

Ethical Governance of Patient-Specific and Biofabricated Photopolymer Devices: Consent, Equity, Evidence and Accountability

A bounded governance review separating patient-specific clinical devices from biofabrication evidence

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Abstract

Ethical governance for patient-specific and biofabricated devices involves questions about consent, privacy, equity, evidence generation, responsibility and institutional oversight, but the available evidence must be kept within its actual scope. This review separates two evidence streams. A systematic review of three-dimensional printed medical devices used directly to treat patients supports the existence of a patient-specific clinical-device population [4], while ethics literature on personalized scaffolds and biofabrication documents concerns around translation, consent, privacy, access, uncertainty, commercialization and responsibility [1-3,5]. The streams are related but are not interchangeable. None of the active sources establishes an ethical effect specific to photopolymer chemistry, and this review therefore does not claim that photopolymer materials create unique consent, equity, evidence or accountability effects. The active evidence base used here consists of bibliographic records and publisher abstracts; none of the five anchors is treated as a full-text source. Accordingly, governance propositions are presented as documented ethical concerns rather than universal requirements, no jurisdiction-independent legal rule or allocation of liability is proposed, no quantitative threshold or disparity estimate is inferred, and whole-organ bioprinting is not presented as clinically established. Within those limits, the review provides a traceable governance architecture for discussing how patient-specific and biofabricated photopolymer devices enter clinical, translational and institutional decision contexts. Two hypothetical governance cases identify concrete decision points while preserving the distinction between patient-specific devices and cell-containing biofabrication.

Keywords: patient-specific devices; biofabrication; photopolymer; consent; equity; evidence; accountability; ethical governance

1. Scope and ownership

ER-487 examines ethical-governance questions associated with patient-specific and biofabricated devices within the photopolymer catalogue. The word photopolymer identifies the material and manufacturing context of the corpus; it is not evidence that photopolymer chemistry itself creates a distinct ethical effect. On the active source base, no photopolymer-specific effect on consent, equity, evidence or accountability is established.

The article therefore treats consent, equity, evidence and accountability as governance domains that may become relevant when patient-specific clinical devices or biofabrication technologies are developed, tested, translated or used. It does not create a universal governance code, a legal rule, a liability allocation or an operational acceptance standard.

2. Evidence basis and public limitation

The evidence base is deliberately narrow. All five active anchors are used at the level of bibliographic records and publisher abstracts rather than full-text reading. This limits the review to broad propositions visible at that depth and excludes normative, quantitative and study-level claims that would require deeper source access.

The sources also divide into two different populations. Kermavnar and colleagues review three-dimensional printed medical devices used directly to treat patients and support the patient-specific clinical-device limb [4]. The ethics literature from van Daal and colleagues, Otto and colleagues, Vermeulen and colleagues, and Kirillova and colleagues supports the biofabrication and tissue-engineering ethics limb [1-3,5]. Evidence from one limb is not used as if it directly characterized the other.

3. Patient-specific clinical devices and the governance boundary

The patient-specific clinical-device limb is supported only by the systematic review of three-dimensional printed medical devices used directly in patient treatment [4]. At the evidence depth used here, that source supports the existence of a clinical population in which patient-specific implants and surgical guides are prominent.

ER-487 does not use that source to claim that patient-specific photopolymer devices have distinctive consent, equity or accountability effects. Nor is it used to support biofabrication ethics. Its role is narrower: it establishes a patient-specific clinical-device context that must remain distinguishable from the biofabrication literature when governance questions are discussed.

4. Biofabrication as a distinct ethical-governance stream

Personalized scaffolds and regenerative biofabrication are addressed directly by the ethics literature [1,2]. Those sources frame ethical analysis across development, clinical translation and implementation, including concerns connected with highly personalized biomedical products, human materials, digital information, uncertainty and the relation between innovation and society.

Socioethical analysis of bioprinting adds prospective questions about responsible development and regulation [3], while the bioethical and legal review by Kirillova and colleagues broadens the discussion to consent, confidentiality, ownership, access and responsibility [5].

