dominant legal cases on tissue and biospecimens have often been forced into the language of property, conversion, gifts, or institutional ownership. *Moore v. Regents of the University of California*, *Washington University v. Catalona*, and *Greenberg v. Miami Children's Hospital Research Institute* each reveal, in different ways, the limits of asking ownership to perform all the work of governance—a limit that recent scholarship on post-*Moore* litigation strategy continues to confirm (Andrews, 2025). Accordingly, the title refers to the emergence of commercial value, not to any presumptive entitlement of contributors to downstream profits.

TTG therefore shifts the inquiry. Instead of asking only, *Who owns the material?* or *Was the original consent broad enough?*, it asks: *What has the material become, what new capacities now exist, and does that transformation require a corresponding change in governance?* That shift is modest in form, but it changes the problem's architecture. It places scientific transformation, not merely the moment of acquisition, at the center of downstream responsibility.

A biospecimen is often described as though it were a stable object. In practice, it is better understood as the beginning of a chain. A blood sample can yield DNA; DNA can yield sequence data; sequence data can be annotated and combined with phenotypic information; the combined data can enter a consortium; consortium data can become a reference resource; and that resource can support discovery far removed from the original study. Jane Nielsen and Dianne Nicol have recently emphasized that genomic data moves through multiple forms across the research life cycle, including raw sequence files, interpreted variants, aggregated datasets, and further derivative outputs. The legal and practical interests attached to those forms are not identical (Nielsen & Nicol, 2024).

The same is true on the biological side. Tissue can be processed, preserved, expanded, genetically manipulated, differentiated, immortalized, or organized into new experimental structures. An immortal cell line is not simply a stored fragment of the original body. Its scientific value arises precisely because it can be reproduced and manipulated in ways that the original specimen could not. Yet its biological continuity with the person of origin does not disappear. The paradox is structural: scientific transformation can increase distance from the original body while simultaneously increasing the quantity, durability, usability, and informational content of what derives from that body.

Property law has struggled with this transition because the categories of body, tissue, information, and invention do not align neatly. In *Moore*, the Supreme Court of California rejected a conversion claim based on the plaintiff's excised cells while allowing claims concerning informed consent and breach of fiduciary duty to proceed. In *Catalona*, the Eighth Circuit treated donated research biospecimens as *inter vivos* gifts to Washington University and rejected the donors' claimed power to direct the transfer of the samples to a departing researcher. In *Greenberg*, a federal district court rejected conversion claims concerning donated tissue and genetic material but allowed an unjust enrichment claim to survive in litigation involving commercialization of discoveries related to Canavan disease. These cases do not establish a single theory of human biological materials. They show instead that ownership questions become increasingly attenuated as biological contributions move into research infrastructures, intellectual work, and commercial development.

Patent law adds another layer. In *Association for Molecular Pathology v. Myriad Genetics*, the United States Supreme Court held that naturally occurring DNA is not patent eligible merely because it has been isolated, while recognizing that cDNA may be patent eligible because it is not naturally occurring (*Association for Molecular Pathology v. Myriad Genetics, Inc.*, 2013). The patent-eligibility inquiry is not a donor-rights inquiry, but it illustrates a broader point: legal categories may turn on transformation. A naturally occurring sequence, an isolated molecule, a synthetically created sequence, an engineered construct, and an application built from them are

not treated as normatively interchangeable. Biospecimen governance should be equally attentive to transformations that matter for autonomy, privacy, justice, and trust.

A similar transformation occurs when identifiability changes. Traditional research governance often distinguished identifiable specimens from de-identified or anonymized materials. Genomics makes that boundary less stable. Whole-genome sequence data is intrinsically rich, relational, and linkable to external datasets. Mostert and colleagues argued that data-intensive medical research challenges a simple "consent or anonymize" model, especially as reidentification risk and data linkage complicate assumptions about anonymity. European law itself reflects this concern by defining genetic data through inherited or acquired characteristics revealed by analysis of a biological sample and by imposing heightened protection on such data (Regulation (EU) 2016/679, 2016). Legal commentary on the GDPR's research pathways has likewise argued that overly restrictive readings of the Regulation can needlessly disrupt secondary research uses of data and biospecimens even where the underlying privacy risk has not materially changed (Peloquin et al., 2020).

The relational character of genomic information also changes the unit of ethical concern. A genome is individual in one sense but shared in another. It can reveal probabilities about biological relatives who never contributed a specimen and never entered the research relationship. The HeLa sequence controversy made this point concrete. When genomic data generated from a long-established cell line became capable of revealing information relevant to living descendants, the governance problem expanded beyond the source individual. The NIH-Lacks Family Agreement responded not by declaring that descendants owned the genome, but by constructing a controlled-access process that acknowledged familial interests and included family representatives in review (National Institutes of Health, 2024).

This is precisely the kind of change that a transformation-based framework can see more clearly than a purely acquisition-based model. The original event—collection of tissue—cannot by itself determine every governance question created by future technologies. Nor is the answer to pretend that every possible future consequence can be fully disclosed in advance. Science creates novelty. Governance must therefore contain a mechanism for recognizing when novelty becomes normatively material. The remainder of this article proceeds as follows. Section 2 describes the doctrinal and conceptual method used to construct and test the TTG framework. Section 3 presents the results of that analysis and discusses them together: it reviews the strengths and limits of existing governance models, sets out the TTG framework and its five triggers, applies the framework diagnostically to HeLa and prospectively to biobanks, organoids, genomic commons, and artificial intelligence, maps its implementation within United States and European law and biobank governance instruments, examines its implications for justice, representation, and benefit-sharing, and addresses anticipated objections. Section 4 concludes.

METHOD

This article reports a conceptual and doctrinal legal-bioethical analysis. It is not an empirical study: it reports no new human-subjects research, collected no primary data from individuals, and used no identifiable participant data. The analysis instead proceeded through structured legal-doctrinal and normative-ethical reasoning, applied in four stages. Doctrinal analysis here means interpreting the scope and limits of statutes, regulations, and judicial holdings, then comparing their legal requirements with ethical guidance and scholarly governance proposals; the latter were not treated as binding law.

