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Legal Regulation of Dynamic Immune Networks and the Translation of lncRNA-IRN1: From Biomedical Research to a Responsible Innovation Model

Liu Gang

Master student,
International Sakharov Environmental Institute of Belarusian State University,
23/1, Dolgobrodskaya str., Minsk, 220070, Republic of Belarus;
e-mail: 16678627520@163.com

Abstract

This article examines research on the dynamic network regulation of immune responses and the identification of lncRNA-IRN1 not merely as an immunological project, but as an object of biomedical law, regulatory governance, and bioethics. The legal object of analysis is not the immune network itself, but the complex set of relations that emerges when human biological material is collected, multi-omics data are processed, animal experiments are conducted, machine-learning models are deployed, and molecular findings are translated into diagnostic and therapeutic products. The legal subject encompasses researchers, clinical sponsors, ethics committees, data controllers, physicians, patients, animal-welfare bodies, technology developers, and public regulators. Through doctrinal, comparative-law, risk-based regulatory, and bioethical analysis, the article demonstrates that IRN1 — simultaneously as a biomarker and as a drug target — activates the regulatory regimes governing human-subject research, personal and genetic data protection, clinical trials, in vitro diagnostic medical devices, artificial intelligence, intellectual property, and tort liability. It concludes that the scientific value of the discovery is inseparable from its legal design, and that responsible translation is possible only through an integrated governance model in which ethical approval, informed consent, data protection, regulatory authorization, quality management, and fair access are planned from the outset.

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Keywords

Biomedical law, research ethics, informed consent, personal data protection, clinical trials, artificial intelligence regulation, intellectual property, tort liability, lncRNA-IRN1, immunotherapy.

Introduction

The immune response is a dynamically complex process whose effectiveness depends on the coordinated action of cells, soluble mediators, and microenvironmental signals. Disruptions of spatiotemporal regulatory plasticity lead to chronic infections, autoimmune pathologies, and cancer. Classical immunology, relying on static snapshots, failed to capture the heterogeneity and dynamics of the response; the development of single-cell technologies and spatial transcriptomics began to dissect this heterogeneity, yet most studies focus on phenotypes rather than network-level dynamics. The present research proceeds from the assumption that the immune response is regulated by spatiotemporal dynamic networks in which key nodes jointly achieve stage-specific reconstruction, and that intervention at these nodes can correct functional abnormalities.

However, once research moves beyond the laboratory bench — collecting patient samples, processing multi-omics profiles, experimenting on animals, building predictive models, and proposing a therapeutic target — it inevitably enters the domain of law. The legal question here is not secondary to the scientific one: it determines the conditions under which knowledge may be obtained, stored, transferred, commercialized, and applied at the patient's bedside. For this reason, the present study should be read in two ways: as an immunological work and as a legal analysis of responsible biomedical innovation.

The aim of this work is to describe the dynamic network regulation of the immune response, to identify lncRNA-IRN1 as a stage-specific regulatory node, and simultaneously to analyze the legal and ethical-regulatory conditions under which this finding can be transformed into a clinically and socially acceptable product.

Main part

Under pathological conditions, to illustrate the spatiotemporal reconstruction of the immune network and the changes in the immune network during health and disease, we first performed time-series single-cell RNA sequencing (scRNA-seq) in mouse models of acute infection (*Listeria monocytogenes*, LM), tumor development (MC38), and chronic inflammation (collagen-induced arthritis, CIA). Additionally, we analyzed samples from human colorectal cancer (CRC) patients. After performing Uniform Manifold Approximation and Projection (UMAP) visualization on over 50,000 single-cell RNA sequencing (scRNA-seq) data points, the changes in dynamic cellular states in acute and chronic immunity revealed immune cell landscapes unique to different immune environments.

