“An Official Conscience and Warranting Agency”: Institutional Isomorphism and the Rise of Dutch Ethics Review in the 1970s and 1980s

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Abstract

Why did medical research involving human subjects, a practice that is arguably as old as medicine itself, come to be regulated by research ethics committees in the late twentieth century? In this essay, I answer this question for the Netherlands, by querying the rise of ethics review in the 1970s and 1980s through the lens of “institutional isomorphism”. Drawing on the classic work of Paul Dimaggio and Walter Powell, I argue that extra-national changes to funding and publishing requirements in this period were identifiably more important for the emergence of ethics review in the Netherlands than were ethical concerns for research misconduct – a process that was marked by definitive elements of internationally coercive, and perhaps also of mimetic isomorphism. In addition, I detail how, as a consequence of these developments, those involved in Dutch ethics review came to consider “variation and inconsistency” as one of the system’s biggest problems in the late 1980s. To remedy this, numerous normative isomorphic attempts were undertaken in the late twentieth century to make all Dutch research ethics committees act in the same way. This emphasis on institutional homogeneity has been borne out in the Netherlands, even though it has repeatedly been criticized for hampering democratic and ethical decision-making.

Keywords

ethics review – history – The Netherlands – institutional isomorphism – critical event narrative

Why did medical research involving human subjects, a practice that is arguably as old as medicine itself,¹ come to be overseen by research ethics committees in the late twentieth century? In the Netherlands, this question has long been answered by pointing to the promulgation of international ethics codes and extra-national research scandals. Texts for Dutch medical students, for instance, tend to follow a similar genealogy. They start with the Nuremberg Code of 1947, a set of now world-famous ethical principles for human experimentation that were formulated at the end of the Nazi Doctors' Trial to condemn the atrocities committed in the Nazi concentration camps in the name of medical science.² They then mention the Helsinki Declaration, another authoritative set of principles that was first published by the World Medical Association (WMA) in 1964 and that is still regarded a cornerstone document for clinical research ethics worldwide.³ Subsequently, they move on to Henry K. Beecher's seminal 1966 article "Ethics and Clinical Research," often followed by Maurice Pappworth's 1967 book *Human Guinea Pigs*.⁴ Both list numerous questionable clinical research studies, many of which had been published in recent years in leading Anglo-American journals. Finally, they discuss the 1972 exposé of the infamous Tuskegee syphilis study, concluding that, since then, stringent regulations for human subjects research have been put in place worldwide – inferring that the regulations were developed *because of* these research scandals.

In the existing medical historiography, this "critical event narrative", as Laura Stark calls it, has been repeatedly questioned in the past decade.⁵ Authors such as Stark and Adam Hedgecoe have shown how ethics review in the United States and United Kingdom did not develop primarily in response to public outrage over research exposés, but to manage the expansion of systematic clinical research with healthy human subjects in the mid-twentieth century (in the

1 Anita Guerrini, *Experimenting with Humans and Animals: From Galen to Animal Rights* (Baltimore, MD, 2003); Susan Lederer, "The Ethics of Experimenting on Human Beings," in *The Cambridge World History of Medical Ethics*, ed. Robert B. Baker and Laurence B. McCullough (Cambridge, 2009), 558–565.

2 George J. Annas and Michael A. Grodin, eds., *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation* (Oxford, 1992).

3 Andreas Frewer and Ulf Schmidt, eds., *History and Theory of Human Experimentation: The Declaration of Helsinki and Modern Medical Ethics* (Frankfurt, 2007).

4 Henry K. Beecher, "Ethics and Clinical Research," *New England Journal of Medicine*, 74 (1966), 1354–1360; Maurice H. Pappworth, *Human Guinea Pigs: Experiments on Man* (London, 1967).

5 Laura J. M. Stark, "Morality in Science: How Research is Evaluated in the Age of Human Subjects Regulation" (PhD thesis, Princeton University, 2006), 32.

States), and to remain eligible for U.S. public funding (in the United Kingdom) at a time when federal regulations there were changing.⁶

In this essay, I investigate which mechanisms drove the Netherlands to develop research ethics committees in the 1970s and 1980s. Elsewhere, I have argued that we need more national histories of these developments, as the current dominance of the American narrative hides the fact that “new oversight mechanisms and ethics frameworks emerged at different times in different places and continue to have distinct national traditions.”⁷ As Duncan Wilson points out, comparative histories of such developments help us “identify the mechanisms that underpin [their] emergence in specific times and places, and how these lead to some issues and not others being designated as ‘bioethical.’”⁸ Thus, even if research ethics committees emerged across the world in the late twentieth century, they might have been answers to different problems in different communities.⁹ Teasing out these differences makes us appreciate better which specific socio-cultural mechanisms lie at the core of these developments.

Here, however, I take my cue from a point made to me by Laura Stark in 2018, i.e., that in addition to envisioning the Dutch case as a national comparison, we might also understand the Dutch context in a more networked sense, by querying it “in terms of institutional or of extra-national coercive isomorphism.”¹⁰ The definition of “institutional isomorphism” stems from a classic 1983 text by Paul DiMaggio and Walter Powell, in which they trace homogenization processes among institutions that result from external environmental factors, distinguishing between three of them: coercive, mimetic, and normative.¹¹ Coercive isomorphism denotes homogenization processes that occur primarily due to external pressures, be they formal or informal, such as government mandates or financial threats. Mimetic isomorphism points to uncertainty as a powerful force in encouraging homogenization. Normative isomorphism, finally, points to professionalization, whereby formal education

6 Laura Stark, *Behind Closed Doors: IRBs and the Making of Ethical Research* (Chicago, IL, 2012); Adam Hedgecoe, “A Form of Practical Machinery: The Origins of Research Ethics Committees in the UK, 1967–1972,” *Medical History*, 53 (2009), 331–350.

7 Noortje Jacobs, “A Moral Obligation to Proper Experimentation: Research Ethics as Epistemic Filter in the Aftermath of World War II,” *Isis*, 111 (2020), 759–780.

8 Duncan Wilson, *The Making of British Bioethics* (Manchester, 2014), 6.

9 Also: David Reubi, “The Will to Modernize: A Genealogy of Biomedical Research Ethics in Singapore,” *International Political Sociology*, 4 (2010), 142–158.

