

Perspective

FORETHICS: From Principles to Operational Decisions in Forensic Research

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Abstract

Forensic research may involve living persons, deceased persons, human tissues, genetic data, records and images, judicial exhibits, animals, and artificial-intelligence systems. Although existing ethical instruments establish essential principles, they provide limited operational guidance for determining what must be authorised, protected, and documented before a specific study begins. FORETHICS was developed through a normative functional analysis of internationally recognised ethical instruments and selected forensic literature. Requirements were organised according to the governance function performed and examined across object-specific research scenarios. The resulting framework translates general principles into a common decision grammar comprising five foundational components, seven independent ethical axes, eight object-specific modules, cross-cutting modifiers, fifteen Hard Stops, a ten-gate decision pathway, and ten study-specific Decision Cards. Its Core Rule requires every project to establish who lawfully controls access for the proposed use, why the research is scientifically necessary, which safeguards are required, and what minimum documentation demonstrates decision readiness. The ethical object assessed is therefore the proposed research use rather than the specimen, record, or dataset in isolation. FORETHICS does not replace national law, ethical review, judicial authority, data-protection assessment, or animal-welfare oversight. It provides a candidate architecture for making forensic research governance more explicit, traceable, and comparable across jurisdictions while preserving locally lawful pathways. The framework has undergone internal scenario-based examination but has not yet been externally or empirically validated. Multidisciplinary consensus, inter-rater testing, cross-jurisdictional evaluation, and prospective usability studies are therefore required before implementation as an international decision-support standard.

Keywords: forensic research ethics; decision algorithm; research governance; genetic data; 3Rs; animal research; Lawful Control and Purpose Principle; Genomic Specificity; Minimum Ethical Impact



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1. Introduction

Forensic medicine occupies a unique position at the intersection of science, law, and public interest. Its practitioners contribute to truth-finding, accountability, prevention of harm, human-rights protection, and access to justice [1,2]. Ethical governance must therefore account for a dual responsibility: respect for persons, the dead, relatives, animals, and data subjects; and responsibility towards society when reliable knowledge is needed to investigate death, violence, neglect, abuse, or wrongful accusation. Conventional

research-ethics models were developed primarily around living participants, consent-based enrolment, and clinically framed risk-benefit assessment [3–6]. Forensic research introduces materially different challenges, including deceased persons who cannot consent, judicial evidence that must remain available, non-therapeutic public interests, contested authority, and implications for relatives extending beyond the individual [7–9]. Consequently, a framework centred on the therapeutic doctor-patient relationship cannot be transferred automatically to medico-legal research. Recent editorial guidance and empirical studies have documented uncertainty and inconsistent ethical reporting in forensic publications [10–12]. The next step is an operational model that distinguishes research types, recognises jurisdictional diversity, and defines what must be addressed before a specific project may begin [13]. Building on prior analysis of secondary research using genetic data acquired for criminal investigation purposes [11], the present framework translates these requirements into a comprehensive operational system. The practical problem is decision uncertainty. Researchers may not know which determinations to request; institutions may be uncertain whether ethics referral is necessary; custodians and judicial authorities may address access or evidentiary integrity without evaluating all relevant ethical functions; and editors may be unable to compare different authorisation pathways across jurisdictions. Existing instruments establish principles such as autonomy, dignity, justice, and proportionality, but rarely identify the actors, safeguards, and documentary outputs required to determine when a project is ready to begin [14]. This study therefore aimed to develop a structured, object-sensitive, and jurisdiction-adaptable ethical decision framework for forensic research and to define a pathway for its subsequent multidisciplinary and international validation. FORETHICS is intended primarily for forensic researchers and research teams as a pre-study decision-support framework to identify applicable governance pathways, required safeguards, documentation, and unresolved issues before research begins; it may also support structured review by ethics bodies and forensic institutions. It is not a software application, automated approval system, or substitute for the determinations of competent ethical, legal, judicial, custodial, data-protection, or animal-welfare authorities.

What FORETHICS Is and Is Not

FORETHICS is a framework and, more specifically, a decision grammar. It structures questions, actors, safeguards, and documentary outputs so that different jurisdictions can articulate and compare the protections applied to a proposed research use. FORETHICS does not replace national law, confer authorisation, override judicial authority, or substitute for ethics committees, custodians, prosecutors, coroners, animal-welfare bodies, or data controllers. It classifies the decision pathway; competent bodies make the formal determinations required within the applicable jurisdiction.

The ethical object of FORETHICS is the proposed research use, not the specimen itself. The same tissue, profile, image, record, trace, or carcass may be acceptable for one purpose and unacceptable for another. Different actors may fulfil distinct governance functions, but functional equivalence exists only when all ethically relevant functions are covered. The framework therefore does not prescribe who must authorise research in every jurisdiction; it specifies what must be authorised, protected, and documented.

2. The Fragmented Landscape of Ethical Guidance

Ethical guidance relevant to forensic research is distributed across human-subjects ethics, forensic professional conduct, data governance, publication ethics, and animal-research regulation, without supplying a unified operational pathway (Figure 1) [3–6,15–37].

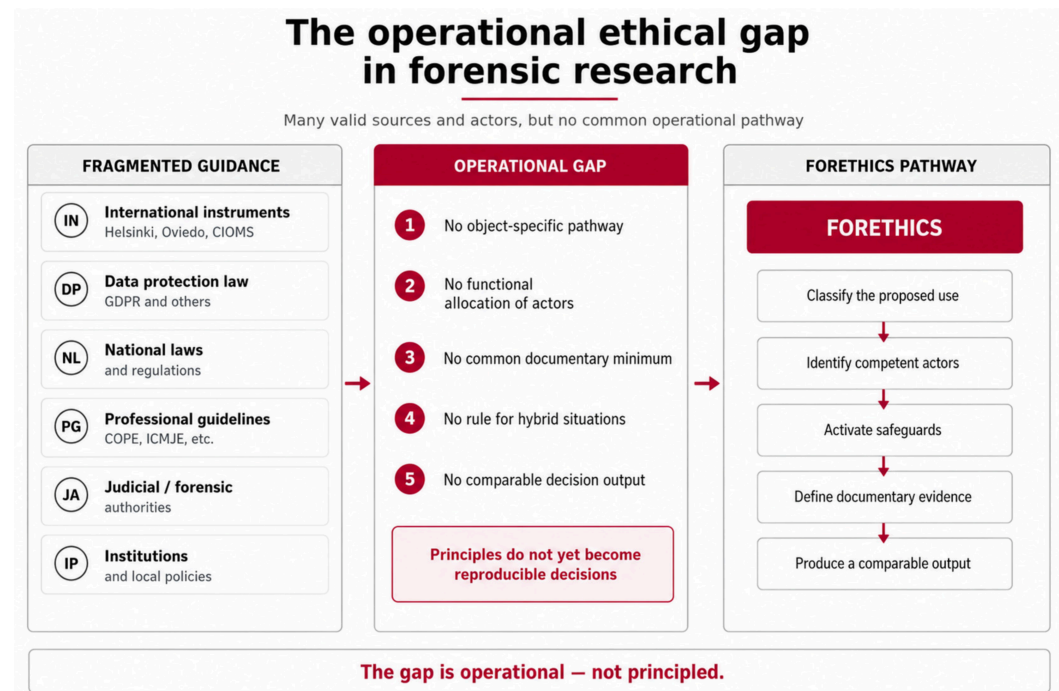


Figure 1. The operational ethical gap in forensic research. Existing forensic research is governed by numerous international instruments, legal frameworks, professional guidelines and institutional policies. Although these sources provide important ethical principles, they do not constitute a unified operational decision pathway. FORETHICS addresses this gap by transforming fragmented normative guidance into a structured sequence of operational decisions capable of producing consistent and comparable ethical outputs across different study types and jurisdictions.