These are documented areas of concern, not evidence of a single mandatory framework. ER-487 therefore preserves them as questions to be made explicit rather than converting them into universal requirements.

5. Consent, privacy and the provenance of participation

The biofabrication sources identify consent as a relevant ethical concern when human materials and personalized biomedical technologies are translated toward clinical use [2,5]. Within this review, consent is therefore treated as a governance question about how participation, material use and information use are represented and documented, not as a claim that one consent procedure is universally sufficient.

The evidence also permits recognition of privacy and digitalization concerns in personalized scaffolds and regenerative biofabrication [1,2]. It does not support a photopolymer-specific privacy effect or a jurisdiction-independent data-governance prescription. Any operational consent or privacy procedure would require a separate normative and jurisdictional evidence base.

6. Equity, access and distributional questions

Equity appears in the biofabrication ethics literature as a concern about access, affordability, distribution and social justice rather than as a measured disparity specific to photopolymer devices [2,5]. ER-487 therefore uses equity as a question to keep visible when highly personalized technologies move toward clinical or societal use.

No numerical disparity, access threshold or population effect is inferred. A governance discussion can identify who may benefit, who may bear burdens and whether access could be uneven, but the existence, direction and magnitude of any real disparity require direct evidence beyond the abstracts used here.

7. Evidence generation, uncertainty and oversight

The translation of regenerative biofabrication into clinical use raises questions about evidence generation under uncertainty, particularly around first-in-human use and the movement from experimental platforms toward patient-facing applications [1,2]. ER-487 treats that uncertainty as a reason to preserve what evidence exists, what remains unknown and what kind of decision is being made.

The patient-specific clinical-device literature provides a separate direct-use context [4]. The review does not merge these populations or infer common safety performance from them. It also does not propose quantitative evidence thresholds. The governance task at this level is to prevent the existence of a technically feasible device or biofabricated construct from being mistaken for evidence that all clinical, ethical or societal questions have been resolved.

8. Accountability, responsibility and commercialization

The active ethics sources identify responsibility, commercialization, ownership and accountability-related questions as part of the governance landscape [1,5]. ER-487 uses these terms to mark where decisions and consequences may need traceable institutional ownership. It does not allocate legal liability, assign fault or declare which actor must bear a specific duty in a particular jurisdiction.

This distinction is essential because accountability can be discussed as a governance concern without being converted into a legal conclusion. At the evidence depth available here, the article can ask whether responsibilities are visible and whether decision pathways can be reconstructed; it cannot state a jurisdiction-independent rule for manufacturers, clinicians, researchers, institutions, donors or patients.

9. Bounded governance architecture

The following architecture summarizes how ER-487 keeps the four title domains visible without exceeding the active evidence. It is an author-proposed organizational framework for this review, not an external standard or compliance checklist.

Domain	Documented concern supported by the active base	Boundary in ER-487
Consent	Participation, use of biological material and information, and comprehension during translation may require ethical attention.	No universal consent procedure; no photopolymer-specific effect.
Equity	Access, affordability, distribution and social-justice implications may require explicit consideration.	No measured disparity or quantitative access claim.
Evidence	Clinical translation and first-in-human uncertainty make the status and limits of evidence ethically relevant.	No performance threshold, safety threshold or study-level inference.
Accountability	Responsibility, ownership, commercialization and institutional oversight may require traceable discussion.	No jurisdiction-independent legal rule and no allocation of liability.

10. Separating the two evidence streams in practice

For patient-specific clinical devices, ER-487 uses [4] only to define the direct-treatment device population and its clinical-use context. It does not import the biofabrication ethics claims of [1-3,5] into that population as if they had been measured there.

For biofabrication and personalized tissue-engineering contexts, ER-487 uses [1-3,5] to identify documented ethical concerns. It does not use those sources to make claims about the clinical prevalence, performance or regulatory status of patient-specific printed devices. Whole-organ bioprinting is treated as a prospective socioethical subject in this evidence base, not as a clinically established capability.

