

# Clinical trials, social movements and bioactivism: notes for a(nother) genealogy of the Brazilian research ethics system<sup>1</sup>

Ensaio clínico, movimentos sociais e bioativismos: notas para uma (outra) genealogia do sistema brasileiro de ética em pesquisa

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## Abstract

A significant part of the literature on the genesis of the Brazilian institutions devoted to the ethical regulation of scientific research involving human beings usually recalls international events, such as those that occurred during and after the II World War, as triggers of a global ethical conscience of which Brazil would have taken part. Based on review of literature, and a genealogical approach, this essay investigates how certain events that occurred in Brazil, such as the actions of social movements in face of clinical trials with Norplant in the 1980s and with antiretrovirals in the 1990s, are fundamental for understanding the different moments of institutionalization of **research ethics** in Brazil, and its political orientations. Based on the reconstruction of these episodes, it is argued that particular contents of public agendas on biomedical scientific practices were anchored in specific contexts of contestation led by social movements, whose political demands were described in notably ethical terms. The historical configuration of **research ethics** in Brazil gathers subjects, factors, and political struggles that provide it with a dynamic character. Understanding this context demands considering the actions of social movements aimed at the regulation of clinical trials.

**Keywords:** Research Ethics; Social Movements; Social Activism; Biomedical Technology; Science, Technology, and Society.

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## Resumo

Parte significativa da literatura sobre a gênese das instituições brasileiras voltadas à regulamentação ética de práticas de pesquisa científica envolvendo seres humanos costuma remontar a eventos internacionais, a exemplo dos ocorridos durante e após a Segunda Guerra Mundial, como disparadores de uma consciência ética global da qual o Brasil teria tomado parte. A partir de revisão de literatura e recurso de abordagem genealógica, investiga-se como certos eventos ocorridos no nosso país, como a atuação de movimentos sociais frente aos ensaios clínicos com Norplant, nos anos 1980, e com antirretrovirais (ARV), nos anos 1990, são fundamentais para a compreensão de distintos momentos de institucionalização da ética em pesquisa no Brasil e suas respectivas orientações políticas. Com base na reconstrução desses episódios, argumenta-se que os conteúdos particulares das agendas públicas sobre as práticas científicas biomédicas se ancoraram em contextos específicos de contestação, cujas demandas políticas foram agenciadas em termos notadamente éticos. A configuração histórica da ética em pesquisa no Brasil conjuga sujeitos, fatores e lutas políticas que lhe conferem um caráter dinâmico, cuja compreensão demanda levar em conta a atuação de movimentos sociais com relação à regulamentação dos ensaios clínicos.

**Palavras-chave:** Ética em Pesquisa; Movimentos Sociais; Ativismo Social; Tecnologia Biomédica; Ciência, Tecnologia e Sociedade.

## Introduction

Established in 1996, the Brazilian Commission on Ethics in Research (*Comissão Nacional de Ética em Pesquisa*, Conep) and the Committees of Ethics in Research (*Comitês de Ética em Pesquisa*, CEP) bound to it perform regulatory, review, management, surveillance and education duties related to the ethical conduct of scientific research involving human beings in Brazil (Brasil, 1996). In its 25 years of existence, several critical reviews of the CEP/Conep System have been conducted, paying attention to persistent or emerging issues that demanded attention from authorities and the general public (Marques Filho, 2007; Novoa, 2014; Amorim, 2019).<sup>2</sup> The objective of this article, however, is another one: to propose a genealogy of the CEP/Conep System that, placing canonical narratives of its construction provisionally in abeyance, reconstitutes some threads of its history based on disputes, tensions, and conflicts related to the institutional regulation of clinical trials, with a focus on initiatives led by social movements and civil society organizations.