2.1. Human-Subjects Research Ethics

The Nuremberg Code [3], Belmont Report [4], Declaration of Helsinki [5], and CIOMS guidelines [6] establish voluntary consent, favourable risk-benefit balance, independent review, scientific necessity, and protection of vulnerable persons. Their ethical substance remains indispensable, but their primary object is the living research participant. They provide limited operational direction for research involving cadaveric material, judicial evidence, or post-mortem genetic and genomic data [7,14,18,19].

2.2. Forensic-Specific Ethical Guidance

Professional codes and forensic ethics literature emphasize impartiality, competence, credibility, professional conduct, and the distinctive public function of forensic science [1,2,38–59]. Literature on forensic patients, autopsy biobanks, cadaveric material, and case publication identifies additional vulnerabilities, dignity interests, cultural sensitivities, and custodial complexities [7–10,14,18,19,27,50]. These sources guide forensic practice and professional conduct, but do not yet provide a common research-decision architecture.

2.3. Research Integrity and Publication Ethics

The Singapore and Montreal Statements, ALLEA Code, COPE guidance, and ICMJE recommendations address honesty, accountability, collaboration, authorship, conflicts, and transparent reporting [28–33]. They generally assume that the appropriate authorization pathway has already been identified.

2.4. Data Governance and Genomic Oversight

The Oviedo Convention, UNESCO bioethics instruments, GDPR, and the European Health Data Space emphasize privacy, proportionality, confidentiality, and controlled sec-

ondary use [21–24,46]. Forensic-specific contributions include global DNA-database analysis, digital-readiness governance, and regional bioethics frameworks [25–27]. Genetic data add persistent identifiability, familial implications, function creep, and database-linkage risks that cannot be managed by ordinary de-identification alone. For AI-enabled research, these data-governance requirements increasingly intersect with specific AI-governance obligations concerning intended use, risk management, transparency, human oversight, accountability, and protection against discriminatory or otherwise rights-infringing outcomes, as reflected, *inter alia*, in Regulation (EU) 2024/1689 (EU Artificial Intelligence Act) and the Council of Europe Framework Convention on Artificial Intelligence and Human Rights, Democracy and the Rule of Law (2024) [60–65].

2.5. Animal Research Ethics

The 3Rs, Directive 2010/63/EU, and NC3Rs guidance establish requirements for replacement, reduction, refinement, and appropriate welfare oversight, whereas ARRIVE 2.0 provides standards for transparent reporting of animal research [34–37]. Forensic animal research adds a contested benefit category: knowledge serving justice rather than therapy. Existing forensic analyses demonstrate both the methodological value and the ethical limitations of animal models, as well as the importance of realistic experimental design and cross-jurisdictional welfare standards [38–43].

2.6. The Unresolved Gap

The unresolved gap is operational. Current guidance does not consistently distinguish research types, identify the competent actor for each ethical function, define hybrid pathways, state minimum documents, or generate comparable outputs. FORETHICS addresses this gap by mapping irreducible ethical functions rather than cataloguing jurisdiction-specific forms.

3. Development of the FORETHICS Framework

FORETHICS was developed through a normative functional analysis and framework-development process, rather than as a systematic or scoping review. Its purpose was to identify the substantive ethical and governance functions that a defensible forensic research pathway must perform. The framework organises safeguards and documentary requirements; it does not harmonise national law or replace jurisdiction-specific determinations.

3.1. Source Selection and Functional Extraction

Core international instruments and selected forensic-specific literature were examined across six domains: human-subject research ethics; human rights and dignity; research integrity and publication ethics; data and genomic governance; evidentiary and material stewardship; and animal research ethics. Sources were selected purposively according to their normative relevance, international recognition, or direct forensic applicability. A systematic review was not undertaken because the objective was not to estimate the prevalence of particular ethical positions or to exhaustively catalogue the literature, but to identify and functionally organise normative and governance requirements relevant to forensic research. The source set was expanded iteratively when additional documents identified, clarified, or challenged a function relevant to the provisional architecture. Sources that did not contribute a distinct ethical or governance requirement were not retained in the functional mapping. For each source, the authors identified the protected interest, research object, competent actor, applicable requirement, required safeguard, documentary output, and any condition potentially incompatible with ethically defensible research. Requirements were organised according to the function they performed rather than their originating document. Overlapping requirements were consolidated when they addressed the same protected

interest and governance function; requirements were retained separately when their fulfilment depended on different actors, safeguards, or documentary evidence. The seven axes were therefore not selected from a predetermined set of candidate domains. Rather, they emerged from the functional decomposition of the normative and governance requirements identified during framework development. A function was retained as a separate axis when its fulfilment protected a distinct interest, required action by a distinct competent actor, or generated documentary evidence that could not be substituted by fulfilment of another function. Conversely, requirements were consolidated when they addressed the same governance determination without adding an independent protected interest, competent actor, safeguard, or documentary output. No formal thematic-saturation threshold or candidate-axis elimination procedure was used; iterative source expansion and functional refinement continued until the author group judged that additional requirements either mapped to an existing governance function or identified a function requiring separate treatment. The analysis and preliminary mapping were iteratively reviewed by the author group. Interpretive differences concerning the allocation, overlap, or independence of governance functions were discussed collectively and resolved by informal author consensus. No predefined number of consensus rounds, formal voting or Delphi procedure, or prospective disagreement log was used. The architecture was iteratively revised until the author group agreed that each retained function addressed a distinct governance question and that further consolidation would leave a non-substitutable governance requirement unresolved. Accordingly, this process should be understood as an author-led iterative framework-development process rather than a formal consensus exercise. No external stakeholders or advisors were consulted during this developmental phase. External multidisciplinary stakeholder evaluation therefore remains a subsequent stage of validation and refinement, together with inter-rater, cross-jurisdictional, and prospective testing as outlined in the Validation Roadmap.

The number of axes was therefore an outcome of this functional decomposition rather than an a priori design constraint. This process generated seven non-substitutable decision functions: independent review, lawful authority, consent or representation, data governance, material and evidentiary safeguards, animal welfare, and scientific quality. Their functional derivation and the basis for retaining each as an independent governance dimension are detailed in the Supplementary Source-to-Function Mapping and Table S1.