1. Stage one: review of existing governance models. The article first identified and critically reviewed four recurrent, analytically distinct approaches to biospecimen and genomic-data governance—consent-based models (including broad consent and dynamic consent), fiduciary and stewardship theories of biobank governance, privacy and data-protection frameworks, and property-based approaches. This review drew on primary legal sources, including the revised United States Common Rule (45 C.F.R. § 46.116), the European Union's General Data Protection Regulation (Regulation (EU) 2016/679), and leading United States judicial decisions on the legal status of human tissue and biospecimens—*Moore v. Regents of the University of California* (1990), *Washington University v. Catalona* (2006), *Greenberg v. Miami*

Children's Hospital Research Institute, Inc. (2003), and *Association for Molecular Pathology v. Myriad Genetics, Inc.* (2013)—together with international ethical guidance (CIOMS, 2016) and biobanking standards (Snapes et al., 2023). It was supplemented by secondary scholarship in bioethics, health law, and science and technology studies on consent, stewardship, data protection, and property in biological materials. This review was used to identify the specific normative gap that existing models left unaddressed: the approaches examined did not, individually, set out the event-based decision criterion proposed here for determining when, after valid initial authorization, a downstream scientific change was substantial enough that governance itself should be reconsidered. The sources were selected purposively for their direct bearing on authorization, continuing institutional responsibility, information protection, or proprietary claims. They were mapped against four common questions: what interest each approach protected, which actor held decision-making authority, what continuing oversight it contemplated, and whether it specified a point for reassessing unexpected downstream uses. This was a structured conceptual comparison of the cited sources, not a systematic review or a claim that these approaches exhausted the field.

2. Stage two: framework construction. Building on that identified gap, the article developed an original governance framework, Transformation-Triggered Governance (TTG), through inductive doctrinal and conceptual analysis. Five categories of downstream transformation—biological, informational, purposive, relational, and commercial—were constructed by grouping recurring changes to legally or ethically relevant interests across biobanking practice, genomic-data governance, community-engaged research, and biospecimen litigation, and were organized into a three-stage decision architecture: (1) identification of whether a recognized transformation had occurred, (2) assessment of its normative materiality using a six-question proportionality test, and (3) selection of a governance response proportionate to the new normative profile, ranging from documentation and traceability to renewed ethics review, controlled access, community representation, renewed consent, or benefit-sharing conditions. The five groups reflected different objects of change: biological capacity Bredenoord et al. (2017), informational power Nielsen & Nicol, (Nielsen & Nicol, 2024) divergence from the authorized purpose (CIOMS, 2016), familial or community impact Claw et al. (2018), and appropriation of commercial value (Moore, 1990; Greenberg, 2003). Categories could overlap; classification identified the reasons for review rather than mutually exclusive types of specimens.
3. Stage three: diagnostic case study. The framework was then examined through a single diagnostic case study: the history of HeLa cells. HeLa was selected purposively rather than randomly because it was, to the authors' knowledge, a well-documented biospecimen lineage whose seventy-plus-year trajectory instantiated all five transformation categories within one continuous factual record—biological transformation through immortalization, informational transformation through whole-genome sequencing, purposive and distributive transformation through decades of wide research use, relational transformation through implications for living descendants, and commercial transformation through licensing and product development, including recent litigation such as *Lacks v. Ultragenyx Pharmaceutical, Inc.* (2024) and *Lacks v. Novartis Pharmaceuticals Corp.* (2024), as well as the governance response embodied in the NIH-Lacks Family Agreement (National Institutes of Health, 2024). Consistent with instrumental case-study logic in qualitative legal and policy research, HeLa was used not for statistical generalization but to illustrate the framework's internal coherence, to stress-test whether its five triggers could be mapped onto a real and thoroughly documented trajectory, and to show what a contemporary application of TTG would look like at each stage of that trajectory. The unit of analysis was each documented transformation and the corresponding governance decision point, not the person of origin or the cell line treated as a single static object. Because the original collection lacked a modern research-consent framework, HeLa episodes illustrated what TTG would flag prospectively; they did not

establish the legal liability of historical actors or show that this proposal had been empirically validated.

4. Stage four: implementation analysis and objection-testing. Finally, the article examined the framework's compatibility with existing legal and institutional architectures—United States human-subjects regulation, European Union data-protection law, and biobank governance instruments such as the transformation register and governance passport proposed in this article, material-transfer and data-use agreements, and international standards (ISO 20387; ISBER Best Practices)—and considered its implications for justice, representation, and benefit-sharing beyond individual consent, drawing on community-engaged genomics scholarship and data-solidarity approaches. The framework was then subjected to five anticipated objections—administrative burden, definitional indeterminacy, potential chilling effects on valuable research, the absence of automatic compensation rights, and its principally prospective orientation—to test its robustness and clarify its limits. Unlike existing material-transfer agreements and biobanking standards, the register and passport were conceptual implementation instruments proposed here; their feasibility and institutional effects remained to be assessed.

Throughout, the method was qualitative and normative: no statistical analysis, survey instrument, or empirical data collection was used. The scope of the analysis was deliberately prospective. The framework was designed to guide the governance of future biospecimen transformations rather than to adjudicate the legality of past conduct, and it was explicitly bounded to exclude techno-economic, actuarial, or damages-quantification questions—such as the calculation of individual compensation or the valuation of commercialized biospecimen-derived products—which lay outside the scope of a governance-design framework and were left to the separate legal and regulatory mechanisms designed for those purposes.

RESULTS AND DISCUSSION

Results

Informed consent remains necessary, but it cannot carry the whole lifecycle

Informed consent is indispensable because it protects persons against unauthorized intervention and requires disclosure adequate to the decision at hand. The difficulty is temporal. Consent is given under conditions of partial knowledge, while biobanking and genomic research are designed precisely to preserve future possibilities. The revised Common Rule acknowledges this tension. It permits broad consent for the storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens, and it requires disclosures concerning possible commercial profit and whether research may include whole-genome sequencing. These provisions matter because they bring commercialization and genomic transformation into the consent conversation (45 C.F.R. § 46.116, 2026).

Yet broad consent remains a decision made at one time about categories of future activity. The problem arises when future activity is materially different in kind, not merely another instance within an anticipated category. A participant can be told that a sample may be used for future research, shared with other researchers, or sequenced. What is harder to specify is the downstream architecture through which the sequence may later be linked, aggregated, recomputed, used to train models, or incorporated into products. A consent form can describe possibilities, but it cannot eliminate the need for judgment after those possibilities become concrete. This temporal limitation complements, rather than displaces, accounts of consent to governance Sheehan et al. (2019) and the documented instability of a consent-or-anonymize approach in data-intensive research (Mostert et al., 2016). The unresolved issue is which later event warrants review, not whether advance authorization has ethical value.

