THREE FOUNDATIONAL TEXTS OF RESEARCH ETHICS

The Ethics of Human Research

From the Nuremberg Code to the Declaration of Helsinki, and the WMA's practical guidance for physicians in between.

- Nuremberg Code (1947)
- WMA Declaration of Helsinki (1964–2024)
- WMA Medical Ethics Manual, Ch. 5 (2015)

Three Texts, One Purpose

Each document plays a distinct role in protecting people who take part in medical research.

1947

The Nuremberg Code

Ten principles set out by a war-crimes tribunal after physicians conducted lethal experiments without consent. The founding document of research ethics — brief, absolute, born of atrocity.

1964–2024

Declaration of Helsinki

The WMA's living statement of ethical principles for research on human participants — 37 paragraphs, revised ten times to meet new science and new questions.

2015

WMA Medical Ethics Manual

A practical teaching guide that explains how physicians apply these principles day to day — case studies, common pitfalls, and the physician's dual role as clinician and researcher.

ORIGINS

Why These Documents Exist

During the Second World War, physicians in Nazi Germany conducted lethal, non-consensual experiments on prisoners. After the war, a special tribunal at Nuremberg tried and convicted some of those physicians. The tribunal's judgment set out ten principles for permissible human experimentation — the Nuremberg Code — built on the idea that valid research “satisfies moral, ethical, and legal concepts.”

A living response

The newly founded World Medical Association (also 1947) moved to ensure physicians understood their obligations, eventually producing the Declaration of Helsinki in 1964 — revised repeatedly since as medicine and society have changed.

From principle to practice

Decades later, the WMA's Medical Ethics Manual translates these high-level principles into everyday guidance — helping physicians recognize and navigate the tension between their role as caregiver and their role as researcher.

Eight Decades of Research Ethics

From a tribunal judgment to a living, regularly revised international standard.

1947

Nuremberg Code

Ten principles from the doctors' trial. First requirement: voluntary consent.

1954–64

WMA Principles → Helsinki

WMA principles evolve into the first Declaration of Helsinki, adopted in Helsinki.

1975–2013

Seven Revisions

Tokyo, Venice, Hong Kong, Somerset West, Edinburgh, Washington/Tokyo, Seoul, Fortaleza.

2015

WMA Ethics Manual

3rd edition publishes practical, case-based guidance for physicians on research ethics.

2024

Helsinki, 10th Revision

Returns to Helsinki; adds equity, community engagement, sustainability, and data governance.

NUREMBERG 1947

The Nuremberg Code's Ten Points

1. Voluntary consent is absolutely essential
2. Results must benefit society, unobtainable by other means
3. Design must rest on animal data and knowledge of the problem
4. Avoid all unnecessary physical and mental suffering
5. No experiment if death or disabling injury is expected
6. Risk must never exceed the humanitarian importance of the problem
7. Adequate facilities must protect subjects from harm
8. Only scientifically qualified persons may conduct it
9. The subject may end participation at any time
10. The researcher must be ready to terminate it at any stage

ACROSS ALL THREE

Foundation Principle: Voluntary, Informed Consent

NUREMBERG 1947

Point 1

“The voluntary consent of the human subject is absolutely essential.” Requires legal capacity, freedom from force or fraud, and enough understanding to make an informed decision. This duty rests personally on whoever conducts the experiment, and “may not be delegated.”

HELSINKI 2024

§25–27

Consent must be voluntary, plain-language, and cover aims, methods, risks, funding and conflicts of interest — with the right to refuse or withdraw at any time, without reprisal. Extra caution applies where the participant is in a dependent relationship with the researcher.

WMA MANUAL

Getting Consent

The Manual stresses that consent doesn't begin and end with a signature — it requires careful oral explanation. In some countries, consent forms have grown so long and detailed that they no longer actually inform the subject.

ACROSS ALL THREE

Weighing Risk Against Benefit

NUREMBERG 1947

Points 5–6

No experiment may proceed where death or disabling injury is expected. The degree of risk taken should never exceed the humanitarian importance of the problem the experiment aims to solve.

HELSINKI 2024

§16–18

Research may only proceed if the objective's importance outweighs the risks and burdens. Risks must be assessed before starting, minimized, and continuously monitored — with a duty to stop or modify the study if risk comes to outweigh benefit.