3.2. Module Development and Scenario Exploration

Research objects were grouped according to whether they generated materially different ethical obligations, producing eight object-specific modules. Cross-cutting characteristics that could modify the required level of protection without defining a different research object were treated as modifiers. Conditions that would prevent a project from proceeding unless clarified, remediated, or resolved through fundamental redesign were classified as potential Hard Stop triggers; a confirmed and unresolved Hard Stop results in a Red outcome. The provisional architecture was examined using ten representative scenarios corresponding to the principal study types addressed by the Decision Cards: case reports, retrospective observational studies, prospective observational studies, interventional studies, human-tissue research, genetic research, records and images research, forensic traces and exhibits research, animal research, and AI or computational studies. For each study type, the developing framework was examined across a common set of operational dimensions: applicable modules, key ethical questions, potential Hard Stops, minimum required documentation, cross-cutting modifiers, and resulting decision pathway. These dimensions are now explicitly represented in the corresponding Decision Cards included in the Supplementary Operational Manual. The scenarios were used formatively to

identify ambiguities, overlaps, missing safeguards, inconsistent module activation, unclear escalation through modifiers, and gaps in documentary requirements, with the framework and Decision Cards refined iteratively in response. No predefined scoring instrument or formal assessment grid was used prospectively, and no quantitative performance criteria were applied. The exercise was conducted by the author group as part of framework development; it did not constitute formal validation, inter-rater reliability testing, or external stakeholder evaluation. Accordingly, the ten scenarios should be understood as developmental stress tests rather than validation cases. Formal inter-rater, cross-jurisdictional, external multidisciplinary, and prospective validation are reserved for subsequent phases of the FORETHICS validation roadmap. The formative scenario exploration and the resulting framework refinements are summarized in Supplementary Table S2. A complementary study-type operational summary is provided in Supplementary Table S3.

3.3. Qualitative Risk Assessment

Risk assessment within FORETHICS is qualitative and context-sensitive rather than based on a numerical risk score. Where a potential ethical or governance risk is identified, its relevance is considered in relation to four complementary dimensions: the likelihood of the adverse consequence, its severity, its reversibility or remediability, and the persons, groups, institutions, or legal interests potentially affected. These dimensions are used to determine whether additional safeguards, documentation, or remediation are required and whether a cross-cutting modifier or potential Hard Stop should be activated. Risk assessment does not constitute an additional FORETHICS axis and does not generate an additive or weighted score. Rather, it informs proportionality judgments across the applicable R–A–C–D–M–W–Q axes. A low-probability event may therefore remain ethically significant when its consequences are severe or irreversible, while a more probable but readily reversible consequence may require a different safeguard pathway. Similarly, risks affecting vulnerable individuals, third parties, judicial proceedings, evidentiary integrity, or fundamental rights may require enhanced protection even when the underlying research procedure is otherwise low burden. The resulting judgment remains qualitative: identified risks are linked to the relevant governance function, applicable modifier, required safeguard, documentary evidence, and, where appropriate, Hard Stop screening. FORETHICS therefore uses risk analysis to structure ethical deliberation and remediation rather than to calculate a global risk value or mechanically determine ethical acceptability.

4. The FORETHICS Thesis: A Common Decision Grammar

The central thesis of FORETHICS is that forensic research ethics requires a common decision grammar—a set of substantive safeguards that can be implemented through locally lawful pathways. This grammar is intended to be transferable across jurisdictions, but not uniform in the sense of imposing identical authorization procedures.

Throughout FORETHICS, an axis denotes one of the seven non-substitutable governance questions that must be addressed independently; a module denotes a set of object-specific safeguards activated by the persons, materials, data, evidence, animals, or technologies involved; a modifier is a cross-cutting contextual feature that may alter the level or type of protection required without constituting a separate research object; a Hard Stop is a condition that prevents progression unless clarified, remediated, or resolved through fundamental redesign; a Decision Card is a study-type-specific operational guide for applying the framework; and an outcome (Green, Amber, or Red) summarises decision readiness after the applicable axes, modules, modifiers, and Hard Stops have been considered. The complete operational sequence of FORETHICS is summarized in the Master Workflow (Figure S1, Supplementary Operational Manual), which provides

the primary operational map for applying the framework from study classification and module activation through axis assessment, Hard Stop screening, modifiers, remediation, decision outcome, and final documentation. The components described below correspond to successive elements of this workflow.

4.1. The FORETHICS Core Rule

Every forensic research project should be capable of explaining, before it begins, who lawfully controls access to the relevant persons, materials, data, evidence, or systems for the proposed use, why the research is scientifically necessary, what safeguards are required, and which minimum documentary evidence demonstrates ethical compliance (Figure 2).

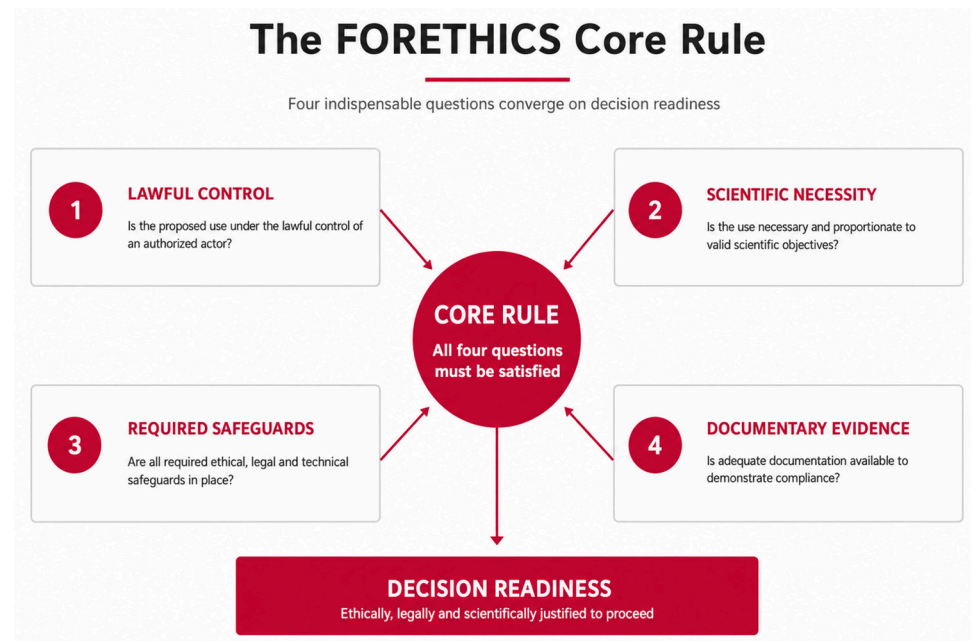


Figure 2. The FORETHICS Core Rule. Every proposed forensic research activity is evaluated through four indispensable questions concerning lawful control, scientific necessity, required safeguards and documentary evidence. Ethical decision readiness is achieved only when all four questions are satisfactorily answered. None of the four domains can compensate for deficiencies in another.

4.2. Five Foundational Components

The Core Rule is operationalized through five foundational components. Each produces a specific output.

The Lawful Control and Purpose Principle. The relevant question is not whether one universal form of authorization exists, but who holds lawful authority over the material, data, body, evidence, animal source, or dataset for the specific proposed use. Physical possession, custody, technical access, and authority over the specific use do not necessarily coincide. This principle produces the Authority axis and resolves the false choice between family, prosecutor, custodian, and committee models: each actor may cover a different function.

