Public Consultation

Guidelines 1/2026 on processing of personal data for scientific research purposes

Part 3

The Clinician's Perspective: Beneficence, Scientific Progress, and the Future of Research Governance

1 Contributors

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Part 3 has fewer contributors than Parts 1 and 2 because it was circulated for comments later than the first two documents. The contact point for correspondence is Peter Villax, peter@villax.net, Mediceus Ltd.

2 Introductory note

This is part 3 of Contributors' response with respect to the public consultation concerning these Guidelines, and this part 3 focuses on the future of research from a clinician's perspective. Part 1 covers central concepts in GDPR and Part 2 technical safeguards.

3 From protection against abuse to promotion of human benefit

The 20th century witnessed some of the most serious ethical failures in the history of scientific research involving human beings. The Tuskegee Syphilis Study, the experiments conducted in Nazi concentration camps, and other abuses involving vulnerable populations revealed how scientific ambition, when unconstrained by ethical principles, can violate human dignity and fundamental rights.

Modern research ethics emerged from these failures with a clear message: the interests of science can never prevail over the dignity, rights and welfare of the individual. Ethics

committees, informed consent requirements, regulatory oversight and legal protections were developed to ensure that such abuses would never happen again. In this, we were successful and the protection of human dignity is one of the great accomplishments of modern democratic societies.

The regulatory framework that emerged from these historical failures was primarily designed to prevent harm. Its central concern was the protection of individuals against abuse by researchers, institutions, corporations and states. Over time, this protective paradigm expanded beyond clinical research into data protection law, culminating in comprehensive regulatory frameworks such as the GDPR.

EDPB's Guidelines probably indicate that we are at an inflection point. There is an increasing realisation, not that t we have gone too far, but that certain areas have fallen behind and need to catch up. In the present context, the question that Europe should now ask itself is not whether these protections remain necessary. They undoubtedly do. The question is whether a framework primarily designed to prevent harm has become less capable of promoting good.

In the field of health research, this question is particularly important. Every delay in the generation of new knowledge may represent delayed diagnoses, delayed treatments, avoidable suffering and avoidable deaths. The ethical challenge of our time may no longer be how to protect individuals from uncontrolled scientific research, but how to protect individuals while simultaneously enabling responsible scientific research upon which future health depends.

The idea is not novel. Article 27 of the Universal Declaration of Human Rights already states that everyone has the right to share in scientific advancement and its benefits. Therefore we should consider the human interest in benefiting from scientific progress at the same level that we seek to protect individual rights and freedoms.

Pope Leo XIV 's encyclical "Magnifica Humanitas" takes this view as well. It states that scientific discoveries are gifts entrusted to humanity (para. 9) but argues that its legitimacy is measured by whether it advances human dignity, solidarity, justice, and the common good rather than mere technical capability or economic power. The dignity of the person remains the measure by which progress must be judged (para. 58).

Essentially, we believe it is time to evolve from an ethics framework focused primarily on preventing abuse towards an "Ethics 2.0" approach, one that balances safeguarding against harm with a proactive responsibility, to enable meaningful benefit. That is, protecting human dignity requires both the protection of rights and the promotion of scientific progress, so that science itself can be an expression of human dignity when ethically governed.

4 The forgotten ethical principle: beneficence

Biomedical ethics has traditionally been founded upon four principles: autonomy, non-maleficence, beneficence and justice. The principles of autonomy and non-maleficence have become deeply embedded within European data protection law. Data subjects enjoy extensive rights over their personal data. Controllers must minimise processing, limit

purposes, justify retention periods, ensure transparency and implement safeguards. These protections are essential and should remain so.

The principle of beneficence in medicine, which is the obligation to act for the benefit of others – preventing disease, reducing suffering, prolonging life and improving quality of life – however, occupies a less prominent position within these safeguards. While scientific research is one of the principal means to achieving these objectives and is often seen as a matter of innovation or competitiveness, its purpose is also moral, in that it seeks to generate knowledge capable of improving human lives.