Dynamic consent responds to this temporal problem by using information technology to create an ongoing interface between participants and research systems. Lay and colleagues' rapid review characterizes dynamic consent as a personalized mechanism for communication, preferences, and continuing interaction across research networks (Lay et al., 2025). A longer-term retrospective on the same approach shows that, more than a decade after its introduction, dynamic consent has demonstrated real value for participants who want granular, ongoing

control, while also exposing practical limits as digital health infrastructures have matured (Teare et al., 2021). It offers real advantages where participants want granular control and where digital infrastructure can sustain repeated engagement. But it is not a universal answer. Some participants do not want repeated requests; some projects span decades; some participants die or lose capacity; some data are embedded in widely distributed resources; and some ethically important interests are collective rather than reducible to individual preference. Equity concerns compound these limits: because dynamic-consent platforms depend on sustained digital access and literacy, they risk favoring participants who are already comparatively well resourced while further marginalizing groups already underrepresented in biobank research (Pictor et al., 2018). Newer technical proposals, including blockchain-based and generative-AI-assisted "demonstrated consent" systems, aim to make consent management more auditable and responsive over time, but they still confront the same underlying question TTG addresses: which downstream events should be treated as significant enough to reopen the governance conversation in the first place (Barnes et al., 2025).

Broad consent has also been reconceptualized as consent to governance rather than consent to a list of unspecified future studies. Sheehan and colleagues argued that broad consent becomes ethically defensible when participants authorize a governance structure capable of deciding responsible future uses. That is a crucial move. It recognizes that uncertainty cannot be solved by ever more elaborate disclosure alone. TTG begins from the same insight but asks a further question: what should cause that governance structure to reopen or intensify its review? The answer proposed here is material transformation (Sheehan et al., 2019). In TTG, materiality means a consequential change, assessed against the risk, purpose, access, and participant expectations documented in the original governance arrangements, that those arrangements do not adequately address.

Fiduciary and stewardship models identify continuing responsibility

Recent work has strengthened the case for viewing biobanks as institutions with continuing obligations rather than passive storage facilities. Tsuruyama and Hiratsuka argue that biobanks can be understood as fiduciaries of biosamples and data because they exercise long-term discretion under conditions of informational asymmetry and limited donor monitoring. Their account reframes broad consent as an ongoing governance commitment and links stewardship to duties of care, loyalty, transparency, sustainability, and responsible research facilitation. Earlier work by Milne and colleagues likewise explored data-trust and participatory-governance models for genomic biobanks (Milne et al., 2021; Tsuruyama & Hiratsuka, 2026).

TTG is compatible with these approaches but performs a different function. Fiduciary theory asks what kind of relationship exists and what duties follow from entrusted discretion. TTG asks when the intensity or form of governance should change because the object, use, or effects have changed. The two can be combined. A fiduciary or stewardship institution still needs criteria for deciding when a secondary use exceeds the risk, purpose, access, or stakeholder conditions previously assessed and therefore requires escalation. A transformation trigger supplies that criterion without requiring every routine use to be treated as a new transaction.

International standards point in the same direction. ISO 20387 frames biobanking as a competence-governed activity carried out by a legal entity or part of a legal entity, while professional best-practice regimes emphasize traceability, quality management, access control, documentation, and accountability. CIOMS guidance similarly treats stored biological materials and related data as an area requiring ethical review, governance, and attention to future use. These instruments do not create a general legal trigger doctrine. They do, however, show that longitudinal governance is already part of the institutional reality of biobanking. TTG seeks to make one part of that reality more explicit and operational (International Organization for Standardization (ISO), 2018; Snapes et al., 2023).

Privacy and data protection govern information, but transformation can outrun identifiability categories

Privacy law is strongest when the governance problem is clearly informational. The GDPR, for example, regulates the processing of personal data and gives genetic data special status. It also

provides a research framework that combines scientific-use flexibility with safeguards. This is essential, but the transformation problem extends beyond data protection. Biological derivatives may become ethically significant before they become personal data in the technical legal sense; commercialization may alter participant expectations without changing identifiability; and community consequences may arise from group-level inference even where no single individual is readily identifiable (Regulation (EU) 2016/679, 2016). At the same time, legal scholarship has warned that an overly rigid reading of the GDPR's research pathways can itself become a source of disruption, discouraging the very secondary research uses the Regulation was designed to accommodate under appropriate safeguards, without a corresponding gain in privacy protection (Peloquin et al., 2020).

Nor is de-identification a permanent fact. It is a condition produced by technical, organizational, and informational circumstances. As external data ecosystems grow, the practical possibility of linkage can change. Genomic research therefore requires governance that can respond to changes in informational power, not merely to the identifier status recorded when a dataset was created. TTG treats a material increase in identifiability, inferential capacity, or sensitivity as an informational transformation that can trigger re-review.

Property is an incomplete proxy for control, recognition, and fairness

The attraction of property language is understandable. People often experience tissue and genomic information as intimately theirs, and property appears to promise control, exclusion, and a share in value. Recent doctrinal analysis of post-settlement litigation strategy following the Lacks family's dispute with Thermo Fisher Scientific illustrates the point: even where a settlement is reached, the underlying legal theories available to similarly situated patients—conversion, unjust enrichment, lack of informed consent, breach of fiduciary duty—remain fragmented and case-specific, offering no general property-based solution (Andrews, 2025). Genomic data, moreover, are non-rivalrous, duplicable, relational, and commonly valuable only when aggregated. Nielsen and Nicol show that ownership claims become more complicated as genomic data move through raw, curated, annotated, and aggregated forms and through institutional consortia. A rule that assigned exclusive ownership at every stage could obstruct research without necessarily protecting the interests participants actually care about (Nielsen & Nicol, 2024).

TTG therefore does not convert bodily origin into perpetual proprietary title. It separates governance interests from ownership. A participant may have a legitimate claim to transparency, limits on certain uses, community consultation, controlled access, or fair treatment even when property doctrine locates ownership elsewhere. Conversely, the existence of a commercial product does not prove that the source participant owns the product. The relevant question is whether commercialization creates a sufficiently material change in the relationship between contribution, risk, institutional discretion, and value that governance should be reconsidered. Separating claims to participation in governance from claims to proprietary title is therefore a core proposition of TTG, not merely a limit on the remedies it can offer.

Transformation-Triggered Governance: A Proposed Framework

Transformation-Triggered Governance begins with a simple proposition: downstream authorization should not be judged only by the breadth of the initial consent; it should also be judged by whether later transformations materially change the normative profile of the biospecimen or its derivatives. A transformation is normatively material when it creates or substantially increases one or more of the following: identifiability, persistence, reproducibility, inferential power, relational reach, divergence from the original research purpose, commercialization, or distributional consequence. Materiality is determined relative to the approved governance baseline and available safeguards; a technical change alone is insufficient. TTG describes a proposed ethical and institutional overlay, not an independent source of legal rights or duties.