The Principle of Genomic Specificity. Genetic and biometric data must be generated, retained, linked, and shared only to the extent necessary for declared scientific objectives [23–25,46]. The principle addresses persistent identifiability, familial implications, re-identification, unauthorized linkage, incidental findings, and function creep [23,25,44–46]. It requires purpose limitation, linkage limits, familial-implications assessment, retention and deletion policies, management of incidental findings, and prohibition of unauthorized secondary use. It triggers the genetic/biometric data module and the highest data-governance level.

The Sensitive Data Trigger. Genetic, biometric, identifiable-image, geolocation, high-dimensional, and linked judicial data trigger proportionate escalation according to persistence, linkability, consequences of disclosure, and reversibility of harm [23–26,46]. The trigger determines when additional review or enhanced data safeguards must be considered.

The 3Rs as an Operational Algorithm. Before dedicated animal experimentation, investigators must ask sequentially whether the question can be answered without animals, with validated alternatives, with existing biological material, or with animals already destined for an independent lawful purpose [34,35,37–39,43]. Dedicated live-animal use proceeds only when these alternatives are inadequate and independent welfare authorization is obtained [34,35,37,38].

The Principle of Minimum Ethical Impact. Research should proceed through the least burdensome pathway compatible with a scientifically valid and reliable result. Existing data are preferred to new collection, archival material to additional sampling, non-destructive to destructive analysis, and opportunistic animal sources to dedicated experimentation.

Public interest or justice-related value may contribute to expected benefit, but cannot independently override dignity, proportionality, scientific validity, animal welfare, evidentiary integrity, or non-derogable rights.

5. The FORETHICS Architecture: A Functional Analysis

The architecture of FORETHICS was derived through the functional analysis of distinct governance requirements described in Section 3. Its components represent functions that cannot be collapsed without obscuring relevant actors, safeguards, or documentary requirements (Figure 3).

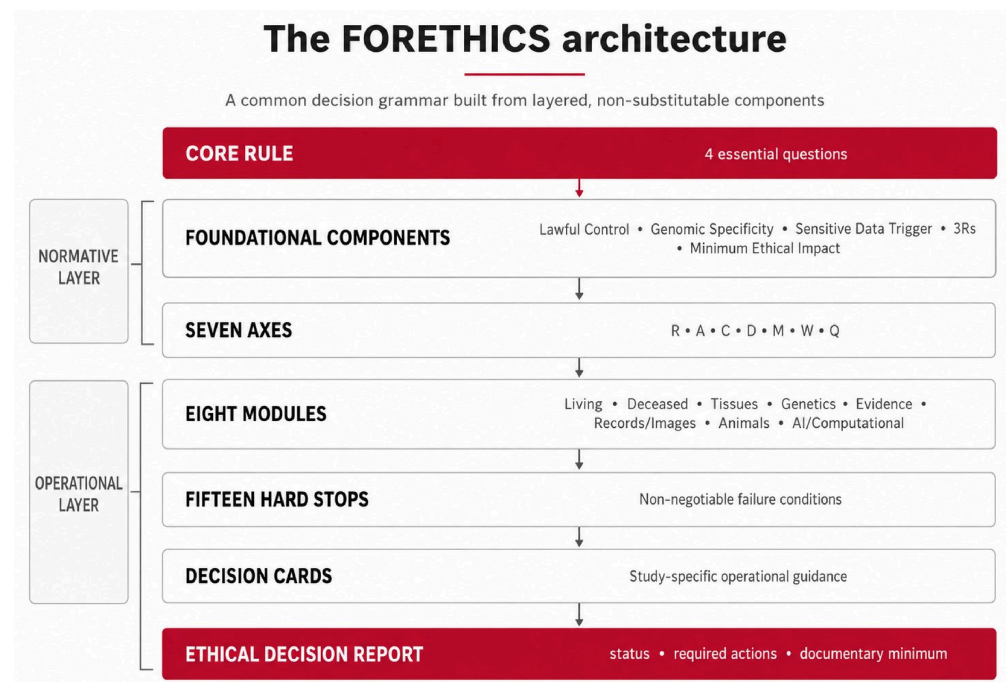


Figure 3. Overall architecture of the FORETHICS framework. The framework is organized as a hierarchical decision architecture in which the Core Rule is operationalized through five foundational components, seven independent ethical axes, eight object-specific modules, fifteen Hard-Stop conditions, study-specific Decision Cards and a standardized Ethical Decision Report.

5.1. Why Seven Axes?

No single actor can answer every ethical question arising in forensic research. Legal authority, ethical review, consent, data governance, material governance, animal welfare,

and scientific validity represent independent functions. As described in Section 3.1 and detailed in Supplementary Table S1, the seven-axis architecture was not imposed a priori but resulted from the functional decomposition of the normative and governance requirements considered during framework development. Because these functions cannot be collapsed into one another without losing essential protections, FORETHICS represents them as seven parallel and non-substitutable decision axes. These seven axes were retained because each answers a distinct governance question and may involve a different competent actor or require distinct documentary evidence. Ethical review asks whether a proposed use is ethically defensible; authority asks who may lawfully permit that use; consent addresses the individual or representative basis for participation or secondary use; data governance addresses informational risks; material governance protects physical scarcity and evidentiary integrity; welfare governs animal involvement; and quality determines whether the proposed exposure, consumption, or harm can generate valid knowledge. Collapsing any two axes would obscure a function that may remain unsatisfied even when the other is adequately addressed. The number seven is therefore descriptive of the resulting functional architecture rather than an a priori design constraint: within the present normative analysis, seven governance functions could not be further consolidated without leaving an independently relevant question unresolved.

Research integrity and publication ethics were not represented as additional axes because they operate as cross-cutting obligations governing the conduct, documentation, and dissemination of research rather than as separate governance determinations parallel to R–A–C–D–M–W–Q. Their exclusion as independent axes does not remove them from FORETHICS. Where failures of integrity or publication practice compromise ethical defensibility—for example, through falsified provenance or authorization, concealed conflicts of interest, or unauthorized identifiable disclosure—they are captured by the relevant axis and/or by dedicated Hard Stop conditions.

The profile is conjunctive, not compensatory. Compliance on one axis cannot offset a deficiency on another. High scientific quality cannot compensate for the absence or inadequacy of lawful authority; strong public interest cannot compensate for the absence of lawful authority; good data governance cannot remedy invalid consent. FORETHICS structures deliberation but does not automate it. Assignment of an ordinal profile requires context-sensitive qualitative judgment, and the same profile may require different locally lawful pathways in different jurisdictions (Tables 1 and 2).

Table 1. The seven ethical axes.

Axis	Function	Why Independent
R (Review)	Research ethics review	Ethical review ≠ legal authority
A (Authority)	Lawful control and purpose	Who controls ≠ who reviews
C (Consent)	Consent/representation	Consent ≠ custodial control
D (Data)	Data privacy governance	Privacy ≠ material governance
M (Material)	Material/evidentiary safeguards	Material ≠ data
W (Welfare)	Animal welfare	3Rs ≠ human-subjects protections
Q (Quality)	Scientific/technical quality	Science ≠ ethics

An output may therefore read: R3–A3–C4–D4–M3–W0–Q3, Amber. Each code identifies the applicable safeguard pathway on one independent axis. The ordinal codes are descriptive classifiers rather than additive scores and do not form a global severity score. They must not be summed, averaged, weighted, or interpreted as an automated measure of ethical acceptability. Their purpose is to make the applicable safeguard pathway explicit and to support, rather than replace, structured qualitative judgment by competent

decision-makers. Complete coding definitions and assignment rules are provided in the Supplementary Operational Manual.