The historical literature on the constitution of ethics in research in Brazil usually relates its genesis to a series of flows, neglecting the participation of social movements and the contexts of conflict at the moments of its institutionalization. The enactment of the first resolution on the subject, in 1988, is attributed to events such as the monitoring of international trends of scientific practices regulation (Guilhem; Greco, 2008), medical initiatives driven by the identification of a normative vacuum on clinical research (Hossne et al., 2008), demands from researchers for legal support to the pharmaceutical industry activities, or even requests from health surveillance agencies (Freitas, 2006). All these analysis make clear the silence about the actions of patient groups, social movements and activists as vectors for building a public agenda of ethics in research, constituted from local situations, and politically articulated in ethical terms.

2 For critical reviews of the CEP/Conep system, see Fleischer e Schuch (2010); Sarti e Duarte (2013); Sarti et al. (2017).

On the other hand, literature highlights that since 1988 the ethical regulation of scientific research has been carried out by the National Health Council (*Conselho Nacional de Saúde*, CNS). Established in 1937 for consultative purposes, and to advise the head of the then Ministry of Health and Education, during the re-democratization process, the CNS has gradually become an arena for meetings and clashes between different social actors, ensuring the participation of groups, institutions, organizations, and social and union movements (Côrtes et al., 2009). As of the 1990s, the CNS and the state and municipal Health Councils took on a deliberative character, and the representation of users of the Unified Health System (SUS) became “of parity nature in relation to the other segments as a whole” (Brasil, 1990), assigning them half of the seats in these instances.

In this context, in which the CNS has made room for social participation, several analyses have called attention to the insertion of **research ethics** agencies with social control as a distinctive mark of the Brazilian ethical-regulatory system (Freitas; Hossne, 2002; Guilhem; Diniz, 2008). However, the shortages and limitations of Resolution 01/88, as well as the low adherence of research organizations to the document, are usually pointed out as the core reasons for its revision and replacement by Resolution 196/1996 (Freitas, 2006; Guilhem; Greco, 2008), to the detriment of the coordination of social movements for the construction of a **research ethics** agenda. Both in 1988 and 1996, intense public debates were on the scene in Brazil approaching the regulation of clinical trials involving contraceptives and antiretrovirals, respectively, led by social movements and patient organizations, putting into play several demands regarding scientific practices (Pimentel et al. 2017; Oliveira, 2001).

In view of these events, I propose in this article the construction of notes for a(nother) genealogy, which incorporates elements that little come up as components of its foundation and ethical-political grounding. Two fundamental historical episodes in the construction of regulatory instances of **research ethics** in Brazil will be revisited, focusing on the efforts by civil society organizations toward mobilizing a public and political agenda focused on the regulation of research with humans. In order to

update this approach, I briefly discuss a more recent context that makes clear the engagement of rare disease groups in the discussion of the process of reviewing Resolution 196/1996, and the publication of Resolution 466/2021 (Brasil, 2012) that replaced it and is currently in force. In this panorama, analytical approaches shall be made regarding different modes of framing clinical trials and engaging civil society groups in discussions about scientific practices, and the respective senses of **ethics** in these situations.

## Regarding a genealogy

The genealogical notes in this paper draw on the reflections of Michel Foucault (2008a, 2008b) in strategic and methodological terms, considering how genealogy may develop as a tactic for demobilizing hegemonic discourses, and the ways in which its procedures may be pragmatically triggered. According to Foucault, a genealogy is distinct from unifying or essentializing propositions in the historical context, which he calls “research of the ‘origin’” (2008b, p. 16). In undertaking a genealogy, one refuses the excavations in search of a primordial gene that holds within it the necessary development of future events, a fundamental or metaphysical explanation of events, or a transcendental subject that would emanate universal values, tendencies, or inclinations. Instead, it looks for accidents, irruptions, and discontinuities, in whose beginning what one finds is not an untouched essence, but “the discord among things, it is nonsense” (Foucault, 2008b, p. 18, free translation).