10 Personal correspondence with Laura Stark.

11 Paul J. DiMaggio and Walter W. Powell, “The Iron Cage Revisited: Institutional Isomorphism and Collective Rationality in Organizational Fields,” *American Sociological Review*, 48 (1983), 147–160.

and the growth of professional networks both contribute to homogenization. In this article, I draw on these definitions to investigate how the rise of Dutch research ethics committees was shaped in the 1970s and 1980s by the intensification of international scientific networks. I argue that, indeed, extra-national changes to funding and publishing requirements in this period were identifiably more important for the emergence of ethics review in the Netherlands than were ethical concerns for research misconduct – a process that was marked by definitive elements of internationally coercive, and perhaps also of mimetic isomorphism.

I begin this article with a section in which I investigate to what extent public concerns over research misconduct were a driving force in the Dutch governance of human experimentation in medicine in the immediate post-war period. I make clear that these concerns were voiced repeatedly between 1945 and 1975, but never enticed the Dutch government to put oversight mechanisms in place. Next, I show that research ethics committees *were* established in the Netherlands in the 1970s and use the backstory of the oldest Dutch research ethics committee to demonstrate how extra-national changes to funding and publishing requirements influenced this development. In the third section, I trace the mushrooming of Dutch research ethics committees in the 1980s, and point to relevant elements of coercive and mimetic isomorphism there as well. Finally, I detail how, in the absence of any government regulations, those involved in Dutch ethics review came to consider “variation and inconsistency” as one of the system’s biggest problems in the late 1980s. To remedy this, numerous normative isomorphic attempts were undertaken in the late twentieth century to make all Dutch research ethics committees act in the same way. This emphasis on institutional homogeneity, I argue in conclusion, has been borne out in the Netherlands, even though it has repeatedly been criticized for hampering more democratic decision-making.

The analysis is based on a variety of sources. First, to trace the changing public debate on the Dutch governance of human experimentation in the second half of the twentieth century, I analyze parliamentary resources, newspaper articles, and discussion papers published in the two main medical journals of the Netherlands: the *Dutch Journal of Medicine* and *Medisch Contact*. Secondly, to gain a better understanding of why research ethics committees started to be established in the Netherlands in the 1970s and 1980s, I use archival materials and Festschriften published in relation to the Leiden Committee Medical Ethics (the first Dutch research ethics committee) as well as archival materials from Dutch funding bodies. Thirdly, to understand how these changes in the Dutch practice of research ethics governance eventually translated into policy, I use archival materials and policy reports from two government advisory bodies:

the Dutch Health Council and the Central Council for Public Health, as well as the publications from key policy advisors and further relevant parliamentary resources in the 1980s and 1990s. All translations of quotes are my own, unless otherwise stated.

1 The Hands-Off Attitude of the Dutch Government

Did public outrage over unethical human experimentation in medicine drive the establishment of the first Dutch research ethics committees? In the international literature, this suggestion has at times been made. Robert Baker, for instance, has pointed to the Netherlands as one of the first countries to publicly recognize and act upon the ethical principles laid down in the Nuremberg Code:

In 1954, [the WMA] issued formal *Principles for those in Research and Experimentation*, that reiterated the main themes of the Nuremberg Code [...] A year later the Public Health Council of the Netherlands issued guidelines that also attempted to implement and enforce the WMA *Principles* in clinical contexts through the institution of local research councils [later to be called institutional review boards, or IRBs].¹²

Indeed, as I have argued before, the Netherlands was relatively early in issuing ethical guidelines for human experimentation.¹³ It did so, not only after public complaints by antivivisectionists about unethical experimentation in Dutch hospitals had provoked the government to ask for the advice of the national Health Council, an expert medical advisory body to the Dutch government. It also did so, also because the Dutch physicians who gathered in the Health Council to write these guidelines showed genuine ethical concern about the human research studies that were increasingly published in Anglo-American journals under the banner of “clinical research” – even though they also sought to diffuse the damning antivivisectionist complaints by reassuring the government that nothing untoward was happening on this terrain in the Netherlands, and that the Dutch medical profession had a handle on things. One of the ways

12 Robert Baker, “Transcultural Medical Ethics and Human Rights,” in *Ethics Codes in Medicine: Foundations and achievements of codification since 1947*, ed. Ulrich Tröhler and Stella Reiter-Theil (Aldershot, 1998), 312–331, 319–320.

13 Jacobs, “A Moral Obligation to Proper Experimentation.”

they sought to demonstrate this was through their suggestion to implement local ethics review.

However, the Dutch government did not act on this suggestion in 1955, nor were any research ethics committees established in the Netherlands in the two decades thereafter. Quite the contrary, as I show in this section, every time that concerns were raised in Dutch politics in this period, the government brushed them aside as either unnecessary or unwanted. The point I want to make is not that public ethical concerns played no part at all in the emergence of Dutch ethics review. To claim such would be silly, if only because the international isomorphic influences that I discuss later might very well have been developed in response to research exposés. However, I show that public ethical concerns over research misconduct, in and of themselves, were never a *sufficient* cause for the realization of Dutch research ethics committees in the 1960s and 1970s.

One possible reason for this is that the Netherlands did not have a flourishing clinical research climate before the 1980s. Whereas the United States famously developed a clinical research infrastructure during the Second World War that was expanded and heavily funded in the post-war decades, clinical research for a long time remained a “cottage industry” in the Netherlands.¹⁴ Only after the mid-1970s did Dutch clinical research pick up, and only in the 1980s was it propelled to the international forefront due to strategic government investments.¹⁵ Before the 1980s, there simply weren’t that many clinical research studies conducted in the Netherlands that might be in need of ethical oversight.

Still, clinical research did occur and, at times, research scandals did come to the surface. In 1966, for instance, newspapers reported that the pharmaceutical company Philips-Duphar had tested anti-flu tablets on residents of an ‘insane clinic’ in Eindhoven: 250 out of 750 patients, as well as a few staff members, had been given these tablets instead of their yearly anti-flu vaccination to compare for their immunity.¹⁶ In the liberal newspaper *Algemeen Dagblad*, the authoritative Senator Arie Querido strongly condemned the tests: whether or not the pills turned out to be harmless, a line of principle had been crossed by conducting experiments on “the mentally disturbed.” “Even if it is just sugar water,” Querido was quoted to say, “the other end is the gas chamber.”¹⁷

14 David J. Rothman, *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making* 3rd ed. (New Brunswick, NJ, 2003 [1991]).

15 See: Timo Bolt, “A Doctor’s Order: The Dutch Case of Evidence-Based Medicine (1970–2015)” (PhD thesis, Utrecht University, 2015).

16 See: “Anti-griepmiddel op krankzinnigen beproefd,” *De Waarheid*, 17 September 1966, front page.

17 “Nieuw anti-griep preparaat toegepast in psychiatrische inrichting,” *Algemeen Dagblad*, 19 September 1966, 4.