Table 2. Ordinal codes used in the FORETHICS profile (summary).

Axis	Range	Meaning
R	R0–R3	Increasing level of independent review
A	A0–A4	Increasing complexity of lawful authority
C	C0–C5	Consent, representation, waiver or unavailability
D	D0–D4	Increasing informational sensitivity
M	M0–M4	Increasing material scarcity or evidentiary relevance
W	W0–W4	Increasing animal involvement and welfare burden
Q	Q0–Q4	Validation status and scientific adequacy

5.2. Why Eight Modules?

Forensic research objects differ fundamentally in their ethical implications. A living person can consent, whereas a deceased person cannot but may retain dignity-related, cultural, and relational interests [3–8,18,19]. Human tissues may be scarce or possess evidentiary value, while genetic profiles generate persistent, familial, and database-linkage risks [7,14,23–25,44–46]. These differences require distinct safeguards rather than a single template. The eight modules reflect ethically material differences among research objects rather than disciplinary convenience. Living persons can exercise autonomy; deceased persons cannot, but may retain dignity-related, cultural, and relational interests. Human tissues introduce scarcity and custodial concerns, whereas genetic and biometric data create persistent and familial informational risks. Traces and exhibits require evidentiary preservation; records, images, and narratives create publication and third-party risks; animal involvement requires species-specific welfare assessment; and AI systems introduce dataset, validation, bias, and deployment concerns. These differences justify separate modules, although more than one module may be activated within the same project (Table 3).

5.3. Cross-Cutting Modifiers

Cross-cutting modifiers are required because ethically significant characteristics do not always define a separate research object. Vulnerability, identifiability, destructive use, active proceedings, international transfer, commercial involvement, deployment, cultural, jurisdictional, or infrastructural context, and role conflict may alter the safeguards required within any module. Treating them as modifiers avoids unnecessary multiplication of modules while preserving proportionate escalation. Modifiers include prospective interaction, additional procedures beyond routine practice, vulnerability, identifiability, genetic or biometric analysis, database linkage, destructive testing, scarcity, active proceedings, international transfer, commercial use, AI deployment, publication of images, cultural, jurisdictional, or infrastructural context, and role conflict. This contextual modifier applies where local legal or institutional arrangements, community or culturally specific governance structures, humanitarian or post-conflict conditions, or resource and infrastructure constraints materially affect the availability, identity, or operation of competent authorities, safeguards, or documentary pathways. Its activation requires the relevant FORETHICS requirements to be interpreted and documented through contextually appropriate and locally legitimate pathways rather than assuming the availability of a particular institutional model. Role conflict is coded as RC0 (none), RC1 (manageable), RC2 (independent separation required), or RC3 (irresolvable; Red). In AI-based studies, the required level of scrutiny depends on the intended purpose, affected parties, deployment context, and potential consequences of error. Particular attention should be given to data provenance,

validation and robustness, bias and non-discrimination, transparency and traceability, privacy and security, meaningful human oversight, and the possibility that an AI system may fall within a regulated high-risk category under applicable law, including Regulation (EU) 2024/1689 (EU Artificial Intelligence Act), while the Council of Europe Framework Convention on Artificial Intelligence and Human Rights, Democracy and the Rule of Law (2024) provides a complementary human-rights, democracy, and rule-of-law framework for AI governance [47,60–62]. Where an AI system falls within a high-risk category under applicable regulation, FORETHICS does not replace the corresponding legal classification or conformity and governance obligations; rather, it identifies the ethical and documentary functions that must be addressed alongside them.

Table 3. The eight FORETHICS modules.

Module	Primary Concern	Characteristic Safeguards
Living persons	Autonomy, consent, coercion	Independent recruitment, voluntariness, withdrawal, incidental findings
Deceased persons	Dignity, lawful custody, relatives' interests	Authority mapping, cultural assessment, additional-procedure control
Human tissues and biological materials	Custody, secondary use, scarcity	Consumption log, preservation, transfer and biobank governance
Genetic and genomic material	Familial and persistent identifiability	Purpose limitation, linkage control, familial-risk and retention policy
Forensic traces and judicial exhibits	Evidentiary integrity	Chain of custody, non-interference, counter-analysis preservation
Records, data and images	Confidentiality, publication risk	Identifiability assessment, minimization, third-party protection
Animals	Welfare, killing, 3Rs	Source attribution, alternatives sequence, welfare and veterinary review
Artificial intelligence and computational systems	Intended use, data provenance, bias, validation, transparency, human oversight, and high-impact deployment	Dataset provenance and governance; intended-use specification; validation and robustness assessment; bias/non-discrimination assessment; traceability and documentation; human oversight; risk and impact assessment where applicable

5.4. Why Fifteen Hard Stops?

A potential Hard Stop trigger is a condition requiring clarification or remediation and results in an Amber outcome while feasible corrective action remains pending. A confirmed Hard Stop that remains unresolved or cannot be remediated results in a Red outcome regardless of other approvals. The current framework identifies fifteen overarching Hard Stop categories. Their number and formulation may be refined through external validation (Table 4). Operational manifestations of these Hard Stops and the corresponding remediation requirements are provided in Supplementary Table S4.

Hard Stops concern absence of lawful authority, prohibited or unauthorized use, invalid consent or coercion, unacceptable risk, irremediable evidentiary interference, grossly inadequate data protection, unjustified animal use, and scientific invalidity incapable of supporting the proposed exposure or resource use.

Table 4. The fifteen FORETHICS Hard Stops: conditions precluding project progression while unresolved.

Category	Hard Stop
Authority	No lawful basis for access or control of the proposed use (#1)
Consent	Required consent is absent, invalid, coerced, or inseparable from pressure (#2)
Risk	Risk, burden, intrusion, or harm is disproportionate to expected value (#3)
Science	Design or method is incapable of supporting the proposed use (Q4) (#4)
Evidence	Material required for justice, identification, appeal, or counter-analysis would be consumed or compromised (#5)
Chain of custody	Evidentiary integrity or traceability cannot be maintained (#6)
Alternatives	An equivalent less harmful or less intrusive pathway is available but unused (#7)
Animals	W3/W4 use proceeds without a valid 3Rs analysis and independent welfare authorization (#8)
Genetic/data governance	Genetic, biometric, familial, or linked data are generated without enhanced governance (#9)
Publication	Identifiable material is disclosed without authorization or overriding justified necessity (#10)
Integrity	Source, consent, authorization, provenance, procedures, or conflicts are concealed, falsified, or misrepresented (#11)
Role conflict	The research, clinical, custodial, investigative, or expert roles cannot be ethically separated (#12)
Responsibility	Accountability for decisions, data, material, harm, or publication cannot be assigned (#13)
Law	The proposed use violates a non-derogable local prohibition (#14)
Genomic purpose	Genetic objectives are undefined or permit unauthorized secondary use or function creep (#15)

5.5. Scientific Quality as an Ethical Requirement

Scientific quality is included as an ethical axis because exposure of persons, consumption of scarce material, disclosure of sensitive data, or use of animals cannot be justified by a study incapable of answering its question. Quality requirements must be proportionate to the claims and intended use of the research. Invalid or biased methods may compromise the reliability of forensic evidence and adversely influence judicial decision-making [49,52–54,63–65]. This principle reflects the established position that research lacking sufficient scientific validity cannot ethically justify the risks, burdens, or resources it entails [48].