11. Two cases that expose different governance questions

A hypothetical patient-specific guide produced from an anatomical image and a hypothetical cell-containing biofabricated construct should not be assigned the same governance record merely because both are personalised. The first case raises questions about the purpose and handling of patient-derived information, the evidence for the device and responsibility for decisions along the design-to-use chain. The second may add questions concerning biological material, donors, future uses and uncertain translational outcomes. These are analytical cases, not findings about a particular institution or statements of universal legal duties.

For each case, the proposed record would identify the person or institution making a decision, the information available to the affected participant and the uncertainty relevant to that decision. Consent to one activity should not be assumed to describe every later use of material or information. Whether an additional use is permissible requires the applicable consent, institutional and jurisdictional context.

This approach makes ethical analysis more specific than a list of values. It asks where a decision occurs, whose interests are affected and what information or governance process can address the question.

12. Make equity and accountability questions assessable

An equity analysis would begin by specifying a proposed benefit or burden and the population for which it is being considered. Unequal access is a question to investigate, not a measured result that follows from the label personalised. Relevant evidence might concern eligibility, availability, cost to participants or representation in studies, but the choice must follow the actual decision. The framework should not assign a numerical disparity without data.

Accountability can be examined by tracing a hypothetical design change. Who requests the change, who assesses its consequences, who approves the revised object and who communicates the resulting uncertainty? A record showing each role can expose an unowned decision without pretending to settle legal liability. The author proposes this as a governance exercise rather than an externally mandated allocation.

Finally, communication should distinguish experimental possibility from demonstrated benefit. A technically successful fabrication may be relevant to a development decision while leaving a patient-facing benefit uncertain. The governance analysis should preserve that difference and identify what additional evidence would change the decision. This provides practical content while maintaining the separation between patient-specific clinical devices and biofabrication research.

Supplementary critical engineering analysis: Consent and evidence generated through design iterations: Patient-specific device production may involve repeated changes to images, segmentation, geometry and clinical instructions. Consent and accountability should distinguish permission to use patient information for an individual care episode from permission for secondary research or model training. Traceable decision records should identify which design version was clinically accepted and which changes altered the risk profile. The ability to produce a custom geometry does not itself demonstrate clinical benefit or informed participation.

Equity as a measurable production question: Equity assessment can be operationalised through access to imaging, device turnaround, availability of qualified manufacturing sites and the effect of rework or failed devices on patients who cannot readily return for care. Different populations may experience unequal access even when technical performance is equivalent. These are proposed evaluation dimensions; evidence on distributional outcomes must be gathered rather than inferred from the technical promise of patient-specific production.

Critical evidence synthesis: Governance evidence: consent, provenance and accountable decision gates: For patient-specific photopolymer devices, consent to a clinical procedure should not be presumed to cover secondary reuse of image data or new manufacturing research. The governance record should identify the purpose for which data were collected, the authorised design iterations, access permissions, and whether changes to the intended use require renewed oversight. Clinical decision responsibility, software design responsibility and manufacturing release authority may reside with different institutions; a defensible workflow makes these boundaries explicit before a case reaches production.

Equity cannot be established by a general commitment to access. Relevant measures include excluded patient groups, imaging quality constraints, geographic availability, reimbursement barriers and the resources required for rework. Biofabrication experiments and patient-specific devices must be evaluated as distinct evidence streams because an in-vitro tissue result does not establish clinical device performance. Ethical review should be joined to technical release gates, with recorded decisions on data quality, consent, material qualification and clinical benefit-versus-risk.

Consent and evidentiary provenance in individualized clinical workflows: Consent to a procedure, consent to use imaging information for design and consent to secondary research are separable decisions. The clinical record should identify the intended use of the anatomical information, the responsible design reviewer and the point at which changes to the plan require renewed authorization. A signed general consent does not demonstrate that an unanticipated manufacturing deviation was communicated.

An equity analysis should assess who is excluded by scan availability, image quality, specialized imaging cost, local manufacturing capacity and follow-up infrastructure. The review cannot infer equitable access from technical feasibility. Evidence registers should record denominator populations and missingness, rather than report successful fabrication cases alone.