In parliament, Querido requested the government to forbid all human experimentation in state-supervised facilities.

Scandals such as these, however, never became a “critical event” in the Netherlands. In 1966, the matter was easily settled by an admission from the government that such practices indeed should not take place, a reminder it promised to convey to the Superintendent for Mental Health and the Royal Dutch Society of Medicine (KNMG).¹⁸ Similarly, every time that foreign research exposés were covered by the Dutch media in the 1960s and 1970s, such as with the publication of *Human Guinea Pigs* in 1967 or the revelations of the Tuskegee scandal in 1972, they were treated as “foreign problems” by the Dutch media and did not translate, at least in writing, into heightened awareness that unethical human experimentation in medicine might present a problem “at home” as well.

In 1968, Dutch parliament did inquire about the permissibility of a new research method in medicine: the randomized controlled trial. In 1971, a Health Council committee led by pharmacologist Erik Noach concluded that this practice *should* be publicly regulated, with local review committees overseeing clinical research studies. In 1973, however, the incumbent Minister of Health rejected this proposal, as ethics review might “put a break on clinical investigations, which are necessary.”¹⁹

In 1975, the authoritative legal scholar Henk Leenen published two articles in the Dutch medical weekly *Medisch Contact*, in which he discussed Beecher’s 1966 article and recommended the installation of local ethics committees. In the United States, Leenen wrote, a similar system already existed.²⁰ Leenen’s articles were discussed in Dutch parliament, with members querying the government as to why such oversight mechanisms did not yet exist in the Netherlands.²¹ According to the State Secretary responsible, however, the existing Dutch disciplinary laws and oversight mechanisms for clinical practice were sufficient for clinical research as well. In addition, “the possibility of being held liable in civil courts for any possible damages in the treatment of patients (resulting from experimentation) will surely prevent irresponsible experiments.”²²

18 Aanhangel Eerste Kamer 1966–1967, nr. 19, 39.

19 See: Gezondheidsraad, *Advies inzake klinische farmacologie* (The Hague, 1982), 13.

20 Henk J.J. Leenen, “Juridische aspecten van medische experimenten op de mens (I) & (II),” *Medisch Contact*, 30 (1975): 746–750 and 753–767, 767.

21 Aanhangel van de Handelingen Tweede Kamer 1974–1975, nr. 1690, 1307.

22 Ibid., 1307.

In 1978, Henk Leenen became the chairman of a national Committee Rights of the Patient – a topic that at the time caused much disquiet in Dutch society and that led the government to request a series of reports on how to better protect the position of the patient in Dutch health care. In its request for advice in 1977, the government had indicated that also “the position of the patient in medical research and in teaching situations (demonstrations) *may deserve* consideration,” a statement which in itself indicates that human experimentation in medicine was still not a topic of immediate concern in Dutch policy-circles in the late 1970s.²³ In any case, the question of the position of the patient specifically in research did not make the Committee’s shortlist – a list that was drafted by Leenen himself. Hence, even the author of the articles that had provoked Dutch parliament to ask questions about human experimentation in 1975 did not consider the matter so urgent in 1978 to make it a part of a committee on patients’ rights. In the Netherlands, not many of the people in charge really seemed too worried about issue of human experimentation.

2 The First Dutch Research Ethics Committee

Even though the Dutch government showed little interest in the 1970s for the oversight of human experimentation, the first Dutch research ethics committee *was* established at the Academic Hospital and Medical Faculty of Leiden University in 1976. It was called the Committee Medical Ethics (CME) and was led by pharmacologist Erik Noach, who had also written most parts of the 1971 Health Council advice recommending the Dutch government to mandate institutional ethics review by law.

In 1979, Noach proudly reported in *Medisch Contact* that the CME had received more than sixty requests for ethical advice over the past three years, most of which had been handled within six weeks.²⁴ This advice was not binding and researchers were not obliged to ask the CME for advice. However, the academic hospital and medical faculty had agreed to be held liable only for clinical studies that the CME had authorized. This “threat,” Noach expected, would incite most researchers to pay the CME a visit. However, there was no

23 Adviesaanvraag inzake patiëntenrecht, 26 oktober 1977, Nationaal Archief, Den Haag (NL-HaNA), Centrale Raad voor de Volksgezondheid, access number 2.27.16, inventory number 803. *Italics* added.

24 Erik L. Noach and P.J.W.M. de Kroon, “Medische ethiek: patiënten en proeven. De Commissie Medische Ethiek in het Academisch Ziekenhuis en de Faculteit der Geneeskunde te Leiden,” *Medisch Contact*, 34 (1979), 1575–1583.

cause to fear the CME: protocols were always evaluated in consultation with the applicants, and procedures were designed to pose only a minimal burden. Researchers were encouraged to think of the CME as similar to collegial peer review rather than as a meddlesome form of surveillance.²⁵ Still, ethics review was needed, as “the regularly resurfacing view that patients particularly in teaching hospitals would be used as ‘guinea pigs’ can only be combatted with a clearly coordinated policy, particularly on ethical issues, that does not need to shun publicity.”²⁶

Noach, who remained an important voice in the Dutch debate over research ethics governance in the late twentieth century, stayed committed to this idea throughout his career: ethics review was needed to prevent unethical behavior and would as such help to restore and maintain public trust in the medical research establishment. What he did not point out in 1979, however, was that ethics review at the time was not necessarily experienced *solely* as a meddlesome form of interference. For ethics review was beginning to fulfill an important function for Dutch medical researchers in this period: at a time that clinical research was picking up in the Netherlands, those who sought to apply for extra-national funding or to publish in international journals, increasingly found out that ethics review was becoming an eligibility requirement for participation in the international research community. It was when this coercive isomorphic influence truly came into effect in the 1980s, I argue below, that Dutch research ethics committees shot like mushrooms from the ground.

First, I demonstrate the gradually growing importance of this coercive isomorphic influence by looking at the backstory of the Leiden CME. Although this committee was only officially established in 1976, Noach had been experimenting with ethics review in Leiden since 1965. In June of that year, the Leiden medical faculty received a letter from the scientific director of its Institute for Radio Pathology and Radiation Protection, stating the following:

Given the medical-ethical issues which the leadership of the Institute of Radio Pathology and Radiation Protection faces when it comes to making observations in human research subjects, I would appreciate it if you would install a faculty committee that may provide advice in such cases. It seems to me that it might be useful in general if a permanent faculty

25 Also: P.J.W.M. de Kroon, “De begintijd van de Leidse Commissie voor Medische Ethiek,” in *Geneeskunde en Ethiek in Harmonie. Liber Amicorum voor Prof.Dr E.L. Noach bij diens 80^{ste} verjaardag op 21 november 2001*, ed. F.A. Wolff (’s-Gravenhage, 2001), 93–95.