Yet beneficence rarely appears explicitly in discussions concerning the governance of personal data. Regulatory debate frequently focuses on preventing misuse, preventing disclosure, preventing harm and preventing risk, legitimate objectives indeed, but which represent only one side of the ethical equation.

Therefore, what we propose as clinicians and as researchers is that the ethical obligation to protect individuals from harm should coexist with an ethical obligation to enable beneficial research capable of improving human health. The challenge is not to choose between privacy and research. It is to recognise that both privacy and scientific progress are expressions of human dignity and that both deserve protection.

There is an interesting parallel argument. Tuskegee was active harm, but has one of its unintended consequences been foregone benefit? Ethics committees are extremely competent at evaluating active harm and at evaluating the risks of research but have less experience in evaluating lost benefit. Less attention is often paid to the ethical consequences of not conducting research. Delayed discoveries, delayed treatments and delayed improvements in healthcare also have human consequences, even if those consequences are less visible than the immediate risks associated with a particular study.

5 The clinician's dilemma

For clinicians involved in research, the balance between protection and beneficence derives directly from the Hippocratic oath and is an ever-present question. Every physician encounters patients whose conditions could be better understood through research. Every specialist sees opportunities to improve treatment pathways, identify risk factors, personalise therapies or discover previously unknown associations. Every hospital generates data that could contribute to better outcomes for future patients.

At the same time, clinicians increasingly encounter complex governance frameworks that are fragmented and resource-intensive. Ethics approvals, data protection assessments, contractual negotiations, cross-border legal reviews and multiple layers of administrative oversight frequently consume substantial amounts of time and resources, yet it is reasonable to ask whether the cumulative effect of these requirements is always proportionate to the risks involved. The dilemma can be expressed simply: how much potentially life-saving research should society be prepared to sacrifice in order to eliminate every conceivable privacy risk?

Ignoring privacy and autonomy would be ethically unacceptable, but impeding responsible research capable of saving lives may also be unethical. The solution to the dilemma must be based on balance: how can we protect fundamental rights and freedoms without excluding the beneficence of scientific research from the domain of the rights we seek to uphold?

6 From rule-based protection to beneficent governance

European regulation has traditionally relied on formal and detailed compliance mechanisms and on extensive procedural requirements. While they promote legal certainty, they follow their own rules and pace, which do not always mirror those of scientific research. Indeed, research takes place in complex technological ecosystems that evolve more rapidly than legislation.

The question therefore arises whether future governance should depend exclusively upon increasingly detailed rules, or whether greater emphasis should be placed upon principles, accountability and expert oversight. The answer could be provided by beneficent governance, a model where research activities are evaluated not only according to the risks they create, but also according to the benefits they are reasonably expected to generate for patients, health systems and society. The model should not weaken fundamental rights but lead decision-makers to explicitly consider both sides of the ethical equation, without relying on deregulation but rather resorting to governance systems capable of balancing protection and beneficence in a transparent and accountable manner.

Beneficent governance would have at its centre the benefit of society as a whole and it would address:

- risk to participants;
- benefit to participants;
- benefit to future patients;
- scientific value;
- societal value.

Beneficent governance could contribute to quicker assessments, more predictable decisions and a more enabling environment for scientific research, with one important objective for all: the right to benefit from scientific progress.

The following Sections 7-10 address operational issues and are practical implications of beneficent governance.

7 Predictability, accountability and regulatory certainty

Predictability is key in this governance model. Currently, regulatory frameworks leave substantial discretion to supervisory authorities, ethics committees and data protection officers, which may result in different interpretations of legal requirements. Conflicting decisions may prevent researchers from understanding the conditions under which compliance is likely to be achieved and discourage them from initiating research projects.