In his genealogical proposal, Foucault articulates two notions from Friedrich Nietzsche: provenance and emergence. While the former designates a type of research that, according to Foucault, “does not found, quite the contrary: it shakes what was perceived to be immobile, it fragments what was thought to be united; it shows the heterogeneity of what was imagined to be in conformity with itself” (2008b, p. 21, free translation); emergence signals “the entry into the scene of forces; it is their interruption, the leap by which they pass from the backstage to the theater, each with its own vigor and its own youth” (2008b, p. 24, free translation). By approaching both elements, genealogy suspends the built-up

discourses about an object and draws attention to the unique gathering of forces and devices in dispute in a particular context. “Genealogy restates the many systems of submission: not the anticipatory power of a sense, but the causal play of dominations” (2008b, p. 23, free translation).

Foucault also highlights a political dimension of genealogy, related to its mobilization as a method. If, in synchronic terms, it is “meticulous and patiently documentary” (2008b, p. 15), implying the survey of a series of sources and records; diachronically, the historical recovery of the struggles of forces constituted, especially in the 1950s and 1960s, a strategy to cope with the epistemic and institutional hegemonies of the medical, legal, and academic fields in the French context. According to the author, in that context of insurrection of the subjugated knowledges<sup>3</sup> (2008a, p. 170), genealogical researches supported a series of “dispersed and discontinuous offensives” (2008a, p. 168). This process, in turn, allowed the reemergence of genealogy as an activity that, by “activating local discontinuous, disqualified, non-legitimized knowledges against the unitary theoretical instance that intended to debug, hierarchize, order them in the name of a true knowledge, in the name of the rights of a science held by a few” (Foucault, 2008a, p. 171), articulating a series of relations that “allow the constitution of a historical knowledge of struggles, and the use of this knowledge in current tactics” (Foucault, 2008a, p. 171).

Following this genealogical proposal, this essay performs two interrelated movements. First, sources and official documentary records, academic articles, public reports and journalistic publications will be revisited to outline the struggles of forces involving the conduct of specific clinical trials at times when the institutionalization of the field of ethics in research in Brazil was approaching. However, less than taking them as events that carried the germ of an ethical

debate about scientific practices, this essay seeks to understand how players involved in these practices ethically articulated the confronts about experimental practices. I will also highlight the specific contents of research ethics agendas articulated by social movements and bioactivists,<sup>4</sup> in the field of relations they started sharing with scientists, pharmaceutical laboratories, medical authorities, and public administrators.

Two clinical trials will be described. The first of them concerns the research with the Norplant contraceptive implant, carried out in the 1980s. Here, the description will explore the correlations with the release of the first normative ruling on ethics in research in Brazil - Resolution 01/88 (Brasil, 1988). The second study, called *Protocolo 028*, was aimed at investigating the safety and efficacy of Indinavir, an antiretroviral drug developed in the 1990s. The study was interrupted amid clashes between scientists and bioactivists in the field of HIV/AIDS. This was one of the first official acts of the then recently founded Conep, in 1996. As we resume these moments, we are facing not only the debate on the main documents of ethical regulation in Brazil, but the presence of a series of public, scientific and economic debates about the regulation of scientific practices, the role of the State, and the rights of citizens.

## The Norplant study: democratic transition, feminist movements, and the role of the State

Norplant was developed by the Population Council, an institution founded by the Rockefeller Foundation in 1952. It started being studied in the 1970s as part of an international effort to develop technologies aimed at population control in countries then called the “Third World” (Manica, 2009).<sup>5</sup> Norplant is a

3 Subjugated knowledges are those considered “unqualified” or “below the required level of knowledge or scientificity,” notably those coming from “the psychiatrized, the patient, the nurse, the parallel and marginal doctor in relation to medical knowledge, the delinquent, etc.” (Foucault, 2008a, p. 170, free translation).

4 Here I get the notion of bioactivism closer to that of biosocial activism by Valle (2015), which points to biosocialities articulated in the production of identities based on the sharing of genetic mutations or diagnoses (Rabinow, 1999) and, above all, to processes of struggle for rights based on such relations.