6. Overview of the Ten-Gate Decision Pathway

The FORETHICS algorithm progresses through ten decision gates. Each gate filters through a specific ethical, legal, or technical lens. The profile is conjunctive: a deficiency on any gate cannot be offset by performance on another. The seven operational steps described in the Supplementary Operational Manual explain how users apply FORETHICS in practice, whereas the ten decision gates define the substantive checks performed during that application. The relationship is functional rather than strictly sequential because individual operational steps may activate more than one gate (Figure 4).

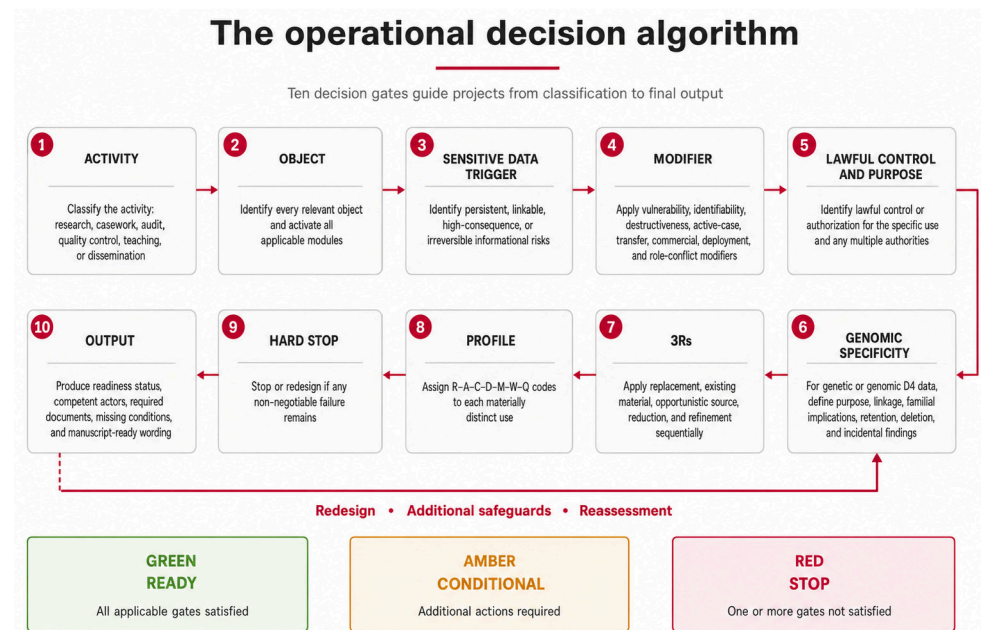


Figure 4. Operational decision algorithm of the FORETHICS framework. The framework guides each proposed forensic research project through ten decision gates addressing activity classification, research objects, sensitive data, cross-cutting modifiers, lawful control and purpose, genomic specificity, the 3Rs, profile assignment, Hard Stop screening, and final reporting. The process is iterative rather than linear: projects that fail one or more mandatory gates require redesign, additional safeguards, or reassessment before an ethically defensible decision can be reached. The final outcome is expressed as a standardized decision status (Green, Amber, or Red). These statuses indicate decision readiness rather than degrees of ethical acceptability or legal or ethical authorization. Green indicates that the applicable FORETHICS requirements are documented and no unresolved Hard Stop remains; Amber identifies requirements that remain incomplete, uncertain, or remediable and require additional conditions, safeguards, documentation, or redesign before reassessment; Red indicates a confirmed and unresolved Hard Stop that prevents progression within the assessed pathway. The operational sequence is summarized here to demonstrate how the architecture translates into a decision pathway. Complete definitions, decision rules, documentary requirements, and study-specific applications are provided in the Supplementary Operational Manual. FORETHICS is operationalized through ten interrelated decision gates. The algorithm may be iterative, particularly where an Amber outcome requires remediation followed by reassessment.

1. Activity gate: classify the proposed activity as research, professional casework, audit, quality control, teaching, or research-related publication/dissemination.
2. Object gate: identify every relevant object and activate all applicable modules.
3. Sensitive Data Trigger: identify persistent, linkable, high-consequence, or irreversible informational risks.
4. Modifier gate: apply vulnerability, identifiability, destructiveness, active-case, transfer, commercial, deployment, cultural/jurisdictional/infrastructural-context, and role-conflict modifiers.
5. Lawful Control and Purpose gate: identify who lawfully controls or authorizes access for the specific proposed use and whether multiple authorities are required.
6. Genomic Specificity gate: where genetic or genomic D4 data are involved, define exact purposes, linkage limits, familial implications, retention, deletion, and incidental findings.
7. 3Rs gate: where animals or animal-derived materials are involved, apply replacement, existing-material, opportunistic-source, reduction, and refinement questions sequentially, distinguishing between opportunistic materials and live-animal use where appropriate.
8. Profile gate: assign R-A-C-D-M-W-Q codes to each materially distinct use.

- 9. Hard-stop gate: identify potential Hard Stop triggers, assign Amber while feasible remediation remains pending, and assign Red when a confirmed Hard Stop remains unresolved.
- 10. Output gate: produce Green (Ready), Amber (Conditional), or Red (Stop), together with competent actors, required documents, missing conditions, and manuscript-ready wording, documented through the Ethical Decision Report (Template S1).

6.1. Unit of Assessment

The primary unit of assessment is the proposed research use. Complex projects containing materially different objects or uses should be decomposed into subprofiles. Subprofiles should be integrated axis by axis using the highest applicable safeguard requirement for each proposed use. This principle is applied in the illustrative case below (Figure 5).