26 Noach and De Kroon, “Medische ethiek: patiënten en proeven,” 1581.

committee were to be created for medical-ethical problems which are related to research on human subjects.²⁷

In response to this request, the faculty board approached three colleagues – the scientific director, an internist, and the newly appointed professor in pharmacology Erik Noach – to write a report on the matter. In December 1965, they presented their report, in which they recommended the installation of a “permanent faculty committee” that could help formulate standards for human experimentation and help decide in specific cases if researchers acted in accordance with these standards.²⁸

At the time, the faculty board did not follow this advice, for reasons which are unclear. In the period thereafter, however, it did sometimes send clinical research protocols to the report authors with the request to evaluate their ethical permissibility. At first, Noach et al. were asked only to advise on *ultimum refugium* experiments: experimental interventions that were a last resort to save a patient. From 1967 onwards, however, they were also asked to review the occasional research protocol for a randomized controlled trial.

A letter by the Leiden medical faculty to the U.S. Department of Health, Education and Welfare from July 1967 provides insight as to why this development took place. It was written in the context of a grant-application and served to reassure the U.S. government of the following:

[...] In 1965, the Faculty of Medicine at the University of Leiden instituted a committee to investigate all proposed experimental procedures involving humans which are to be undertaken by the members of the faculty.²⁹

This was quite an exaggeration, given that Noach et al. by no means evaluated all or even most clinical research protocols in Leiden. In 1966, however, the U.S. Public Health Service (PHS) had made “prior review of the judgment of the principal investigator or program director by a committee of his institutional associates” an official eligibility requirement for those who wished to receive PHS-grants. Soon thereafter, this policy was also adopted by the U.S. Food and Drug Administration (FDA) and the U.S. Department of Health, Education and

27 D.P. Engberts, “De vroege jaren. Ontstaan en werkzaamheid van een medisch-ethische (toetsings)commissie in Leiden in de Jaren zestig van de vorige eeuw,” in *Dilemma's getoetst. Liber Amicorum voor prof.dr. H.M. Dupuis en prof.dr. P.Vermeij*, ed. D.P. Engberts, Y.M. Reidsma and A.R. Wintzen (Leiden, 2003), 9–28, 9.

28 J. Bennebroek Gravenhorst, “Medisch-ethische toetsing van wetenschappelijk onderzoek in Nederland,” in Wolff, *Geneeskunde en Ethiek in Harmonie*, 97–105, 98.

29 Engberts, “De vroege jaren,” 15.

Welfare.³⁰ Hence, from then onwards, Dutch researchers hoping to receive grant money from the PHS needed to have their human research studies monitored by “a committee of institutional associates.”

As both Adam Hedgecoe and Helena Tinnerholm Ljungberg have shown, this changing U.S. policy was a crucial coercive isomorphic influence for the development of the first research ethics committees, first in the United Kingdom and then in Sweden as well.³¹ In the Netherlands, however, only few clinical research studies were conducted in the 1960s and even fewer clinical researchers seem to have needed the services of “a committee of institutional associates”: only Leiden had some sort of review board in the late 1960s, and even this group disbanded after a few years of semi-active duty.

In November 1973, the Leiden medical faculty received another in-house request to install an institutional ethics board. The reason underlying this request, the applicant wrote, was that medical research increasingly seemed to be subjected internationally to “ethical demands.” Publications, in particular, “are [now] sometimes made dependent on the existence of a written verdict of an ethics committee”. Hence, it would be helpful if the Leiden medical faculty was willing to install a review committee that “can operate as official conscience and warranting agency.”³² Again, the faculty board commissioned Noach for a response, who explained that he had not taken any further steps on this terrain, since he had thought that the government would have filled this gap after his 1971 Health Council report. Still, since it now appeared that the government was not doing anything, he was willing to reactivate the faculty’s dormant ethics group. In June 1976, this resulted in the establishment of the Leiden CME, often taken to be the oldest Dutch research ethics committee.

In the late 1970s, Noach et al. worked hard to establish the CME as a self-evident authority for clinical researchers in Leiden. The 1979 article in *Medisch Contact* was part of this strategy. Still, international coercive isomorphic influences continued to play a key role in this period in pressuring researchers to actually engage with the CME. In 1980, for instance, news broke in the Netherlands that a Leiden internist had taken blood samples from fetuses aborted in the fifth month of pregnancy to investigate fetal blood coagulation processes.³³ Due to recent developments in chemical abortion techniques,

30 Stark, *Behind Closed Doors*, 154.

31 Hedgecoe, “A Form of ‘Practical Machinery’”; Helena Tinnerholm Ljungberg, “Regulating Research: The Origins and Institutionalization of Research Ethics Committees in Sweden,” in the present issue.

32 Engberts, “De vroege jaren,” 22.

33 Frits Gonggrijp, “Commissies gepasseerd: Bloemenhove liet experimenten toe na late abortus,” *De Telegraaf* (21 December 1979), 7.

fetuses were often left intact by the procedure and sometimes still showed signs of life such as muscular movement or a heartbeat.³⁴ Although there was no question of survival outside of the womb, newspapers soon reported that experiments were conducted on “live-aborted children” in the Netherlands.³⁵ In the months after the incident, a heated and emotional public debate broke out in the Netherlands about the moral permissibility of fetal experimentation. The internist, it quickly became clear, had never asked for permission to use these blood samples from the women who had undergone the abortions, although he did acquire the permission from the abortion clinic itself. Still, it was not this lack of the women's permission that had initially gotten him into hot water. Upon submitting his article to the *British Journal of Haematology*, the internist had been requested to procure evidence that his study had been conducted in accordance with the reigning ethical standards for clinical research in the Netherlands. To clear this hurdle, he had knocked on the doors of the Leiden CME. “A bit naïve that he did not already do so before he began,” Noach was quoted as saying by one newspaper. Nonetheless, he and his team agreed to take on an after-the-fact ethics review of the blood tests taken from the aborted fetuses.³⁶ A few months later, the *British Journal of Haematology* published the article.

3 The Mushrooming of Dutch Ethics Review in the 1980s

The Leiden CME was not the only research ethics committee active in the Netherlands at the end of the 1970s. In 1973, an ethics committee had been established at the Free University of Amsterdam that gave advice about euthanasia and abortion cases, but occasionally also about clinical research.³⁷ In 1977, a survey conducted by the Netherlands Organization of Applied Scientific Research (TNO) brought back that a “committee research subjects” had recently

34 Brief van de Hoofddirecteur Gezondheidszorg aan de Hoofdafdeling Staats- en Strafrecht, Ministerie van Justitie, 25 februari 1980, National Archive, The Hague (NL-HaNA), DG Volksgezondheid, access number 2.15.65, inventory number 2456.