WMA MANUAL

A Two-Part Test

The Manual frames risk as likelihood × severity of harm. An unknown risk means researchers should wait for reliable data — e.g. from laboratory or animal studies — before proceeding with human subjects.

ACROSS ALL THREE

Scientific Validity and Qualified Researchers

NUREMBERG 1947

Points 2, 3, 8

The experiment must yield results “unprocurable by other methods,” be grounded in prior animal data and knowledge of the problem, and be conducted only by “scientifically qualified persons” exercising the highest skill and care.

HELSINKI 2024

§21–22

Research must be rigorously designed to produce reliable, valid, valuable knowledge and avoid research waste, grounded in the literature and, where appropriate, adequate animal experimentation — fully described in a written protocol.

WMA MANUAL

Scientific Merit

The Manual explains this as a gatekeeping question for ethics committees: is the project methodologically sound enough that, even if successful, it wouldn't produce merely trivial results?

ACROSS ALL THREE

The Right to Withdraw, at Any Time

NUREMBERG 1947

Points 9–10

The subject is free to end participation if continuation seems physically or mentally impossible to them. The scientist in charge must also be ready to terminate the study at any stage if continuation is likely to cause injury, disability or death.

HELSINKI 2024

§26, 31

Participants must be told of their right to withdraw at any time without reprisal. Refusing or withdrawing from research must never adversely affect the standard of care or the patient–physician relationship.

WMA MANUAL

In Practice

The Manual's case study warns against enrolling a fixed quota of patients, since this can tempt a physician to pressure patients to stay in — undermining the freedom to withdraw that all three documents protect.

HOW THE STANDARD EVOLVED

Independent Oversight: From Absent to Essential

One of the clearest lines of development across these texts: the Nuremberg Code relies entirely on the individual researcher's judgment and conscience. It has no external review requirement at all — a gap later documents closed.

1947 — No external check

The Code places the entire duty and responsibility for consent and safe conduct on “each individual who initiates, directs or engages in the experiment.” No committee, no external approval.

2024 — A required gate (§23)

Every protocol must be reviewed and approved by an independent research ethics committee before research begins — with authority to monitor, amend, suspend, or withdraw approval.

Manual — Why it matters

Neither researchers nor subjects are always objective enough to judge a project's soundness alone. The committee protects subjects and confirms scientific and social value — before harm can occur.

MANUAL + HELSINKI

The Physician–Researcher Role Conflict

This tension is largely absent from the Nuremberg Code, which addresses researchers only. Both the Manual and the 2024 Declaration treat it directly, because physician-researchers are common in modern clinical trials.

HELSINKI §14

Physicians who combine research with care may involve patients only to the extent justified by potential preventive, diagnostic or therapeutic value — and only where the physician has good reason to believe participation will not adversely affect the patient's health.

MANUAL'S FRAMING

The physician's primary duty is the patient's health; the researcher's primary duty is generating knowledge, which may or may not benefit the individual subject. When the two conflict, “the physician role must take precedence over the researcher.”

A MODERN ADDITION

Vulnerable Populations and Equity

The Nuremberg Code says nothing about vulnerability or equity — it assumes a subject capable of consenting. Helsinki and the Manual both address what happens when that assumption doesn't hold.

HELSINKI 2024

§19–20, 28–30

Vulnerable individuals and groups face greater risk of being wronged; excluding them can worsen their disparities. Research is justified only if it responds to their own health needs and they stand to benefit — and only when it can't be done in a less vulnerable population. Legally authorized representatives may consent for those unable to, with assent and dissent both respected.

WMA MANUAL

Structural Concerns

The Manual raises the 10/90 gap: only 10% of global research funding addresses the health problems of 90% of the world's population. It also flags recurring tension between researchers' ethical outlook and that of the communities where resource-poor research takes place — an issue it calls still unresolved.

HELSINKI + MANUAL

Confidentiality and Privacy

> ***Every precaution must be taken to protect the privacy of research participants and the confidentiality of their personal information.***

— Declaration of Helsinki, §24 (the whole of the paragraph)

MANUAL'S ADDITION

Research, unlike routine clinical care, often requires disclosing health information to the wider scientific community — and sometimes the public. The Manual specifies the practical safeguard: information should generally be de-identified, and stored and transmitted securely, with subjects told in advance how their data will be used. (Note: the Nuremberg Code does not address confidentiality at all.)