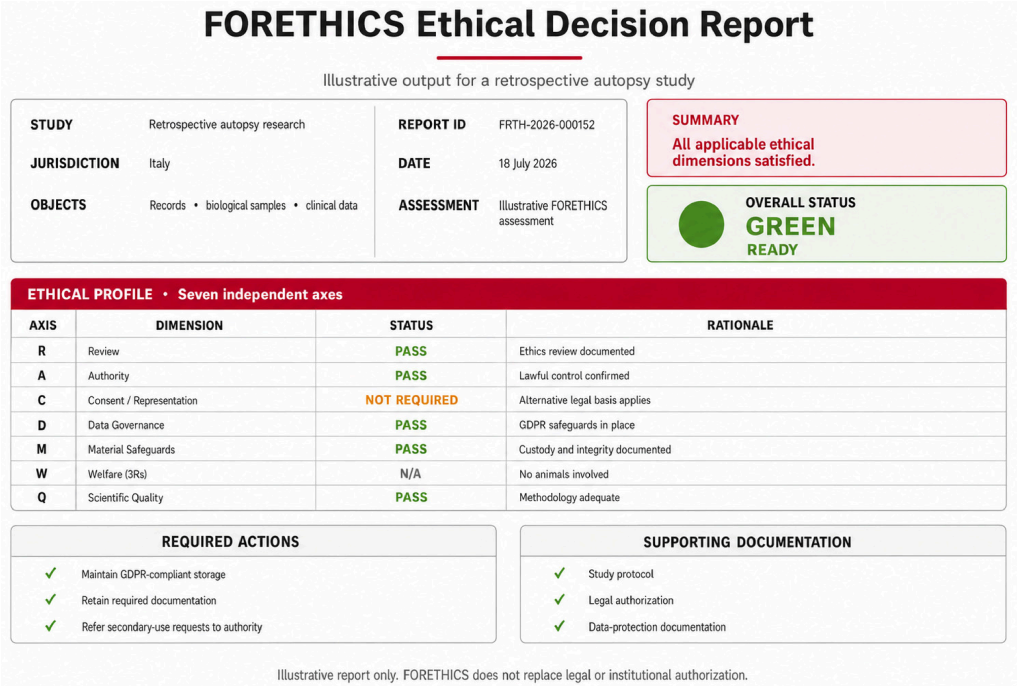


Figure 5. Example of a FORETHICS Ethical Decision Report. Illustrative standardized output generated following completion of the operational assessment. The report summarizes the project’s ethical profile across the seven independent decision axes, documents the overall decision status, identifies any required actions, and specifies the minimum supporting documentation needed to justify the decision. The example is intended solely to demonstrate the structure and function of the reporting system and does not represent a real assessment.

6.2. Decision Cards

Researchers do not think in axes; they think in study types. Decision Cards bridge the gap between the overarching architecture and the specific research context. Each card identifies the applicable modules, key ethical questions, potential Hard Stop triggers, minimum required documentation, cross-cutting modifiers, decision outputs, and a manuscript-ready ethical statement.

Decision Cards do not constitute new modules. They are study-type applications of the modular architecture. A single Decision Card may activate multiple modules simultaneously. Full cards belong in the Supplementary Material so that the main article can explain and justify the architecture without becoming an operational manual.

7. Illustrative Case

The following entirely hypothetical case demonstrates how FORETHICS transforms fragmented ethical and governance questions into a structured decision. It does not represent a real assessment or a universally applicable legal pathway. For illustrative purposes, the scenario assumes that archived autopsy tissue from a closed judicial proceeding remains under judicial control after closure and is proposed for use in a genetic study. The proposed use is first classified as human-tissue and genetic research, activating the deceased-person, human-tissue, and genetic/genomic modules. Relevant cross-cutting modifiers include genomic analysis, material scarcity, and continuing judicial control and potential evidentiary relevance. Qualitative risk assessment identifies persistent and potentially familial informational consequences, possible irreversible loss of scarce material, and potential effects on relatives and evidentiary interests. Hard Stop screening therefore focuses on lawful authority, the applicable consent or waiver pathway, preservation of material required for forensic purposes, genomic-purpose limitation, and adequacy of scientific validation. Under the illustrative assumptions, these issues are potentially remediable but require formal determination and documentation before the project can proceed.

The seven axes are then coded individually. Authority is A3 because judicial control remains applicable. Consent is C4 because a formal waiver or determination of non-applicability is required under the illustrative assumptions. Data are D4 because genomic information is persistent and familial. Material is M3 because the archived tissue is scarce and potentially evidentiary. Review is R3 because the combination of genomic, judicial, and material considerations requires full independent review. Welfare is W0. Quality is Q3 because the proposed method is innovative and requires formal validation.

The resulting profile is R3–A3–C4–D4–M3–W0–Q3, with an Amber outcome while the required determinations, safeguards, and documentation remain pending. The assessment may be changed to Green only after full independent review, a formal waiver or non-applicability determination, judicial authorization, a purpose-specific genomic governance plan, a preservation and consumption plan, a validation protocol, and a policy for incidental or familial findings have been obtained, documented, and verified, with no unresolved Hard Stop remaining (Table 5).

Table 5. FORETHICS profile for the illustrative case.

Axis	Code	Meaning
Review	R3	Full independent review for genomic research on judicial material
Authority	A3	Judicial authority retains lawful control
Consent	C4	Formal waiver or determination of non-applicability required under the illustrative assumptions
Data	D4	Persistent genomic and familial information requires enhanced governance
Material	M3	Scarce archived material with potential evidentiary relevance
Welfare	W0	No animal involvement
Quality	Q3	Innovative method requires full validation

8. Validation Pathway

FORETHICS is proposed for multidisciplinary scrutiny and empirical validation rather than presented as a completed international standard (Figure 6).

Future validation should proceed through eight distinct phases: (1) multidisciplinary expert and stakeholder review, involving, as appropriate, bioethicists, legal scholars, forensic practitioners and scientists, regulators, judicial and prosecutorial authorities, data-protection specialists, and representatives of relevant professional and affected commu-

nities; (2) Delphi consensus; (3) standardized vignette-based testing; (4) inter-rater reliability assessment; (5) cross-jurisdictional testing; (6) prospective usability pilots involving researchers, ethics committees, custodians, and editors; (7) module-specific validation, particularly of the 3Rs algorithm and genetic, biometric, and AI governance; and (8) implementation as a digital decision-support system. Evaluation outcomes should include agreement, usability, completion time, error rates, stakeholder acceptability, transparency, and cross-jurisdictional applicability.

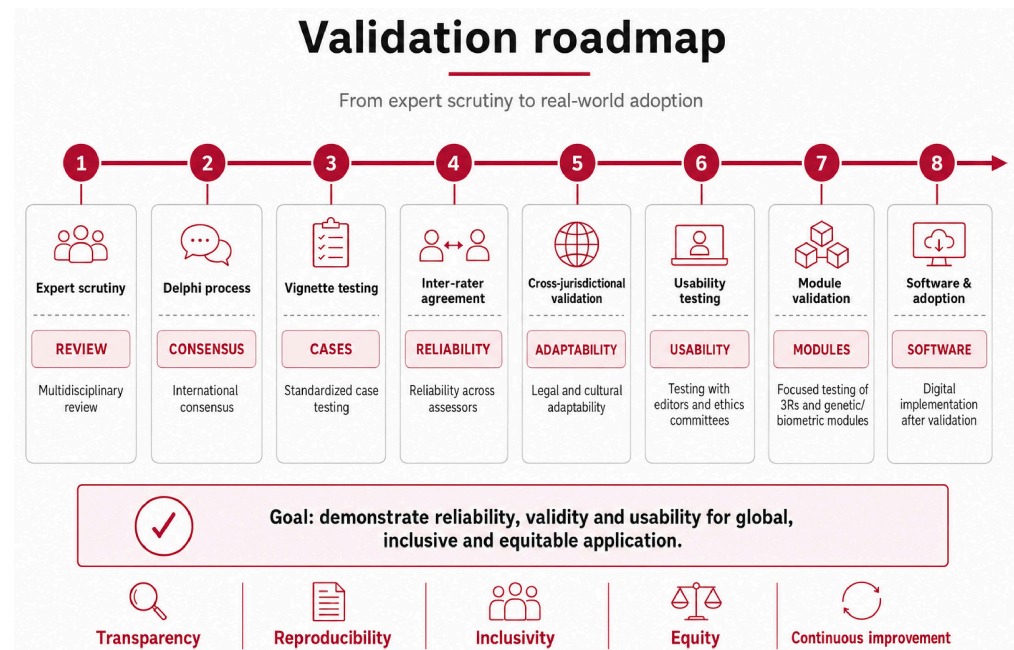


Figure 6. Proposed roadmap for international validation of the FORETHICS framework. FORETHICS is presented as a candidate framework requiring progressive multidisciplinary evaluation rather than as a completed international standard. The proposed validation pathway includes expert scrutiny, Delphi consensus, vignette-based testing, inter-rater agreement studies, cross-jurisdictional evaluation, usability assessment, module-specific validation, and subsequent implementation as a digital decision-support system. The objective is to evaluate inter-rater agreement, usability, completion time, error rates, stakeholder acceptability, transparency, and applicability across diverse legal and forensic settings.