The framework has three stages. First, an institution identifies whether a recognized transformation has occurred. Second, it assesses materiality using a proportionality test. Third, it selects a governance response proportionate to the new profile. This is not a requirement to stop research each time a sample is processed. Most laboratory transformations are routine and

already contemplated by protocol. The trigger concept is reserved for changes that meaningfully alter the ethical or legal stakes. Initial screening compares the proposed activity with the approved consent or lawful basis, protocol, permitted recipients, access conditions, and recorded community commitments. A documented material departure, or unresolved uncertainty about one, is referred to the competent oversight body rather than treated as routine by default.

Materiality can be assessed through six questions: (1) Was the transformation reasonably foreseeable from the original governance documents? (2) Does it materially increase the capacity to identify, infer information about, or affect the source participant or related persons? (3) Does it substantially depart from the purposes or institutions originally described? (4) Does it create a new and durable research resource capable of independent circulation? (5) Does it introduce commercial appropriation or concentrated economic value not previously salient? (6) Does it impose externalities on relatives, communities, or populations that were not adequately represented in the original decision process? The more strongly these factors are present, the stronger the case for governance escalation. These questions operationalize respect for authorized purposes, privacy and proportionality under data-protection law, stewardship accountability, the relational commitments articulated by CARE, and fair distribution of research benefits (CIOMS, 2016; Regulation (EU) 2016/679, 2016). Reviewers should record the original baseline, the evidence of change, affected interests, mitigating safeguards, and reasons for the resulting oversight level. The six questions guide consistent judgments; they are not a validated numerical score.

Trigger One: Biological transformation

Biological transformation occurs when a specimen is changed into a new biological resource with materially different persistence, reproducibility, functionality, or experimental potential. Immortalization is the clearest historical example. A tumor fragment that would ordinarily decay can become a self-reproducing cell line distributed across laboratories for decades. Organoids, induced pluripotent stem-cell derivatives, engineered cell lines, and other living models can create similar discontinuities (Bredenoord et al., 2017). The governance significance lies not in metaphysical claims about identity but in altered capability. A renewable biological resource can be copied, manipulated, transferred, sequenced, and used in contexts that the finite original specimen could never support.

A biological trigger does not mean that routine cell culture requires re-consent. The relevant threshold is a transformation that materially expands persistence, functionality, or downstream possibility beyond what the existing governance plan reasonably covered. The minimum response should be traceability and institutional documentation. Where the transformation creates a durable new resource, ethics re-review and confirmation of downstream-use conditions should follow. The operational threshold is reached when an investigator documents a newly renewable or functionally distinct derivative outside the capabilities and transfer conditions already reviewed—for example, immortalization or organoid derivation when the original approval covered only finite storage. Repeated culture within an approved cell-line protocol remains routine unless a further material capability emerges.

Trigger Two: Informational transformation

Informational transformation occurs when analysis generates a qualitatively richer or more sensitive form of information. Whole-genome sequencing is paradigmatic because it converts biological material into a persistent, portable, computationally reusable representation with implications for relatives. The Common Rule itself recognizes whole-genome sequencing as sufficiently distinctive to warrant specific disclosure when known or possible. The HeLa genome episode likewise demonstrates that informational transformation can create concerns that did not exist in the same form when the biological material was first distributed (45 C.F.R. § 46.116, 2026). The same dynamic underlies the broader debate over returning individual genomic research results: once sequencing generates findings with potential clinical significance for a participant or relatives, governance regimes worldwide diverge sharply on whether, when, and how those findings must be returned, precisely because the informational profile of the material has changed in ways the original consent process did not anticipate (Thorogood et al., 2019).

Other examples include reidentification through data linkage, the addition of highly granular phenotypes, spatial or single-cell data that permit novel inferences, and the transformation of raw data into predictive models. The governance response should turn on the new information's sensitivity and reach. Controlled access, data-use restrictions, security enhancement, renewed privacy assessment, and data-access committee review may be more appropriate than renewed consent in many cases.

Trigger Three: Purposive transformation

Purposive transformation occurs when use moves materially outside the purposes that structured the original contribution. No research system can specify every future project in detail, which is why broad consent exists. The trigger should therefore not be activated by ordinary scientific evolution within a reasonably described field. It is activated when the new use changes the moral meaning of participation, exposes participants to a qualitatively different kind of risk, or enters a field that participants could not reasonably have understood as included. Institutions should compare the proposed use with the consent language, participant-facing materials, protocol, and recorded community agreements, then seek input from affected representatives when a foreseeable cultural or stigmatic consequence is disputed. A purpose shift is therefore evidenced by a documented departure and its consequences, not inferred solely from an investigator's characterization of moral meaning.

The Havasupai controversy remains an instructive example of why purpose matters. Blood samples initially associated with diabetes research were later used for studies involving other topics that the community regarded as culturally sensitive. Scholarship on the dispute documents the long-term effect on trust and research relationships. The lesson is not that every new hypothesis requires new consent. It is that a profound purpose shift, especially one with cultural or stigmatic consequences, should trigger renewed governance review and meaningful community engagement ([Garrison et al., 2019](#)).

Trigger Four: Relational transformation

Relational transformation occurs when a use that initially appeared individual becomes materially consequential for relatives, a community, or a socially identifiable population. Genomics makes this especially visible because biological relatedness distributes information across persons. Population genomics can also generate group-level claims with implications for identity, stigma, disease classification, or access to benefits. The appropriate unit of governance may therefore expand beyond the individual donor.

Community-engaged genomic research has developed principles that are directly relevant here. Claw and colleagues proposed a framework for ethical genomic research with Indigenous communities emphasizing collaboration, cultural competence, transparency, capacity building, and dissemination. Work on *Ubuntu* and genomics governance similarly emphasizes solidarity, reciprocity, fairness, and shared benefit ([Munung et al., 2021](#)). The internationally adopted CARE Principles for Indigenous Data Governance—Collective Benefit, Authority to Control, Responsibility, and Ethics—provide a further, more operational articulation of the same logic, insisting that data governance be accountable to the people and communities the data describe, not only to the individual from whom a sample was first collected ([Carroll et al., 2020](#)). These approaches do not displace individual rights. They show that governance can become relational when the effects of research are relational.