35 “Bloemenhove experimenteerde al op levend-geaborteerde kinderen,” *Nederlands Dagblad*, 22 December 1979, 2.

36 Gonggrijp, “Commissies gepasseerd,” 7.

37 Lucas Bergkamp, “American IRBs and Dutch Research Ethics Committees: How They Compare,” *IRB: Ethics & Human Research*, 10 (1988): 1–6; see Brief van Chr. L. Rümke aan TNO, 01-04-1977, Nationaal Archief, Den Haag (NL-HaNA), Nederlandse Organisatie voor Toegepast Natuurwetenschappelijk Onderzoek (TNO): Gezondheidsorganisatie, access number 2.14.36.06, inventory number 481.

been established at the university of Rotterdam, and that small informal review groups were active at the universities of Nijmegen and Utrecht. TNO, however, was skeptical about the effectiveness of these committees. "With the exception of Leiden," an internal memo stated in 1977, "the situation with regards to monitoring the use of human subjects is so miserable at the Dutch teaching hospitals and medical faculties that it does not appear sensible to trust the judgment of these self-styled local committees."³⁸

This changed spectacularly in the 1980s. In 1981, the University of Groningen proudly announced that "after Leiden now also Groningen has its CME."³⁹ In 1985, Noach reported in *Medisch Contact* that 20 ethics boards were now active in the Netherlands.⁴⁰ One year later, legal scholar Lucas Bergkamp – writing a doctoral thesis on the Dutch regulation of human subjects research – already counted 63 of them. In a few years' time, Bergkamp predicted, their total would likely amount to more than a hundred.⁴¹ Sure enough, by 1989 their grand total was estimated to lie at around 150.⁴²

Commentators in the 1980s at times puzzled about the explosive increase in Dutch research ethics committees in the absence of any government regulations. However, if we approach this from the perspective of internationally coercive isomorphism, clear environmental factors can be identified. When Bergkamp asked 25 Dutch research ethics committees in 1986 why they had recently been established, two factors that scored high on their lists were changing grant and publishing policies.⁴³ By then, especially Anglo-American journals and funding bodies had made written approval of an ethics board a strict requirement for funding applications or article submissions involving human experimentation. These extra-national pressures, in other words, appeared to have played an important role in why Dutch biomedical research institutes started to develop similar governance structures in the 1980s.

Around 1980, Dutch funding bodies also began to adopt this policy. In 1978 and 1980 respectively, the Dutch Foundation for Fundamental Medical

38 Brief van T. Gerritsen aan H.G. van Brummen, 20-04-1977, NL-HaNA, TNO / Gezondheidsorganisatie, 2.14.36.06, inv.nr. 481.

39 "Medisch Ethische Commissie," *Medisch Contact*, 36 (1981), 776.

40 Erik L. Noach, "De functie van ethische commissies bij medische experimenten met mensen," *Medisch Contact*, 40 (1985), 872–874.

41 Lucas Bergkamp, *Medisch Ethische Commissies en het Toezicht op Experimenten met Mensen. Verslag van de eerste fase van een onderzoek naar de structuur en het functioneren van medisch ethische commissies* (Universiteit van Amsterdam: Instituut voor Sociale Geneeskunde, 1986), 204, 14.

42 E.J. Boer, "Medisch-ethische commissies, taak en functie bij wetenschappelijk onderzoek," *Nederlands Tijdschrift voor Geneeskunde*, 133 (1989): 1659–1664.

43 Bergkamp, *Medisch Ethische Commissies* [...] *Verslag van de eerste fase*, 28–29, 31.

Research (FUNGO) and TNO issued the same set of guidelines, stipulating that all grant applications for human subjects research now had to be accompanied by a positive verdict from a “committee research subjects.”⁴⁴ FUNGO and TNO declared themselves to be basing this policy on the 1975 Tokyo revision of the Helsinki Declaration, which demanded that all human research protocols should be submitted to “a specially appointed independent committee for consideration, comment and guidance.”⁴⁵ In *Medisch Contact*, this initiative was interpreted somewhat cynically by the philosopher Matthijs Visser as an attempt to “prevent outside interference by putting one’s own house in order” – a pre-emptive action that, if true, would point to elements of *mimetic isomorphism* in the rise of Dutch ethics review: in an uncertain and quickly changing medical research climate, two of the most influential Dutch financiers of clinical research decided it was better to keep in line with international developments than to await government regulations.⁴⁶ In turn, for Dutch biomedical researchers dependent on the funds of FUNGO and TNO, these new guidelines became additional *coercive isomorphic* incentives to push for the establishment of research ethics committees at their local institutions.

Indeed, when going through the archive of the committee that prepared the FUNGO-TNO guidelines, one comes away feeling somewhat ambivalent about the reason why these were promulgated precisely around 1980. In 1977, this committee, led by biochemist Theo Gerritsen, had set to work to formulate guidelines that would strictly limit the possibilities for conducting human experiments in the Netherlands. Section 6, for example, stipulated that human experiments were only ever to be allowed if no coercion had been exercised and that experiments with people in some way dependent on those carrying out the experiments – like employees and soldiers – should be discouraged. In addition, Section 6 contained a substantial list of people who should never be allowed to serve as research subjects; this list included children, “imbeciles,” “the mentally disturbed,” comatose patients, dying people, prisoners, and patients suffering from a disease other than the one studied.⁴⁷ However, when

44 Brief van TNO aan de directies van Academische Ziekenhuizen en besturen van Medische Faculteiten in Nederland, 1 April 1980, NL-HaNA, TNO / Gezondheidsorganisatie, 2.14.36.06, inv.nr. 481. See also: Matthijs B.H. Visser, “Nieuwe richtlijnen voor biomedisch onderzoek,” *Medisch Contact*, 36 (1981), 23–24.

45 Robert V. Carlson, Kenneth M. Boyd and David J. Webb, “The revision of the Declaration of Helsinki: past, present and future,” *British Journal of Clinical Pharmacology*, 57 (2004), 695–713.

46 Matthijs B.H. Visser, “Medische experimenten. Van experimenten op mensen naar experimenten met mensen,” *Medisch Contact*, 37 (1982), 711–713.