Creating safe harbours based on predefined combinations of safeguards, governance structures and technical controls would provide for much-desired clarity. Where such conditions are met in well-defined, low risk research projects without specific concerns, compliance could be presumed.

Similarly, regulatory systems should seek to establish greater symmetry of accountability. Researchers, sponsors and institutions are rightly accountable for delays, failures and non-compliance. Yet delays in administrative decision-making may also have significant consequences for patients and society. Prolonged uncertainty can prevent studies from commencing and delay scientific discoveries. Predictable timelines and, where appropriate, deemed approvals following the expiry of clearly defined review periods could improve both accountability and efficiency.

8 The challenge of regulatory fragmentation

One of the greatest obstacles to European scientific research is not the GDPR itself, but the fragmentation resulting from divergent national interpretations and implementations. As article 89 permits national derogations, Europe is increasingly operating with a single regulation but multiple research governance regimes. Researchers conducting multinational studies frequently encounter differing requirements regarding consent, ethics review, secondary use, retention periods and participant rights. To the list of higher costs, delays and uncertainty, legal fragmentation adds friction in cross-border scientific collaboration.

The European Union was founded upon the principle of integration. Scientific research should benefit from that same ambition. The mutual recognition of ethics approvals, safeguards and governance mechanisms would create conditions for a study considered ethically acceptable in one Member State not to require fundamentally different treatment in another and strengthen European research capacity without reducing standards of protection.

9 Proportionality, scalability and research diversity

Regulations that grow in complexity end up favouring large institutions with substantial administrative resources. Excessive compliance costs risk concentrating research capacity in a small number of large organisations while reducing diversity, innovation and local initiative. Academic researchers, small hospitals and clinician-led initiatives may struggle to satisfy increasingly complex compliance requirements even when their studies involve relatively limited risks.

This increased complexity can be seen as driven by a desire for legal excellence, perhaps even perfection, but we need to consider that a sustainable research ecosystem requires proportionality and scalability, concepts which do not co-exist well with absolutes. Governance obligations should scale according to risk, sensitivity and potential impact. Low-risk observational studies should not necessarily bear the same administrative burden as large-scale interventional research programmes.

Therefore, the evaluation of risk in research projects would help identify the appropriate safeguards. One size must not fit all. Identifying the correct technical and organisational means which take into account the level of risk to which study participants may be exposed would provide for adaptive models, ranging from maximum protection in the case of a clinical trial testing an experimental drug with a novel mechanism of action, to minimum requirements in the case of observational studies using real-world data obtained in routine clinical practice.

The objective should be a research environment that remains accessible to institutions of different sizes while maintaining appropriate safeguards for participants.

10 Interoperability, portability and participant freedom

Future research infrastructures should avoid creating dependency on specific platforms, providers or technological ecosystems. Data subjects should remain free to move between healthcare providers, research infrastructures and digital platforms without losing control over their information or their ability to participate in scientific research. Similarly, researchers should be able to collaborate across institutional and national boundaries without unnecessary technical barriers.

Interoperability and portability should therefore be viewed not only as technical objectives but also as ethical ones. They help ensure that neither participants nor researchers become captive to particular infrastructures. A European research ecosystem should be open, interoperable and participant-centred.

11 Towards a European model of beneficent research governance

Europe has every reason to remain proud of its commitment to privacy, dignity and fundamental rights. These values distinguish the European model and should continue to do so. At the same time, Europe should also recognise that scientific research is one of the most powerful instruments available to improve human welfare. The challenge for the coming years is not to choose between protection and progress. It is to develop governance models capable of achieving both.

The future of research governance should continue to protect autonomy, privacy and dignity. But it should also explicitly recognise beneficence, scientific advancement and the reduction of human suffering as legitimate objectives deserving equal consideration. The central argument of this paper is that they are not conflicting goals, and they need to be pursued with equal commitment.

A Europe capable of combining strong safeguards with effective scientific research will not merely protect its citizens from harm. It will also improve their lives.

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