5 In the 1990s, the use of Norplant was extended to birth control for Black women in the United States, especially those living in urban peripheries (Roberts, 2017).

contraceptive implant composed of six rods that are inserted subcutaneously through a surgical procedure, which slowly releases the hormone levonorgestrel and inhibits pregnancy for up to five years. In 1980, Norplant was registered, and “expanded” or “pre-introductory” clinical studies were initiated in countries such as the United States, Finland, Indonesia, India, Chile and Brazil. The purpose was less of investigating its safety and efficacy than to publicize the implant in the medical-scientific environment, train professionals to handle it, check its effectiveness and acceptability with users, and prepare its introduction into family planning programs (Reis, 1990; Corrêa, 1994; Pimentel et al., 2017).

The study in Brazil began in 1984, under the coordination of physician Aníbal Faúndes, a researcher at the Center for Research and Control of Maternal and Child Diseases of Campinas (*Centro de Pesquisa e Controle das Doenças Materno-Infantis de Campinas, Cemicamp*) (Pimentel et al., 2017). However, several events led to its interruption in early 1986, among which are highlighted those that, by pointing criticism to some contraceptive technologies, contributed to the thickening of an agenda related to scientific research regulation. In that period, several strategies to fight policies on population control, especially those led by international organizations, and criticism to national health policies that failed to guarantee women’s access to contraceptive technologies gained prominence. In 1986, for example, Black feminist groups in the state of São Paulo reported “the interests of governments and international agencies in controlling the birth rate of the Black population, by inducing the indiscriminate use of contraceptives, especially sterilization” (Geledés, 1991, p. 9).

In the context of greater participation of civil organizations in decision-making agencies in the executive branch, the Commission for the Study of the Rights of Human Reproduction (*Comissão de Estudos dos Direitos da Reprodução Humana, CEDRH*) was established within the Ministry of Health in 1985. That group, formed by representatives of the Ministries of Education, Foreign Affairs and Social Security, also included members of the Federal Council of Medicine (*Conselho Federal de Medicina, CFM*) and the National Council of Women’s Rights (*Conselho Nacional de Direitos da Mulher*) that represented feminist groups and

parliamentarians (Reis, 1990). Soon after its foundation, the CEDRH deliberated a review of the Norplant study, provoked by denouncements about the ongoing research in Brazil. Based on its report, the Drugs Division (*Divisão de Medicamentos, Dimed*) of the Ministry of Health suspended the study in January 1986 (Pimentel et al., 2017). The investigations about the study, as well as the decision for the interruption, were directly associated with the action by feminist movements. As Suely Rozenfeld, who held the position of Director of Dimed at that time, reported: “When I took over, in 1985, a sanitarian, feminist doctor, Ana Regina Reis, sent a warning signal about the need to look into the matter” (Zorzanelli, 2018, p. 4, free translation).

The complaints about the Norplant study procedures comprised a series of technical, material, scientific, operational and gender elements, whose content gradually took on ethical traits in the discourses and practices of activists, public managers, researchers, and doctors in the field of public health. This process becomes evident when we take into account the content of reports and studies about Norplant, notably those produced by the CFM and by feminist researchers, in contrast with the norms for experimental therapeutic research in force at the time: CNS Normative Resolution 1/1978 (Brasil, 1978) and Administrative Rule no 16, published in 1981 by the National Division of Drugs Sanitary Surveillance (*Divisão Nacional de Vigilância Sanitária de Medicamentos*) of the Ministry of Health (Brasil, 1981).

Following the suspension of the research authorization, the CFM issued a technical statement at Dimed’s request, in which it identified that the research had been initiated without requesting the “due authorization” from Dimed and the Cemicamp’s Ethics Commission. It also identified the absence of provision for assistance and follow-up, and the significant increase in the number of research centers and women in the sample (from 7 to 18 and from 2000 to 3103, respectively) (CFM, 1986). The report drafted by the Ministry of Health, in turn, identified that “several women did not know they were participating in a research, and that the method was distributed as an alternative form of contraception; the clinics did not meet the criteria for participation in the tests, and very often the method was imposed on women” (Ministry of Health Working Group, 1987 *apud*

Reis, 1990, p. 3, free translation). The very material specificities of Norplant were questioned in ethical terms, considering that, as cisgender women would be users of the implants, “the technical and non-technical characteristics of the method enable situations of abuse” (Corrêa, 1994, p. 89).