47 Voorlopige richtlijnen voor onderzoekingen met proefpersonen”, 12-10-1977, NL-HaNA, TNO / Gezondheidsorganisatie, 2.14.36.06, inv.nr. 481.

these draft guidelines were discussed by the board of TNO in February 1978, it became clear that not everyone in the upper echelons of the organization was equally enthusiastic about such strict guidelines.

One board member, in particular, had fundamental objections: "Human research will be seriously hampered on non-scientific grounds, on grounds of sensitive social repression, if Section 6 is accepted."⁴⁸ While it was important to protect research subjects, this board member argued, these guidelines also had to protect research from overly rigid regulations: "It would be disastrous for human research if universal guidelines are imposed, as these make very important research impossible through their formal and literal application, and this on pseudo-ethical grounds." One apparently only had to look at the United States for this fear to be confirmed. There, research was made impossible "on grounds that are little scientific and apparently ethical." Really, it was "unacceptable if human research is substantially curtailed under the guise of medical ethics."⁴⁹

Gerritsen, who had previously chaired an American IRB, tried to reassure this board member that he essentially agreed with such objections, which was why the guidelines had been "phrased sufficiently relativistic" and recommended local review committees that could decide on a case-by-case basis whether a research study was ethically acceptable or not, allowing them to make flexible decisions.⁵⁰ However, this admission was not enough to persuade the Executive Committee that the guidelines were ready to be published. In the months thereafter, Section 6 was watered down to state that experiments could "as a rule" not be conducted with special groups or with coercion and that, if researchers wanted to make an exception to this rule, they had to provide persuasive motives for it.⁵¹ While this addition saved Section 6 from elimination, it also gave researchers enough freedom to deviate from its recommendations if they felt this was needed. In an internal memo, Gerritsen concluded disappointedly that the guidelines were essentially a compromise: at a time that international pressure was mounting, they served to protect clinical research as much as they served to protect research subjects.⁵²

48 Gedeelte van de notulen van de vergadering van het dagelijks bestuur van de gezondheidsorganisatie TNO van 15 februari 1978 (78 H 02411), 3, NL-HaNA, TNO / Gezondheidsorganisatie, 2.14.36.06, inv.nr. 481.

49 Ibid., 1–2.

50 Ibid., 2.

51 Brief aan de leden van de Commissie Medische Ethiek Proefpersonen van Dr. Th. Gerritsen, 16 June 1978 (78 H 10984, B), NL-HaNA, TNO / Gezondheidsorganisatie, 2.14.36.06, inv.nr. 481.

52 Notitie aan de leden van het dbGO van Dr. Th. Gerritsen, 3 november 1978, Betreft: voorlopige richtlijnen voor onderzoekingen met proefpersonen. NL-HaNA, TNO / Gezondheidsorganisatie, 2.14.36.06, inv.nr. 481.

Still, even if the precise reasons of FUNGO and TNO for implementing the 1975 Helsinki Declaration might have been more ambiguous than they were publicly made out to be, the fact that, around 1980, two of the biggest sponsors of medical research in the Netherlands came to demand that all human research studies funded through their channels first had to go through ethics review became a significant driver in the realization of Dutch research ethics committees. As ethicist Maurice de Wachter wrote of this financial incentive in 1978: "Recently, one can recognize a trend of financial sponsors explicitly demanding safeguards [for human experiments] as a condition for funding." "What morality itself could not effectuate," the ethicist concluded both cynically and expectantly of this development, "will probably thus be achieved with some pressure on the purses."⁵³

Other international incentives had similar isomorphic effects. In 1981, the FDA reached an agreement with the U.S. Department of Health, Education and Welfare which mandated institutional review for all FDA-regulated activities involving human research subjects.⁵⁴ From there on out, clinical research studies regulated by the FDA could not commence before an IRB had given its permission. Although these regulations were not directly applicable to studies conducted outside of the United States, it is likely that pharmaceutical companies active in the Netherlands decided to comply with these conditions in order to be able to sell their products on the lucrative American consumer market. Likewise, the European Economic Community (EEC) began to develop harmonization requirements in the 1980s for products traded within its member states. In 1990, this resulted in the position paper "Good clinical practice for trials of medicinal products in the European Community," stipulating the need for prior ethics review of human research protocols.⁵⁵ While this document at the time only had the status of a "compelling recommendation," it is likely to have contributed significantly to the explosive rise of Dutch research ethics committees in the late twentieth century.

53 Maurice A.M. de Wachter, "Toestemming van proefpersonen," *Medisch Contact*, 33 (1978), 925–928, 925.

54 John C. Petricciani, "An Overview of FDA, IRBs and Regulations," *IRB: Ethics & Human Research*, 3 (1981), 1–3.

55 H.D.C. Roscam Abbing, "EG-aanbevelingen inzake experimenten met geneesmiddelen bij mensen," *Nederlands Tijdschrift voor Geneeskunde*, 134 (1990), 2124–2125.

4 “The Biggest Problem We Have to Deal with”

As a result of these developments, a dense and at times impermeable forest of research ethics committees had sprung up in the Netherlands by the end of the 1980s. These committees operated under various guises – interchangeably called institutional review boards, medical ethics committees, independent review councils, or ethics committees – with hardly any rules for their composition. Anyone, really, could claim the existence of a Dutch research ethics committee in the late 1980s.

People did. In 1987, general practitioners warned in *Medisch Contact* that “the Netherlands is (becoming) an international testing ground for all sorts of experimental research.”⁵⁶ In recent years, they claimed, they increasingly received requests from international pharmaceutical companies to enroll patients in clinical trials in return for financial rewards or lucrative gifts like a computer.⁵⁷ The Deputy Superintendent of Public Health confirmed these claims: in the past few years, the Dutch State Inspectorate had received multiple complaints from general practitioners about advances of Big Pharma, which would be drawn to the Netherlands because of its lack of systematic oversight.⁵⁸ Although the State Inspectorate tried to fill this lacuna as best it could, the Deputy Superintendent wrote half apologetically–half angrily, “it can only effectively perform this task, if a legal basis exists for it.”⁵⁹ In response, *Medisch Contact* published another letter, this time by two members of an unnamed Dutch research ethics committee angrily bemoaning that “the State Inspectorate apparently is not aware of the fact that an objective review option most certainly does exist.” Did the Deputy Superintendent not know the Foundation Independent Review Board was active in the Netherlands? And that it had been brought into existence to “advocate the importance of assessing the ethical and legal acceptability of extramural experimental research in an impartial manner, irrespective of any institution and without any commercial intention?”⁶⁰ Well, clearly, the Deputy Superintendent did not. From

56 E.G. Scholten, “Wetenschappelijk onderzoek huisartspraktijken,” *Medisch Contact*, 42 (1987), 1188.

57 J.W. van Ree and B. Bottema, “Wetenschappelijk onderzoek huisartspraktijken,” *Medisch Contact*, 42 (1987), 953.

58 Herman A. van Geuns, “Uit de Geneeskundige Hoofdinspectie: Medische experimenten in de huisartspraktijk,” *Medisch Contact*, 42 (1987), 694.