Immune-network research creates a conflict of legally protected interests. On the one hand, freedom of scientific research and the public interest in new immunotherapies support the collection and analysis of large biological datasets. On the other hand, the dignity, privacy, autonomy, bodily integrity, and safety of participants require strong safeguards. The Declaration of Helsinki, the CIOMS Guidelines, and UNESCO bioethics instruments provide a transnational ethical foundation: scientific validity, independent ethical review, respect for vulnerable persons, and fair distribution of benefits [World Medical Association, 2024; CIOMS, 2016; UNESCO, 2005]. In legal terms, these principles operate together with binding national rules and institutional policies.

A responsible regulatory model should be layered:

- National law — the protocol complies with the law of the country of conduct.
- Independent ethics approval — before recruitment begins.
- Enforceable contracts — data-transfer agreements (DTAs) and material-transfer agreements

(MTAs).

- Recognized scientific standards — Good Clinical Practice (GCP) at the stage of clinical translation [European Union, 2014; International Council for Harmonisation, 2025].

Ethics approval does not replace legal assessment and does not eliminate liability; it is only one element of due diligence. A legally defensible program requires continuous risk management, contemporaneous documentation, and a governance structure capable of identifying, reporting, and correcting problems.

The legal subject includes: researchers (duty to follow the protocol), clinical sponsors (quality, safety reporting), ethics committees (independent review), data controllers (personal data protection), physicians (disclosure of risks and alternatives), patients (autonomy, informed consent), animal-welfare bodies (authorization, 3Rs), technology developers (algorithmic transparency), and public regulators (authorization, oversight).

CRC and peripheral blood samples are legally sensitive: they connect biological material with clinical status, treatment response, and possible genetic or molecular identifiers. Informed consent should not be reduced to a signature. It should specify:

- the purpose of collection and the types of omics analyses;
- storage duration and conditions of secondary use;
- possible commercial development and data sharing;
- international transfer and publication of de-identified results;
- the limits of withdrawal once data are irreversibly anonymized or included in aggregate analyses.

For paired biopsies before and after treatment, consent should explain additional physical risks, discomfort, and the possibility that the biopsy will not directly benefit the participant. Where vulnerable patients, advanced cancer patients, or patients dependent on treating physicians are involved, consent procedures must avoid therapeutic misconception and undue influence. The legal validity of consent is strengthened by plain-language information sheets, documented opportunities to ask questions, and separate options for future use of samples.

Single-cell sequencing, proteomics, metabolomics, clinical metadata, and treatment-response information should be treated as highly sensitive data. Under the GDPR model, genetic data and data concerning health fall within special categories of personal data, the processing of which is generally prohibited unless a specific lawful basis and an Article 9 exception apply, together with suitable safeguards [European Union, 2016]. Even where data are pseudonymized, the combination of omics profiles, rare disease features, imaging, and longitudinal sampling creates a realistic risk of re-identification.

A legally robust research protocol should include:

- data minimization and purpose limitation;
- role-based access, encryption, audit logs;
- retention limits and a data protection impact assessment (DPIA) where required;
- clear governance for cross-border transfers;
- documentation of dataset provenance, bias controls, and the legal basis for secondary analysis in machine learning.

The distinction between anonymization and pseudonymization is decisive: anonymized data usually fall outside personal-data regimes, while pseudonymized data remain regulated because re-identification is possible.

The mouse models, including *Listeria monocytogenes* infection, MC38 tumor challenge, collagen-

induced arthritis, gene knockout, and ASO administration, require a separate legal and ethical justification. The EU animal-research model is built around the principles of replacement, reduction, and refinement (3Rs): animals should be used only when scientifically necessary, in the smallest number compatible with valid results, and under procedures that minimize pain, distress, and lasting harm [European Union, 2010].

A compliant protocol should include project authorization, severity classification, humane endpoints, anesthesia or analgesia, veterinary supervision, competence documentation for personnel, and transparent reporting. Because the study also involves pathogenic organisms and genetically modified animals, biosafety and biosecurity controls are relevant: laboratory risk assessment, containment procedures, waste management, exposure-response plans, and transport rules for biological materials should be documented in accordance with institutional biosafety programs and international biosafety guidance [World Health Organization, 2020].