The governance decision needs traceability from source imaging through segmentation, design approval, production release and device-specific acceptance. For biofabricated experimental constructs, biological claims require independent endpoints and model relevance. Geometric conformity is not a substitute for functional or clinical validation.

13. Evidence limitations

This review is constrained by source depth and directness. The five active anchors are used from bibliographic records and publisher abstracts; none is treated as a full-text source. The patient-specific clinical-device limb rests on [4] only, while the biofabrication ethics limb rests on [1-3,5]. Nothing normative, quantitative or study-level is inferred beyond those boundaries.

No active anchor demonstrates a photopolymer-specific ethical effect. The article therefore does not claim unique consent, equity, evidence or accountability consequences caused by photopolymer chemistry. It also does not define legal duties, allocate liability, establish universal governance requirements, quantify disparities or performance, or assert that whole-organ bioprinting is clinically established.

Operational ethics and auditable decision points: Ethical oversight becomes testable only when decision rights are assigned. For an individualized device, a design change may originate in imaging, segmentation, clinical planning, manufacturing or use; the approving role and required evidence should be recorded at each transition. Consent to clinical intervention, handling of patient data and secondary research are distinct decisions. Treating one consent form as sufficient for all purposes risks concealing the actual data flow and the opportunities to withdraw participation.

Equity assessment should examine whether access to scanning, digital planning, qualified manufacturing and follow-up varies across patient groups or care settings. Reporting only technically successful cases can hide exclusions and unsuccessful workflows. Prospective evaluations should therefore document eligibility, non-enrolment, manufacturing cancellations and clinically meaningful outcomes. The governance framework can make these omissions visible, but it does not itself establish the safety or performance of an individual device.

14. Conclusions

Ethical governance of patient-specific and biofabricated photopolymer devices is best approached by preserving both the relevance and the limits of the available evidence. The current source base supports a clinical-device context for patient-specific additive manufacturing and a separate ethics literature for personalized scaffolds and biofabrication. It does not justify merging those streams or attributing ethical effects to photopolymer chemistry itself.

Within that boundary, consent, equity, evidence and accountability can be kept visible as governance questions throughout development, translation and use. The value of the framework is not that it dictates a universal answer, but that it prevents technical feasibility, personalization or innovation from silently substituting for explicit ethical reasoning and traceable decision context.

References

1. van Daal M, de Kanter A-FJ, Bredenoord AL, de Graeff N. Personalized 3D printed scaffolds: The ethical aspects. *New Biotechnology*. 2023;78:116-122. doi:10.1016/j.nbt.2023.10.006.
2. Otto IA, Breugem CC, Malda J, Bredenoord AL. Ethical considerations in the translation of regenerative biofabrication technologies into clinic and society. *Biofabrication*. 2016;8(4):042001. doi:10.1088/1758-5090/8/4/042001.
3. Vermeulen N, Haddow G, Seymour T, Faulkner-Jones A, Shu W. 3D bioprint me: a socioethical view of bioprinting human organs and tissues. *Journal of Medical Ethics*. 2017;43(9):618-624. doi:10.1136/medethics-2015-103347.
4. Kermavnar T, Shannon A, O'Sullivan KJ, McCarthy C, Dunne CP, O'Sullivan LW. Three-Dimensional Printing of Medical Devices Used Directly to Treat Patients: A Systematic Review. *3D Printing and Additive Manufacturing*. 2021;8(6):366-408. doi:10.1089/3dp.2020.0324.
5. Kirillova A, Bushev S, Abubakirov A, Sukikh G. Bioethical and Legal Issues in 3D Bioprinting. *International Journal of Bioprinting*. 2020;6(3):272. doi:10.18063/ijb.v6i3.272.

Competing interests

The author is Founder, CEO and CTO of 3Dresyns by Resyner Technologies S.L. The company develops and supplies photoresins and related process materials. No proprietary formulation, manufacturing sequence, process window or comparative product recommendation is disclosed.

Data availability

No new experimental dataset was generated for this review. The five cited articles are identified by DOI.

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