59 Idem, “Het Staatstoezicht en medische experimenten met mensen,” *Medisch Contact*, 40 (1985), 801–802, 802.

60 E.G. Scholten and L.H.B.M. van Benthem, “Medische experimenten in de huisartspraktijk,” *Medisch Contact*, 42 (1987), 953.

which one may either conclude that the State Inspectorate was not that well informed about these matters, or that the Dutch system of ethics review had become a bit inscrutable in the late 1980s, to say the least. As a result, even though research ethics committees had been envisioned by Noach in 1979 to establish trust in the medical research establishment, they were increasingly turning into objects of distrust in the Netherlands a decade later.

Between 1986 and 1988, legal scholar Lucas Bergkamp researched the daily functioning of Dutch research ethics committees.⁶¹ In two 300-page reports, he analyzed all rulings made by 22 committees in a single year, and wrote up his findings from three protocols that they had reviewed on his request, in which he had included a number of “methodological, ethical and informed-consent problems.”⁶² His analysis made clear that review standards differed in the Netherlands: not all committees under investigation had reviewed the methodological quality of protocols, most had different rules for the required competence of researchers, and they showed little consistency in their evaluation of informed-consent procedures. The cause for all this “variation and inconsistency,” Bergkamp argued, was the large number of committees active in the Netherlands, which made it impossible to “avoid big differences in composition, procedures, and especially employed standards of evaluation.”⁶³ Hence, even though international influences caused a jumble of Dutch research ethics committees to spring up in the 1980s, upon further inspection they turned out to be much less homogenous than initially assumed. What occurred, in other words, was not so much *isomorphism*, but what Hedgcoe calls *pseudo-isomorphism*: a process whereby institutions come to look similar on the face of it, but continue to differ significantly in their actual practice.⁶⁴ According to Bergkamp, in fact, this was “one of the most important problems which the [Dutch] review system by medical ethics committees currently has to cope with.”⁶⁵

Why was this considered a problem? Ethics review, one might have argued, is not an exact science. Hence, different committees might very well reach different decisions, depending on the researchers and protocols they have in front of them, and the particular values they wish to foreground. What is more,

61 Bergkamp, *Medisch Ethische Commissies* [...] *verslag van de eerste fase*; idem, [...] *verslag van de tweede fase* (Universiteit van Amsterdam: Instituut voor Sociale Geneeskunde, 1988).

62 Idem, “Variatie en inconsistentie in de beoordeling van experimenten door medisch ethische commissies,” *Nederlands Tijdschrift voor Geneeskunde*, 133 (1989), 446–449.

63 Boer, “Medisch-ethische commissies,” 1659.

64 Adam Hedgcoe, *Trust in the System: Research Ethics Committees and the Regulation of Biomedical Research* (Manchester, 2020), 5.

65 Boer, “Medisch-ethische commissies,” 1659.

different local committees might factor in different local circumstances to determine whether a protocol can responsibly be executed. Noach, for this reason, very much opposed uniformity in ethics review. As he stated in 1979: “[in research] there are always imponderable elements at play.” Only local committees could truly know their “pappenheimers” [darlings], and only they could therefore emphatically decide whether the research(ers) under review meant to do well.⁶⁶ Likewise, in the late 1970s the critical philosopher Matthijs Visser imagined research ethics committees to function as jury trials, where different groups of laypeople would determine if they found scientific research studies acceptable based upon the values that they personally found important.⁶⁷

By the mid-1980s, however, those involved in Dutch ethics review became increasingly concerned that, with ethics review fulfilling an important function for medical researchers, anything might pass as acceptable in the absence of government involvement, as long as the label “research ethics committee” was clapped upon it. In 1985, health ethicist Inez de Beaufort called for “supervision, coordination, and a certain degree of uniformity” in the jumble of research ethics committees she saw springing up in the Netherlands. This was needed, she argued, to avoid frustration and delays in multicenter trials, and to ensure that researchers trust the professionalism of Dutch review committees. What was more, uniformity would make sure that researchers would not pressure committees “with the argument that their ‘difficult attitude’ blocks a collaboration with other institutions, while another committee, note well, has already given a positive advise.”⁶⁸ In 1986, Bergkamp added “the danger of shopping” to this list: researchers could very well go round the existing committees until they had found one willing to give any research protocol its blessing.⁶⁹

To realize this uniformity, various attempts at *normative isomorphism* were undertaken in the 1980s: i.e., attempts to professionalize and standardize institutional ethics review in the Netherlands. In 1983, Noach started organizing a postgraduate course at Leiden with the up-and-coming health ethicist Heleen Dupuis, focusing on the “ethics review of medical experiments with human beings,” with all those active or interested in reviewing human research

66 8008 51, Notulen van de werkgroep ‘medische proeven op mensen,’ 19 November 1979, 2, NL-HaNA, Centr. Raad Volksgezondheid, 2.27.16, inv.nr. 554.

67 Matthijs B.H. Visser, “Ethische aspecten van medische experimenten op de mens (I) & (II),” *Medisch Contact*, 34 (1979), 1351–1358 and 1386–1390.

68 Inez de Beaufort, *Ethiek en medische experimenten met mensen* (Assen, 1985), 187.

69 Bergkamp, *Medisch Ethische Commissies [...] verslag van de eerste fase*, 166; idem, *Het proefdiert mens: De normering en regulering van medische experimenten met mensen* (Alphen aan de Rijn, 1988).

protocols invited to attend.⁷⁰ In 1984, the newly established Institute for Health Ethics in Maastricht started to offer training courses for members of ethics committees, teaching them the ins-and-outs of reviewing protocols. In 1987, the Dutch Hospital Council and the KNMG co-founded a “national station of support” with information for anyone involved in reviewing “experimental human and patient-related research.”⁷¹ And in 1991, the two organizations joined forces with an informal partnership of research ethics committees to found the Dutch Society for Medical Ethics Review Committees (NVMETC), which was to bring together experts of ethics review, influence national developments in this area, advance cooperation between local committees, and foster reliable and professional review procedures.⁷²

What thus more or less took place in the Netherlands in the 1980s was a process of attempted professionalization of a trade that had barely existed a decade before. The competent ethics reviewer adhered to a communal set of standards and practices, sat in on training sessions to refresh his or her reviewing skills, and was a member of a national society that oversaw the conduct of its members. In these attempts, much emphasis was put on the importance of expertise. Research ethics committees were in need of professionals who knew what they were talking about, and who were equipped to take on the growing number of protocols submitted for review every year. Unwanted variation could only be combatted by implementing nationwide standards that would be applied uniformly by qualified reviewers. Once reviewers were properly trained, it would matter no longer whether a protocol was submitted in Leiden or in Groningen: professional conduct would guarantee that the outcome of all reviews would be sufficiently similar if not the same.