If IRN1 antisense oligonucleotides move from mouse models into human studies, the legal status of the intervention changes: it is no longer merely a research reagent but a candidate investigational medicinal product. Clinical translation would require:

- preclinical toxicology, pharmacokinetics, and pharmacodynamics;
- off-target analysis and manufacturing controls;
- dose-escalation rules and safety monitoring;
- adverse-event reporting;
- a favorable risk–benefit assessment before first-in-human trials.

In the European regulatory model, clinical trials on medicinal products are governed by Regulation (EU) No 536/2014, while ICH E6(R3) Good Clinical Practice provides an international ethical, scientific, and quality standard for trial design, conduct, oversight, recording, analysis, and reporting [European Union, 2014; International Council for Harmonisation, 2025]. The sponsor would need to define responsibilities for monitoring, data integrity, insurance or compensation for research-related injury, and post-trial access if the intervention shows benefit. The law therefore requires that the promising anti-tumor results described in the biological part be converted into a stepwise, controlled, and transparent clinical development program.

The article indicates that high IRN1 expression may be associated with poor response to anti-PD-1 therapy. Once an IRN1 expression assay is used for patient stratification, selection of therapy, or prediction of response, it may be regulated as an *in vitro* diagnostic medical device, and in some circumstances as a companion diagnostic. Under the EU IVDR model, such products must demonstrate analytical performance, clinical performance, scientific validity, quality management, and appropriate conformity assessment before market use [European Union, 2017].

From a legal perspective, the key question is not only whether IRN1 is biologically meaningful, but whether the test is reliable enough to influence medical decisions. False-positive and false-negative results could expose patients to ineffective therapy, deny them beneficial treatment, or increase unnecessary risk. The regulatory file should therefore include validation cohorts, reproducibility data, cut-off justification, intended-use statements, quality controls, and clinician-facing instructions that clearly distinguish exploratory research findings from clinically validated diagnostic claims.

The study relies on machine learning, Bayesian network inference, trajectory modeling, and multi-omics integration. These tools are scientifically useful, but they create legal duties related to transparency, validation, accountability, and bias control.

- If an algorithm remains an internal research tool, governance can focus on documentation,

reproducibility, data security, and peer review.

- If the same algorithm is used to support diagnosis, treatment selection, trial enrollment, or risk prediction for individual patients, it may enter the sphere of regulated medical software or high-risk AI.

The EU Artificial Intelligence Act adopts a risk-based approach and is relevant where AI systems affect health, safety, or fundamental rights [European Union, 2024]. Therefore, any clinical use of immune-network prediction models should include a clear intended purpose, human oversight, performance monitoring, cybersecurity controls, explainability appropriate to clinical users, and procedures for correcting model drift. Legal accountability should remain with identifiable persons and institutions, not with the algorithm as an autonomous actor.

The identification of IRN1 as a potential therapeutic target may generate patentable claims relating to antisense sequences, delivery methods, diagnostic assays, or combination therapies with immune checkpoint blockade. Intellectual property protection can stimulate investment, but it must be balanced against access to diagnostics and treatment.

Where patient samples and publicly supported research contribute to the discovery, legal instruments should regulate:

- ownership of biological materials and rights to inventions;
- publication rights and data access;
- licensing strategy and benefit-sharing;
- prohibition of unauthorized re-identification and secondary use outside the approved purpose (through MTAs);
- reasonable access for independent validation studies and public-health needs.

In this sense, biomedical law connects innovation policy with medical ethics: the same legal system that protects inventors should also prevent exclusive rights from undermining fair access to clinically important biomarkers or therapies.

A legal analysis must also address possible liability.

In the research phase, liability may arise from:

- inadequate consent;
- protocol deviations;
- insufficient monitoring of adverse effects;
- data breaches;
- animal-welfare violations;
- unauthorized transfer of samples.

In the clinical phase — if:

- an IRN1-based diagnostic test is marketed without adequate validation;
- an ASO therapy causes foreseeable harm that was not disclosed or monitored;
- an algorithmic prediction is used beyond its validated scope.