Relational transformation is also important for scientific validity. Underrepresentation in genomic reference datasets can translate into misclassification and downstream clinical harm. Manrai and colleagues showed how variants initially treated as pathogenic could be misclassified when reference populations lacked adequate diversity, with implications for health disparities. Representation is therefore not simply a recruitment objective. It is part of the ethical quality of knowledge production. A transformation that turns individual data into population-level inference should be accompanied by governance that considers population-level consequences ([Manrai et al., 2016](#)).

Trigger Five: Commercial transformation

Commercial transformation occurs when biospecimens, data, or derivatives enter a materially different value regime through licensing, exclusive control, product development, platform formation, or other forms of monetization. The trigger is not the mere presence of money. Research institutions need funding, repositories require cost recovery, and partnerships with industry can generate public benefit. The relevant change occurs when commercial appropriation becomes sufficiently significant that participant expectations, benefit allocation, access conditions, or conflicts of interest require reconsideration.

The revised Common Rule already requires, when appropriate, disclosure that biospecimens may be used for commercial profit and whether the subject will share in that profit. That requirement acknowledges that commercialization is ethically salient even though it does not create a right to profits. Moore and Greenberg likewise show the legal difficulty of translating biological contribution into ownership of downstream inventions, a difficulty that persists in the current generation of litigation arising from commercial use of the HeLa line (45 C.F.R. § 46.116, 2026; Moore v. Regents of the University of California, 1990; Greenberg v. Miami Children's Hospital Research Institute, Inc., 2003). TTG does not resolve that difficulty by fiat. It instead treats commercialization as a governance event. The institution should examine whether existing consent, access rules, conflict-management mechanisms, benefit-sharing policies, and public-interest commitments remain adequate in light of the new value structure.

This distinction is especially important because benefit sharing need not mean individual royalty payments. Depending on context, benefit sharing may take the form of access commitments, community investment, capacity building, return of aggregate findings, nonexclusive licensing, affordable-access conditions, or support for the populations from which data were derived. CIOMS guidance recognizes the broader ethical importance of fair distribution of research benefits, while data-solidarity approaches argue for governance that promotes socially valuable use and addresses harms or inequitable extraction. A recent editorial synthesis of benefit-sharing scholarship in genomic and global-health research similarly argues that benefit sharing must be designed proactively into research programs from the outset, rather than treated as an afterthought once commercial value has already been captured (Yakubu et al., 2023).

Table 1
Transformation-Triggered Governance Matrix

Trigger	Illustrative threshold	Primary risk shift	Proportionate governance response
Biological	Creation of a durable, renewable, or functionally new biological resource	Persistence, reproducibility, expanded downstream use	Traceability; protocol amendment; ethics re-review; downstream-use conditions
Informational	Whole-genome sequencing, materially enhanced linkage or inferential capacity	Identifiability, privacy, familial inference	Privacy reassessment; controlled access; data-use restrictions; security escalation
Purposive	Use outside the reasonably understood field or moral meaning of the original contribution	Autonomy, cultural sensitivity, stigmatic use	Governance re-review; transparency; consultation; renewed consent where feasible and material
Relational	Individual-level material becomes consequential for relatives or a defined community	Group effects, stigma, representation, distributive harm	Family/community representation; engagement; group-sensitive access review

Commercial	Material entry into exclusive licensing, product development, or concentrated monetization	Expectation, conflicts, allocation of benefit and control	Commercialization review; conflict management; benefit- sharing or access conditions
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A graduated response, not an automatic veto

The most important design feature of TTG is that a trigger does not dictate a single remedy. The response should be graduated. At the lowest level, a transformation may require documentation and confirmation that it remains within the approved governance envelope. At the next level, it may require ethics committee or data-access committee re-review. More substantial transformations may justify participant notification, community consultation, additional access controls, independent oversight, or renewed consent. In rare cases, a proposed use may be incompatible with the conditions under which the materials are ethically held and should not proceed. The governance envelope comprises the existing lawful basis or consent, approved protocol and research purposes, permitted users and recipients, access tier, material-transfer and data-use conditions, commercialization disclosures, and any documented commitments to families or communities. Escalation is required when a material change falls outside that envelope or renders its safeguards inadequate.

This graduated structure avoids two errors. It avoids treating broad consent as a blank check, because material transformation can reopen governance. It also avoids treating respect for persons as a requirement of serial permission for every secondary analysis, because routine uses can remain within the original governance envelope. TTG is therefore a trigger-and-escalation architecture, not a perpetual-consent architecture.

HeLa as a Diagnostic Case for Transformation-Triggered Governance

HeLa is useful for TTG not because modern law can simply be projected backward onto 1951, but because the sequence of events makes transformation visible. The original tissue was removed in a clinical context without the form of research consent now expected. That historical fact is ethically central. But if the analysis stops there, it misses the successive changes that made HeLa an enduring governance problem.

The first transformation was biological. The tumor cells did not remain a finite specimen. They became an immortal cell line capable of indefinite propagation. This changed the scale and duration of possible use. A one-time biological extraction became a renewable infrastructure. In TTG terms, immortalization would be a high-salience biological trigger because persistence and reproducibility increase dramatically.

The second transformation was distributive and purposive. HeLa cells circulated widely through research networks, entered innumerable experimental contexts, and became detached institutionally from the original clinical encounter. The wider the distribution, the weaker any single institution's practical capacity to reconstruct or govern the entire downstream chain. That is precisely why transformation governance must attach to institutional decision points rather than to a fiction of continuous physical control by the source individual.

The third transformation was informational. Genome sequencing turned the cell line into a detailed informational resource. Landry and colleagues and Adey and colleagues produced genomic characterizations of HeLa that were scientifically valuable precisely because they made the cell line more intelligible as a research system. Yet sequencing also made clear that a cell line with decades of laboratory history could retain information relevant to a family. The subsequent NIH-Lacks Family Agreement used controlled access and family participation to respond to that new informational and relational profile. This was not restoration of ownership. It was governance adaptation ([National Institutes of Health, 2024](#)).

The fourth transformation was relational. The privacy implications of HeLa sequence data could not be understood exclusively through Henrietta Lacks as an individual research subject, because she had died decades earlier. The concerns implicated descendants. The governance response therefore expanded the relevant constituency. TTG captures this as a relational trigger: the identity of those affected by a downstream use can change even if the material's physical origin

does not.