In this context of public contestation of scientific practices, the support offered by the regulations in force to protect women involved in the studies was ambiguous. Normative Resolution 1/1978, for example, focused mainly on the establishment of “a system for therapeutic experimentation” to support the process of drug registration analysis, reserving for “ethical aspects” only the following lines: “configure obedience to what is stated in the Helsinki declaration, in which, for therapeutic research, *at the discretion of the researcher*, the patient’s consent *may* be obtained verbally or in writing, *when deemed convenient*” (Brasil, 1978, p. 16748, free translation - emphasis added). Thus, the document allowed the researcher to obtain consent from the research subjects, without mentioning the provision of information about the research to its participants.<sup>6</sup>

In this same sense, although it listed considerations to the “risks eventually involved in new therapeutic procedures” and “the ethical duties on the part of the assistant physician and the laboratories that produce new drugs”, Ordinance No. 16 of Dimed (Brasil, 1981) established in the “Risk Awareness Form” a series of measures mainly focused on the exemption of liability of public agencies in cases of deleterious effects of the use of experimental or non-registered technologies in Brazil. Four items in the document were focused on the subjects’ statement that they were “aware” that the product used had no evaluation or recommendation by the Brazilian government; there was no certainty about the risk-benefit relationship; and they used it of their own free will. The ordinance also provided that “the physician who applies this medication or new method is responsible and the producing laboratory is co-responsible for the

medication, *the Federal Government being exempt from responsibility for any damage that may occur to the patient resulting from the use of the product or therapeutic method applied*” (Brasil, 1981, p. 23746, free translation - emphasis added).

In this context, feminist social movements, including those led by Black women, produced an agenda concerning the regulation of clinical research in Brazil, especially those involving reproductive technologies and contraceptives. Its ethical content concerns less the shortage of laws or its challenging by scientists than a set of proposals related to the interposition of mechanisms of governmental and social control of scientific practices, aiming to contain abuses and guarantee social participation. Core elements of this agenda are found, for example, in the report of the National Conference on Health and Women’s Rights (*Conferência Nacional de Saúde e Direitos da Mulher*, CNSDM), held from October 10 to 13, 1986, under the auspices of the 8<sup>th</sup> National Health Conference (*Conferência Nacional de Saúde*). In the section “Rights of human reproduction,” there are claims such as:

Investment in research on contraceptive methods of popular and alternative medicine; control of research on human beings, so that women from the Third World do not continue to serve as guinea pigs; endowment of resources to the SNVS, through DIMED (government agency in charge of surveillance on medicines and research development, with norms already established in this regard), in the sense that it may enforce the law [...].

All research programs with women or men to be carried out in the academic sphere, as well as in health services, should be discussed and approved by the competent organs, after hearing the representative entities of health professionals and organized segments of civil society (Brasil, 1987, p. 13).<sup>7</sup>

6 While the Normative Resolution 1/1978 established that clinical trials should be submitted to the CNS’ Medicines Chamber for authorization, the CFM recognized that “it is unusual for university researchers to inform the DIMED of their research” (CFM, 1986, p. 2, free translation). Thus, despite the existing legal provisions for the government to regulate scientific research, researchers were apparently unclear about the specific agency to which they should submit their protocols.

7 The report also comprises demands for “vetoing the participation of persons committed to controlling practices as representatives of Brazil in international organizations”, Elsimar Coutinho and Aníbal Faúndes being cited by name (Brasil, 1987, p. 13); and evaluation of research in human reproduction, both those in progress and those cancelled (Brasil, 1987, p. 14).