The standard of care will depend on the role of each actor: researchers must follow the approved protocol, sponsors must maintain quality systems and safety reporting, clinicians must explain risks and alternatives, and laboratories must ensure analytical validity. Ethics approval does not eliminate liability; it is only one element of due diligence.

For future IRN1 studies, a practical compliance model should include:

- independent ethics approval before recruitment;
- separate consent modules for treatment, biopsy, omics analysis, storage, secondary use, and

cross-border sharing;

- a data governance plan (lawful basis, security, retention, participant rights);
- animal-welfare authorization and 3R justification for each model;
- biosafety approval for pathogens and GMOs;
- preregistration of clinical trials where applicable;
- GCP procedures for human intervention studies;
- quality management for IRN1 assays;
- AI governance for predictive models;
- material-transfer and data-transfer agreements for collaboration;
- intellectual-property clauses that preserve publication and validation rights;
- insurance or compensation mechanisms for research-related injury;
- a publication policy that avoids overstating exploratory findings.

Such a model translates the biological promise of immune-network regulation into a lawful and ethically sustainable research pathway.

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Conclusion

The scientific findings described in this article demonstrate potential value for precision immunotherapy, but their practical implementation depends on legal design. Biomedical law does not merely restrict research; it organizes trust, defines accountability, and creates conditions under which innovative therapies can move from laboratory evidence to clinical use.

Dynamic immune-network research should therefore be governed as a high-value and high-risk field that combines:

- protection of human participants;
- safeguards for personal and genetic data;
- animal-welfare duties;

- clinical-trial regulation;
- validation of in vitro diagnostic devices;
- artificial intelligence oversight;
- intellectual-property management;
- prevention of tort liability.

If IRN1 is developed as both a biomarker and a therapeutic target, the strongest legal strategy is an integrated governance model in which ethical approval, consent, data protection, regulatory authorization, quality management, and fair access are planned from the beginning rather than added after scientific success. This approach allows the article to be read not only as an immunology study but also as a legal analysis of responsible biomedical innovation.

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Правовое регулирование динамических иммунных сетей и трансляция lncRNA-IRN1: от биомедицинских исследований к модели ответственных инноваций

Лю Ган

Магистрант,
Международный государственный
экологический институт им. А.Д. Сахарова
Белорусского государственного университета,
220070, Республика Беларусь, Минск, ул. Долгобродская, 23/1;
e-mail: 16678627520@163.com

Аннотация

В статье исследуется динамическая сетевая регуляция иммунных ответов и идентификация lncRNA-IRN1 не только как иммунологический проект, но и как объект биомедицинского права, регуляторного управления и биоэтики. Правовым объектом анализа выступает не сама иммунная сеть, а сложный комплекс отношений, возникающих при сборе биологического материала человека, обработке мультимедийных данных, проведении экспериментов на животных, применении моделей машинного обучения и трансляции молекулярных открытий в диагностические и терапевтические продукты. Субъектный состав включает исследователей, клинических спонсоров, этические комитеты, контролёров данных, врачей, пациентов, органы по защите животных, разработчиков технологий и публичных регуляторов. На основе доктринального, сравнительно-правового, риск-ориентированного регуляторного и биоэтического анализа показано, что IRN1 — одновременно как биомаркер и как лекарственная мишень — активирует регуляторные режимы, governing исследования с участием человека, защиту персональных и генетических данных, клинические испытания, медицинские изделия для *in vitro* диагностики, искусственный интеллект, интеллектуальную собственность и деликтную ответственность. Делается вывод, что научная ценность открытия неотделима от его правового оформления, а ответственная трансляция возможна только через интегрированную модель управления, в которой этическое одобрение, информированное согласие, защита данных, регуляторная авторизация, управление качеством и справедливый доступ планируются с самого начала.

Для цитирования в научных исследованиях

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Ключевые слова

Биомедицинское право, этика исследований, информированное согласие, защита персональных данных, клинические испытания, регулирование искусственного интеллекта, интеллектуальная собственность, деликтная ответственность, lncRNA-IRN1, иммунотерапия.

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