The fifth transformation is commercial. HeLa cells have been deeply embedded in biomedical development and commercial research. The legal disputes brought by the Lacks estate, including litigation against Thermo Fisher, Ultragenyx, Novartis, and others, have renewed attention to unjust enrichment, commercialization, and the long afterlife of biological materials. A 2024 federal decision in *Lacks v. Ultragenyx Pharmaceutical, Inc.* allowed important parts of the estate's unjust-enrichment theory to survive a motion to dismiss, while the Novartis litigation was resolved by settlement and dismissal with prejudice in 2026. Recent doctrinal analysis of the parallel Thermo Fisher settlement argues that these disputes expose a durable structural gap: patients whose tissue is used and commercialized without consent still have no reliable, general legal pathway to a remedy, and must instead assemble fact-specific claims in conversion, unjust enrichment, informed consent, and fiduciary duty (Andrews, 2025). These proceedings do not establish a universal right to profit sharing. They underscore that commercialization can remain normatively salient decades after the original biological event.

TTG would not retroactively solve HeLa. No contemporary framework can undo the conditions of 1951 or reconstruct consent that was never sought. Its value lies elsewhere. HeLa shows why governance should be designed with downstream triggers from the beginning. If a modern biobank created an immortal cell line, later sequenced it, linked it to family-relevant information, and licensed it into a commercial platform, the governance system should not have to pretend that these are ethically identical stages merely because the initial consent form included the words "future research."

Table 2
Reading the HeLa Trajectory Through TTG

Stage	Transformation	Normative shift	TTG response in a contemporary system
Tumor tissue	Collection and research use	Autonomy and authorization	Valid research consent or applicable lawful pathway; ethics oversight
Immortal cell line	Biological transformation	Indefinite persistence and reproducibility	Transformation record; re-review; downstream governance terms
Whole-genome data	Informational transformation	Identifiability, inferential power, data portability	Controlled access; privacy review; data-use agreement
Family implications	Relational transformation	Interests extend beyond original source	Family-sensitive governance; representation where justified
Commercial development	Commercial transformation	Concentrated value, access and conflict questions	Commercialization review; transparency; benefit/access conditions where justified

Beyond HeLa: Biobanks, Organoids, Genomic Commons, and Artificial Intelligence

The strongest test of TTG is not whether it can explain a famous historical case but whether it can guide ordinary research systems before controversy arises. Contemporary biobanks are long-lived institutions. They store materials precisely so that technologies and questions not yet known can later be applied. This temporal openness is scientifically valuable. It is also why governance cannot be exhausted at collection.

Consider a biobank that obtains broad consent for cancer research and future genomic

analysis. Five years later, investigators derive organoids from stored tumor tissue. Ten years later, the organoids are sequenced at single-cell resolution and linked with electronic health records. A commercial partner then uses the resulting multimodal dataset to train a predictive model and develops a proprietary diagnostic platform. It would be artificial to treat the final arrangement as ethically identical to the original storage of tumor fragments. Yet it would also be excessive to insist that every intermediate laboratory procedure required new individual consent. TTG separates these questions by identifying moments when capability and consequence change materially.

Organoids and other advanced human models sharpen the biological trigger because they can acquire functional characteristics that make simple tissue terminology inadequate. Bredenoord and colleagues' influential review of organoid technology observed that these living models raise ethical questions that extend well beyond the animal-research and embryo-research debates from which biobanking ethics originally borrowed, precisely because organoids can be stored, distributed, and further developed much like a durable research resource in their own right (Bredenoord et al., 2017). Governance should therefore document the creation of durable derivative resources and specify access, transfer, sequencing, commercialization, and destruction or withdrawal rules where technically possible. The relevant obligation is not to decide in advance every future experiment but to decide in advance what kinds of transformation will require renewed institutional judgment.

Genomic consortia sharpen the informational trigger. Their scientific value depends on aggregation and sharing, yet aggregation changes the governance landscape. Nielsen and Nicol describe consortia as part of a wider medical information commons in which data move through multiple hands and formats. A transformation-based approach would require participating institutions to preserve metadata not only about consent categories but also about governance constraints, community commitments, and trigger conditions. In other words, provenance should include normative provenance (Nielsen & Nicol, 2024).

Artificial intelligence adds another layer because data can be transformed into models whose outputs are not simple copies of the training data. The central issue is not whether a trained model "contains" a participant's genome in a property-law sense. It is whether model development creates a new inferential capacity, a new purpose, a new commercial structure, or a new group-level consequence. Ethical analysis of AI applications in prenatal and pediatric genomic medicine illustrates why this question cannot be deferred: applying AI to early-life genomic data raises distinct concerns about beneficence, autonomy, transparency, and trust that are not resolved merely because the underlying genomic data were lawfully collected for another purpose (Coghlan et al., 2023). If a governance-relevant threshold is crossed, one or more TTG triggers may be activated. This avoids an unhelpful all-or-nothing debate about whether consent to data research automatically authorizes every future computational use.

The framework also helps distinguish public-interest data sharing from unrestricted extraction. Data solidarity argues that governance should enable socially valuable uses of health data while imposing stronger constraints where uses create significant individual or societal risk. TTG can operationalize that insight. A low-risk transformation with strong public value may require documentation and access safeguards, not renewed consent. A high-risk transformation involving sensitive inference, stigmatizing group claims, or exclusive commercial appropriation may require much more (Prainsack et al., 2022).

Discussion

Legal and Institutional Implementation

1. United States research regulation

TTG can be implemented within the architecture of the Common Rule without requiring a new property regime. The revised rule already distinguishes primary collection from storage and secondary research, recognizes broad consent, requires certain disclosures about commercial profit, and highlights whole-genome sequencing. The regulatory opportunity is procedural: institutions can treat specified transformations as events requiring protocol amendment or governance escalation even when the secondary use remains legally permissible (45 C.F.R. § 46.116, 2026). The Common Rule imposes its own consent and review obligations only where its

applicability and relevant regulatory conditions are met. TTG does not assert that the Rule already mandates review after every biological, relational, or commercial transformation; it proposes an additional institutional trigger policy, implemented through applicable protocol, repository, or contractual procedures.

A biobank governance plan could therefore identify trigger conditions prospectively. An institutional review board would not need to review every downstream experiment. It would review whether the repository has a credible trigger policy and whether a particular high-salience transformation falls within the existing approval. Data-access committees could perform parallel functions for informational transformations. Commercialization offices could be required to consult the biobank's governance record before exclusive licensing or transfer into a new product-development context.

This approach also fits Moore's doctrinal lesson. If property law does not give the source person continuing conversion rights in excised cells, the legal system still need not treat downstream institutional conduct as ethically unstructured. Moore itself preserved the significance of informed consent and fiduciary disclosure in the clinical relationship. TTG extends the same general intuition into institutional research governance: absence of donor ownership does not imply absence of responsibility (*Moore v. Regents of the University of California*, 1990).