HELSINKI §33

Use of Placebo

A question the Nuremberg Code never faced — randomized, placebo-controlled trials postdate it.

The default rule: a new intervention must be tested against the best proven intervention available.

A **No proven intervention exists**

Placebo, or no intervention, is an acceptable comparator.

B **Compelling methodological reasons require it**

Necessary to determine efficacy or safety, and participants face no added risk of serious or irreversible harm.

Extreme care must be taken to avoid abuse of this option.

This connects directly to the Manual's point on unresolved debate over when a placebo arm is acceptable in a clinical trial.

HELSINKI + MANUAL

Accountability After the Trial Ends

Post-Trial Provisions

Helsinki §34

Sponsors must arrange, in advance, continued access to a beneficial intervention for participants who still need it — disclosed as part of informed consent.

Public Registration

Helsinki §35

Every study must be registered in a publicly accessible database before the first participant is recruited.

Honest Reporting

Helsinki §36 + Manual

Negative and inconclusive results must be published too. The Manual adds that plagiarism, data fabrication, and 'gift' authorship remain persistent, documented problems.

Whistle-blowing (Manual): anyone aware of unethical research — including students — has an obligation to report it, even though whistle-blowers aren't always appreciated for doing so.

HELSINKI, 10TH REVISION

What's New Since the Manual Was Written

The 2024 Declaration goes beyond both earlier texts on several fronts.

Structural equity (§6)

Explicit attention to how benefits, risks and burdens are distributed amid structural inequities — not present in either earlier text.

Community engagement (§6)

Participants and communities should help shape research design, not just consent to it.

Environmental sustainability (§11)

Research should be designed to avoid or minimize environmental harm — entirely new territory.

Secondary data & biobanks (§32)

Detailed consent rules for future, indefinite reuse of data and biological material, aligned with the WMA Declaration of Taipei.

Underrepresented groups (§13)

A positive duty to provide appropriate access to research participation, not just protection from harm.

Public registration (§35)

Mandatory pre-registration in a public database — a transparency tool unavailable in 1947 or 1964.

MANUAL

Contemporary Challenges

None of these three texts claims to have settled every question. The Manual highlights unresolved debates: when a placebo arm is acceptable, what continuing care trial participants are owed, and how new fields like genetics and neuroscience raise questions with no ready-made answers.

Where researchers address problems in resource-poor regions, they often encounter conflicts between their own ethical outlook and that of the communities where they work — issues the Manual says will require much further analysis and discussion.

THE 10/90 GAP

10%

of global research funding targets health problems affecting

90%

of the world's population

How the Three Documents Work Together

Foundation, living standard, and practical guide — each depends on the others.

FOUNDATION

Nuremberg Code

Establishes the non-negotiable floor: consent, scientific necessity, and the researcher's personal responsibility. Short, absolute, unrevised since 1947.

→

LIVING STANDARD

Declaration of Helsinki

Expands the floor into a detailed, regularly updated international standard — covering committees, vulnerability, data governance, and more.

→

PRACTICAL GUIDE

WMA Ethics Manual

Translates both into the physician's daily reality — case studies, common conflicts, and honest acknowledgment of what remains unresolved.

None of the three stands alone: each paragraph of Helsinki should be read together with the others, and the Manual reads Helsinki through the lens of everyday practice.

Key Takeaways

1. Voluntary, informed consent is the one principle every document treats as absolute — from Nuremberg's uncompromising first point to Helsinki's detailed procedural rules.

2. Independent oversight is the biggest structural addition since 1947: Nuremberg trusted the individual researcher; Helsinki requires an independent ethics committee for every study.

3. Newer concerns — vulnerability, equity, confidentiality, data reuse, environmental impact — simply didn't exist as categories in 1947, and have been built up steadily since.

4. The physician's duty of care always takes precedence over the researcher's pursuit of knowledge, whenever the two roles are held by the same person.

Nuremberg Code (1947) · WMA Declaration of Helsinki (2024) · WMA Medical Ethics Manual, 3rd Ed. (2015)