The current version has undergone internal scenario exploration to identify ambiguities, overlaps, and contradictions, but this does not constitute formal validation or demonstrate reproducibility. Inter-rater reliability was not assessed during this developmental phase. Subsequent validation should therefore involve independent assessors applying FORETHICS to standardized cases, with agreement evaluated for axis classification, modifier activation, Hard Stop identification, and final Green/Amber/Red outcomes. Patterns of disagreement should also be examined to identify components requiring clarification or refinement. Because FORETHICS is a normative decision framework, its evaluation should combine quantitative performance measures with qualitative assessment of clarity, proportionality, practical relevance, and stakeholder acceptance. Digital implementation should follow, not precede, normative and empirical validation. Future validation should also establish a transparent governance process for revising modules, coding rules, Hard Stops, and Decision Cards as legal standards, technologies, and ethical expectations evolve.

9. Limitations

FORETHICS has several limitations. Its development was based on a purposive, non-systematic selection of international instruments and forensic-specific literature; rel-

evant sources or alternative normative interpretations may therefore have been omitted. Although the framework was designed for cross-jurisdictional application, the source set and concepts employed may reflect a predominantly European legal and ethical perspective. Accordingly, FORETHICS should not be assumed to represent a culturally or jurisdictionally universal account of research ethics. Its applicability requires contextual interpretation, particularly in Indigenous, humanitarian, post-conflict, and low-resource settings, where institutional structures, competent authorities, community decision-making processes, or available safeguards may differ substantially from those presupposed by the framework. The framework was developed by a European academic forensic-medicine group, and this disciplinary and geographical positioning may have influenced the selection, interpretation, and organisation of governance functions. Framework development relied on iterative informal consensus within the author group; no formal Delphi process, voting procedure, prospective disagreement log, or external stakeholder consultation was undertaken. Regulators, legislators, judicial authorities, prosecutors, data-protection authorities, bar associations, and representatives of affected communities were therefore not directly involved in this developmental phase. Future evaluation should therefore involve bioethicists, legal scholars, geneticists, veterinarians, data-protection specialists, forensic scientists from non-medical disciplines, relevant institutional and regulatory stakeholders, and representatives of the public and affected communities across diverse legal and cultural settings.

The framework has undergone formative internal scenario exploration using ten representative study types, but this constituted developmental stress-testing rather than formal validation. It has not yet been externally or empirically validated, and its inter-rater reliability, usability, completion time, error rate, and cross-jurisdictional applicability remain unknown. Independent multidisciplinary assessment, formal inter-rater testing, cross-jurisdictional evaluation, and prospective application are therefore required before claims of reproducibility or validated performance can be made. The ordinal codes and structured categories may create an appearance of mechanical precision and may encourage a check-box interpretation of ethical assessment; however, profile assignment requires reasoned qualitative justification and cannot be automated or interpreted as a numerical measure of ethical acceptability. Satisfaction of all applicable components does not establish that a study is ethically acceptable in every relevant respect, and a Green outcome should not be treated as an ethical certification. Green indicates documented decision readiness within the scope of FORETHICS, not formal ethical or legal approval.

Consent after death, relatives' roles, judicial authority, data-protection requirements, evidentiary-retention duties, and concepts such as post-mortem dignity remain legally and culturally variable. These differences cannot be eliminated through a general framework: FORETHICS can identify the governance question that requires resolution, but the substantive answer must derive from the applicable law, institutional structure, cultural context, and competent authority. Similarly, qualitative risk judgments concerning likelihood, severity, reversibility, and affected parties remain context-dependent and cannot be reduced to universally valid thresholds. The framework may also increase the initial documentation burden. Its modules, coding rules, Hard Stops, Decision Cards, and documentary requirements will require periodic review as laws, technologies, research practices, and ethical expectations evolve. FORETHICS should therefore be regarded as a developmental and revisable starting architecture rather than a completed universal standard. It is intended as a structured decision-support framework to be used alongside, and not in place of, the determinations of competent ethical, legal, judicial, custodial, data-protection, and animal-welfare authorities.

10. Conclusions

The gap between ethical principles and operational decisions in forensic research produces inconsistent determinations, unverifiable safeguards, and avoidable delays. FORETHICS addresses this gap by providing a common decision grammar through which relevant actors, safeguards, and documentary requirements can be identified and implemented within locally lawful pathways. It does not seek to harmonise national laws or replace competent authorities, but to make the reasoning underlying forensic research governance more explicit, traceable, and comparable. FORETHICS is presented as a candidate framework for multidisciplinary scrutiny and international validation. Its value will ultimately depend on its inter-rater reliability, usability, transparency, stakeholder acceptance, and applicability across diverse legal, cultural, and forensic settings.

Supplementary Materials: The following supporting information can be downloaded at: <https://www.mdpi.com/article/10.3390/forensicsci6030077/s1>, Figure S1: FORETHICS operational workflow; Table S1: Functional basis for the seven non-substitutable FORETHICS axes; Table S2: Formative scenario exploration used during FORETHICS development; Table S3: FORETHICS study-type operational summary; Table S4: Operational manifestations of the FORETHICS Hard Stops and required remediation; Template S1: Ethical Decision Report.

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Abbreviations

The following abbreviations are used in this manuscript:

AAFS	American Academy of Forensic Sciences
AI	Artificial Intelligence
AI Act	European Union Artificial Intelligence Act
ALLEA	European Federation of Academies of Sciences and Humanities
ARRIVE	Animal Research: Reporting of In Vivo Experiments
CIOMS	Council for International Organizations of Medical Sciences
CoE	Council of Europe
COPE	Committee on Publication Ethics

EHDS	European Health Data Space
ENFSI	European Network of Forensic Science Institutes
GDPR	General Data Protection Regulation
GINA	Genetic Information Nondiscrimination Act
ICMJE	International Committee of Medical Journal Editors
NC3Rs	National Centre for the Replacement, Refinement and Reduction of Animals in Research
OM	Operational Manifestation
RC	Role Conflict
3Rs	Replacement, Reduction and Refinement
UNESCO	United Nations Educational, Scientific and Cultural Organization
WMA	World Medical Association

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