2. European data protection law

The GDPR provides a particularly fertile home for informational and purposive triggers because it already requires controllers to specify purposes, minimize data, provide transparency, and implement accountability, while allowing scientific research under defined conditions and safeguards. TTG should not be confused with a new lawful basis for processing. It is a governance overlay. Where processing remains lawful, a material transformation may still justify a renewed data-protection impact assessment, revised access controls, additional transparency, or reconsideration of compatibility with the stated research purpose (Regulation (EU) 2016/679, 2016). Any such measure must remain compatible with the controller's actual lawful basis, the special-category conditions applicable to genetic data, and the safeguards required in the particular research context; TTG cannot itself authorize otherwise unlawful processing.

This is important because data protection law can become overly focused on formal categories such as anonymized versus personal data. Mostert and colleagues' critique of a simple consent-or-anonymize approach remains relevant: data-intensive research requires a richer account of proportionality and safeguards. Peloquin and colleagues add a complementary caution from the opposite direction: an unnecessarily restrictive interpretation of the GDPR's research pathways can disrupt legitimate secondary research without a corresponding privacy benefit, which is itself a governance failure that a well-calibrated trigger framework should help to avoid ([Peloquin et al., 2020](#)). TTG adds a temporal dimension. A dataset that was low-risk under one technical environment may become more sensitive after linkage, sequencing, or the emergence of new inferential tools. Governance should be able to recognize the change. The gap TTG addresses is narrower than a failure of the GDPR: the Regulation does not prescribe one biospecimen-wide event screen encompassing newly durable non-data derivatives, broader family or community consequences, and commercial changes even when the original processing remains lawful. TTG supplies that additional institutional review step without replacing, weakening, or purporting to amend GDPR obligations.

3. Biobank governance instruments

The most practical implementation route is contractual and institutional. Consent forms, repository policies, material-transfer agreements, data-use agreements, and commercialization policies can contain transformation clauses. These clauses need not promise renewed consent in every case. They can specify that certain downstream events will trigger governance review and identify the range of possible responses.

A transformation register should accompany specimen provenance. For each high-salience derivative, the register would record the originating governance terms, the transformation performed, the new capabilities created, the reviewing body, the decision taken, and any conditions carried forward. Such a register would make longitudinal accountability auditable. It would also address a common practical weakness in distributed research: samples travel more easily than the ethical context in which they were obtained. Structured recording of

downstream findings and their disposition would also help resolve the closely related governance question of whether and how individual genomic research results should be returned to participants—an area where, absent such a register, laws and policies across jurisdictions have developed unevenly and inconsistently (Thorogood et al., 2019).

A governance passport could perform the same function across institutions. Instead of attaching only a binary consent label, it would carry structured information about permissible domains, prohibited or sensitive uses, community commitments, commercial conditions, access tiers, and trigger history. This idea is consistent with the broader move toward traceability and standardized governance in biobanking, while adding a specifically normative layer to sample and data provenance (Tsuruyama & Hiratsuka, 2026).

Finally, trigger review should be multidisciplinary. Biological transformation may require scientific expertise to understand what has actually changed. Informational transformation requires privacy and data-security expertise. Relational transformation may require family or community perspectives. Commercial transformation requires attention to intellectual property, access, conflicts of interest, and distributive consequences. No single committee must perform every function, but the governance system must route the trigger to the right form of judgment.

Justice, Representation, and Benefit Beyond Individual Consent

One reason consent alone cannot carry the entire governance burden is that valid consent does not guarantee a just research system. A participant can consent to a study that is poorly representative, socially extractive, or institutionally unaccountable. Conversely, a research project can impose burdens on communities whose members are not individually identifiable in the dataset. Justice therefore requires attention to how scientific value and risk are distributed.

The history of research with Indigenous communities shows why this matters. The Havasupai experience became a reference point for mistrust because the disputed secondary uses were experienced as departures from the meaning attached to the original participation. Garrison and colleagues' comparative analysis of Indigenous genomic research governance and Barton and colleagues' work on rebuilding research relationships show that formal consent cannot be separated from culture, transparency, and institutional trust. Claw and colleagues' framework moves further by emphasizing research partnerships rather than treating communities as passive sources of specimens (Barton et al., 2024; Claw et al., 2018; Garrison et al., 2019). The CARE Principles for Indigenous Data Governance operationalize the same commitments for data specifically, requiring that governance produce collective benefit, respect community authority to control data about them, assign clear responsibility to those who steward the data, and embed ethics beyond minimal legal compliance (Carroll et al., 2020).

A relational trigger translates these lessons into governance architecture. When research shifts from individual-level analysis to claims about an identifiable population, the reviewing institution should ask whether additional representation is needed, whether stigmatic or political consequences are plausible, whether findings will be returned in an appropriate form, and whether the community shares fairly in the scientific or social benefits. This does not create a collective veto over all research involving members of a group. It requires the governance system to recognize when the scale of consequence has changed. Potentially newly affected parties include living biological relatives subject to familial inference, identified communities exposed to group-level claims or stigma, and populations whose access to resulting diagnostics or benefits may be changed. The institution should specify which interests the new use engages before selecting who, if anyone, should participate in review.

Representation also affects scientific validity. The cardiomyopathy example analyzed by Manrai and colleagues demonstrates that an insufficiently diverse evidence base can produce variant misclassification and downstream clinical error. The ethical problem is therefore double: some populations can be overexposed to extractive research while simultaneously underrepresented in datasets that determine clinical interpretation. A transformation framework should be sensitive to both directions. Data aggregation is not ethically neutral merely because it increases statistical power (Manrai et al., 2016).

Benefit sharing must be equally nuanced. Individual payment for each downstream use is neither administratively realistic nor always ethically desirable. But the opposite position, that no

downstream benefit question survives once consent has been signed, is too thin. Commercial and relational triggers create moments when institutions should examine who bears burdens, who receives access, whose infrastructure made the work possible, and whether the conditions of collaboration remain fair. *Ubuntu*-informed governance, data-solidarity approaches, and the broader benefit-sharing literature converge on the same point: they shift the focus from a binary of private ownership versus unrestricted commons toward reciprocity and socially accountable use, and they argue that benefit-sharing mechanisms are most effective when designed into a research program from its inception rather than negotiated only after commercial value has already been realized (Yakubu et al., 2023).