5 The Lasting Effects of Institutional Isomorphism

As I have shown in this paper, the Dutch system of ethics review largely developed this way because the government for a long time took a hands-off approach in the oversight of human subjects research. Eventually, however, the Dutch government did get involved. In 1997, then Minister of Health Els Borst

⁷⁰ See: “Ethische beoordeling van medische experimenten met mensen. Boerhaave-cursus van het PAOG,” *Medisch Contact*, 38 (1983), 12.

⁷¹ “Landelijk steunpunt experimenteel mens/patiëntgebonden onderzoek,” *Medisch Contact*, 42 (1987), 606.

⁷² “Nieuwe vereniging wil deskundigheid leden van medisch-ethische commissies vergroten,” *Medisch Contact*, 46 (1991): 1409–1410.

brought a bill before parliament that proposed to regulate human subjects research in the Netherlands with a two-tier system: a limited number of local research ethics committees that would be overseen by a Central Committee that would itself take on particularly controversial research protocols, such as studies that involved gene editing or embryo research.⁷³

At the time, the majority of parties in Dutch parliament wanted these research ethics committees to also fulfill a democratic function: many felt that every committee should seat at least one layperson, and that the Central Committee should take the variety of ethical viewpoints in Dutch society into account when making decisions about controversial research studies. As I explain elsewhere, these proposals were much more in line with a very different governance function of research ethics committees that had circulated in Dutch public debate in the 1970s and 1980s: i.e., that they would function as public bodies in which ordinary citizens could participate.⁷⁴ As “only democratic decision-making is acceptable,” philosopher Matthijs Visser argued in 1979, research ethics committees had to operate as jury trials, allowing laypeople to oversee the conduct of biomedical researchers.⁷⁵

The problem with these amendments in the late 1990s, however, was that they were an ill fit for a system that had already congealed around the idea that ethics review should proceed predominantly with uniform procedures and professional reviewers. As a participant to a Dutch conference on “the task and function of medical ethics committees in scientific research” had put it in 1989: “We must prevent that all and sundry can take up a seat in such committees and join in on conversations they don’t understand.”⁷⁶ Els Borst essentially agreed with this assessment. In Dutch parliament, she professed that she saw no use for the participation of laypersons. First of all, she argued, anyone taking part in the review of scientific research could only ever contribute in a meaningful way if they had a big enough understanding of the protocol under review. Hence, no competent reviewer could ever really be called a layperson. Secondly, if laypeople participated to represent interest groups such as patients or research subjects, they would undermine “the independent assessment of a research protocol” and increase the danger that “personal or commercial interests influence the assessment of protocols.” Thirdly, Borst

73 Wet van 26 februari 1998, houdende regelen inzake medisch-wetenschappelijk onderzoek met mensen (Wet medisch-wetenschappelijk onderzoek met mensen).

74 See chapters 3 and 4 of Noortje Jacobs, *Ethics by Committee: A History of Reasoning Together about Medicine, Science, Society, and the State* (Chicago, IL, 2022).

75 Visser, “Ethische aspecten van medische experimenten op de mens.”

76 Boer, “Medisch-ethische commissies,” 1662–1663.

considered it redundant to let laypeople participate to ensure that “opinions from outside medical circles are expressed” or that “reviewers do not start to identify with researchers.” The need to counteract the dominance of researchers, she argued, was already fulfilled by the contribution of “experts on the terrain of law, research methodology, and ethics.”⁷⁷

Borst eventually convinced Dutch parliament that the main problem with the Dutch review system was not that many questionable research practices currently took place that could not bear the light of day. The main problem was that it had sprawled in the absence of public regulation: variation and inconsistency were some of the biggest problems that the government had to deal with. Hence, her human research bill proposed to strictly limit the number of Dutch research ethics committees and to impose strict rules upon their composition and functioning.

In the early 2000s, when the Dutch Medical Research Involving Human Subjects Act (WMO) went into effect, this was precisely what happened. In a few years’ time, the number of Dutch research ethics committees – or medical-ethics assessment committees (METCs), as they officially came to be called – was reduced to a few dozen. Today, only eighteen receive “accreditation” from the Dutch Central Committee on Research Involving Human Subjects (CCMO).⁷⁸

In 2001, in a Festschrift in honor of Noach’s eightieth birthday, ethicist Heleen Dupuis – by then considered one of the doyennes of her field – lashed out in no uncertain terms at this development. Citing letters from the CCMO, threatening local METCs to take away their accreditation if they did not carry out the regulations laid down in the WMO in a uniform manner, Dupuis concluded bitterly:

Moral pathos has disappeared, to be replaced by managerial arrogance and a mania for organization. The patient, who started all this, has disappeared from view, the review committees are threatened with punishment like naughty children if they do not follow [by the CCMO formulated] procedures.⁷⁹

By overly emphasizing rules and regulations, Dupuis felt, ethics review in the Netherlands had become a “bureaucratic straitjacket.”⁸⁰

77 Tweede Kamer 1995–1996, Kamerstuk 22588, nr. 7, 53.

78 See: www.ccmo.nl/metcs/erkende-metcs, accessed 24 July 2021.

79 Heleen M. Dupuis, “Ethische aspecten van experimenten met mensen,” in Wolff, *Geneeskunde en Ethiek in Harmonie*, 155–163, 161.

80 Ibid., 159.

Today, Dupuis' comment remains a familiar catch-phrase for those frustrated with the strict and lengthy procedures that institutional ethics review can bring with it. And, indeed, the dominant refrain refers back to the patient who "started all this": that research ethics committees first emerged in the Netherlands to protect patients from possible research misconduct and to give critical outsiders a voice in the oversight of medical research. However, as this paper has shown, in the Netherlands ethical concerns for the position of patients in clinical research were never a decisive environmental factor in the establishment of research ethics committees. Instead, the decisive factor was the function that ethics review came to fulfill around 1980 for Dutch medical researchers in an internationally changing scientific landscape. It was out of the layered processes of institutional isomorphism that followed this change, that the current system of Dutch ethics review was born.