Objections and Limits

1. The framework may appear too burdensome

The strongest practical objection is administrative burden. Biomedical research already operates under dense layers of ethics review, privacy law, contracts, data-access rules, and quality standards. Adding a new trigger framework could become another checklist. That concern is valid if TTG is implemented indiscriminately. The framework therefore depends on a materiality threshold. Routine processing, ordinary secondary analysis, and uses clearly contemplated by the existing governance envelope should not require escalation. Triggers should identify exceptional changes, not relabel every laboratory step as an ethical crisis. Under the proposed workflow, the principal investigator or repository custodian performs the first comparison with a pre-approved trigger policy and records a reasoned routine-use decision. A material, contested, or uncertain transformation is escalated to the appropriate ethics committee, data-access committee, or other designated oversight body; investigators should not unilaterally exempt their own high-salience uses.

The transformation register should also reduce, not increase, duplication over time. If institutions record trigger decisions and carry forward normative provenance, later reviewers need not reconstruct consent and governance history from fragmented files. A well-designed system converts repeated uncertainty into cumulative institutional memory.

2. Transformation is difficult to define

A second objection is line drawing. Biological and informational systems change continuously, so any attempt to identify discrete transformation events may seem artificial. TTG responds by distinguishing descriptive change from normative materiality. The mere fact that a sample has been processed differently is not enough. The relevant question is whether the change materially affects persistence, identifiability, inferential power, purpose, relational reach, or commercialization. These are evaluative categories, but so are familiar regulatory concepts such as minimal risk, reasonable person, compatibility of purpose, and proportionality. Governance already depends on judgment; the task is to make the judgment transparent and reviewable. For inter-institutional consistency, an adaptable screening form should capture the same six prompts, an agreed baseline, evidence of new capability or exposure, available mitigation, the designated decision-maker, and written reasons. Comparable anonymized decisions can be periodically audited and used to refine domain-specific examples; whether this procedure achieves reliable agreement requires future empirical evaluation.

Institutions can also develop domain-specific examples. A genomics repository may define whole-genome sequencing, linkage to external ancestry databases, and transfer into law-enforcement-accessible environments as high-salience informational events. A stem-cell bank may define immortalization, organoid creation, or germline-relevant differentiation as biological events. A rare-disease consortium may define exclusive licensing or model training by a commercial partner as commercial events. The framework is general, but its thresholds should be local enough to reflect scientific reality.

3. TTG could chill socially valuable research

A third objection is that additional governance may discourage data sharing and collaboration. That risk should be taken seriously. Genomic research depends on large datasets, and excessive fragmentation can reduce scientific value. The answer, however, is not to eliminate downstream accountability. It is to calibrate governance to risk. Data solidarity provides a useful orientation: socially valuable, low-risk uses should be facilitated, while higher-risk uses should

carry stronger accountability. TTG makes that calibration event-sensitive ([Prainsack et al., 2022](#)).

In fact, transparent trigger governance may support research by improving trust. Participants and communities may be more willing to authorize broad future research when broad consent does not mean institutional silence after unexpected transformation. A credible promise that certain high-salience changes will be re-reviewed can make long-term research relationships more legitimate without requiring continuous participant management.

4. The framework does not create automatic compensation rights

A fourth objection may come from the opposite direction: TTG may appear too modest because it does not guarantee participants a share of downstream profits. That limitation is intentional. The normative case for governance change is stronger and more generalizable than a universal property or royalty claim. The contribution of tissue can be causally important without being the inventive contribution that patent law rewards; commercial value can result from decades of scientific labor, capital, validation, and regulatory work. A transformation framework should not erase those contributions.

At the same time, the absence of an automatic royalty does not make benefit allocation irrelevant. Commercial transformation can trigger scrutiny of transparency, conflicts, licensing terms, community benefit, access conditions, and the fairness of institutional arrangements. This is a governance claim rather than a predetermined damages formula. It is intentionally capable of different answers in different contexts.

5. TTG is principally prospective

Finally, TTG should be understood principally as a prospective governance framework. Historical cases can illuminate it, but the framework should not be used casually to declare that past institutions violated duties that did not then exist in law or practice. HeLa is a diagnostic case, not a device for anachronism. The practical contribution is to design contemporary repositories so that future transformations do not become invisible merely because initial consent was formally valid. Historical episodes thus serve explanatory and diagnostic functions, not direct tests of present-day legal liability; any prospective TTG decision must instead be made under the law and governance commitments applicable to that later decision point.

CONCLUSION

The central problem of biospecimen governance is no longer only how material enters research. It is how that material changes once it is there. A legal and ethical architecture built around the moment of collection risks becoming static while the science it regulates remains dynamic. Tissue becomes a renewable biological resource. A cell line becomes a genome. A genome becomes a shared dataset. A dataset becomes an inferential model. A research resource can become a commercial platform. At each stage, the relationship between scientific value and human interests may change.

Transformation-Triggered Governance responds to this instability without treating every downstream event as a new consent transaction. It identifies five material triggers—biological, informational, purposive, relational, and commercial—and connects them to proportionate governance escalation. The framework is compatible with broad consent, dynamic consent, fiduciary stewardship, data protection, community engagement, and responsible commercialization, but it adds a missing temporal rule: governance should reopen when transformation materially changes the normative profile of what is being governed. Its principal practical contribution is a documented screening-and-escalation procedure that links scientific change to the specific consent terms, legal obligations, affected constituencies, and institutional decision-makers engaged by that change. Comparative implementation and empirical assessment are necessary before its administrative consistency or effectiveness can be claimed.

The HeLa story makes the need visible because it spans the entire chain. The cells were not merely used; they repeatedly became something new. The eventual controlled-access arrangement for HeLa genomic data shows that governance can adapt without pretending that a family owns every derivative or that science must stop. That middle position deserves to be generalized.

The next generation of biospecimen governance should therefore ask a different question. Not simply, *Was consent obtained?* Not simply, *Who owns the sample?* The more durable question

is: *What has this biological contribution become, and has governance changed enough to remain legitimate?*

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Author contributions were structured according to the roles undertaken throughout the research and manuscript preparation process. Raymond R. Tjandrawinata contributed to the conceptualization of the study, development of the Transformation-Triggered Governance (TTG) framework, legal-bioethical analysis, interpretation of relevant regulatory and doctrinal materials, and critical revision of the manuscript. Velliana Tanaya contributed to the literature review, analysis of governance theories, examination of ethical and legal perspectives, manuscript drafting, and refinement of the discussion. Both authors contributed to reviewing and editing the final manuscript, approved the submitted version, and agreed to be accountable for all aspects of the work.

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