Some of these elements were comprised ambiguously and asymmetrically in the CNS Resolution 01/88, considered the first resolution on health research ethics published in Brazil.<sup>8</sup> The resolution instituted the “Post-information Consent” (*Consentimento Pós-Infirmação*), which detailed a series of information and guarantees for research subjects, and established a section of rules for research on women of childbearing age, pregnant women, and during labor, puerperium, and lactation. Questions about contraception, however, were not directly listed. Furthermore, it was established that it was only necessary to “inform” the National Division of Health Surveillance (*Divisão Nacional de Vigilância Sanitária*) of the Ministry of Health, and the health institution where the research was to be conducted, with the approval of the Ethics Committee of the unit prior to conducting the research (Brasil, 1988). Despite the limitations in regulatory terms, based on the multiple actions aiming at the termination of the clinical trial with Norplant and proposition of a series of questionings about scientific practices, the feminist movements established a public agenda about ethics in research by means of which “scientific isolation was broken” (Barroso and Corrêa, 1990 *apud* Corrêa, 1994, p. 86, free translation).

## Protocol 028: challenged science, bioactivism and access to treatment

The effectiveness of Resolution 01/88 during the period it was in effect was quite limited, and few Ethics Committees were created for research evaluation (Francisconi et al., 1995). According to the CNS, the 1988 normative was not applied, due to disagreement or ignorance of the scientific community, and operational and technical difficulties of the institutions responsible for housing the committees (Conep, 1998). According to a significant part of the literature these factors,

associated with the increased participation of the Brazilian scientists in international projects (Freitas, 2006), and the persistence of complaints about research involving contraceptives (Hardy et al., 2004), drove a broad and complex process of review and replacement of the document. In 1995, a Working Group<sup>9</sup> was created by the CNS, and its members were responsible for activities such as: sending Resolution 01/88 to about 30,000 people and institutions in the fields of health and education, consulting them about any comments and suggestions for the construction of a new normative; analysis and systematization of the 119 responses received; survey of ethical guides from 18 countries; holding seminars and lectures; and presentation of a draft resolution in the I Brazilian Congress of Bioethics (*Congresso Brasileiro de Bioética*) (Hossne et al., 2008). At the end of the WG’s work, in October 1996, the famous Resolution 196/1996 (Brasil, 1996) was published, replacing Resolution 01/88.

Avoiding a historicization restricted to insufficient adherence to Resolution 01/88 and a “natural” need to update it, this section evokes the processes associated with the clinical trial initiated in Brazil in 1994 with the antiretroviral drug Indinavir (MK-639) as crucial for understanding the context in which new political elements emerged on the national public setting, and contributed to the development of a new ethical regulation. The drug, produced by the pharmaceutical company Merck Sharpe & Dohme (MSD), was part of a phase III clinical trial known as “*Protocolo 028*” (Oliveira, 2001). The context in which the study was conceived was complex - with the advancement of the HIV epidemic in Brazil in the 1980s, and the meager public health policies in place, activist groups formed and established a series of collective health practices and bioactivism,<sup>10</sup> such as mutual aid, exchanges of experiences, production of expertise in care, contact with doctors from different specialties,

8 Resolution 01/88 revoked and replaced Normative Resolution 1/78 and Administrative Rule No. 16 of 1981.

9 The WG included representatives of the CFM, the National Feminist Network for Health and Reproductive Rights, the National Confederation of Brazilian Bishops, the Brazilian Bar, the Brazilian Association of the Medical-Dental Equipment Industry, the Health Surveillance Secretariat of the Ministry of Health, and members of patient NGOs, among other institutions.

10 For an overview on activism related to the history of AIDS in Brazil, see Longhi, Franch, and Neves (2015).

and establishment of connections with international movements (Bastos, 2002; Valle, 2015).<sup>11</sup>

Protocol 028 was initiated in Brazil in 1994, with prospects for recruiting HIV-1 seropositive adults in the city of São Paulo. The study was enthusiastically received by some organizations of people living with HIV, such as *Grupo Pela Vidda* that, in 1995, publicly demanded the MSD to expand the inclusion criteria in the study. At that time, the study was absorbed as an option for treatment and differentiated care, in opposition to the difficulties of access to treatment in public and private healthcare services (Oliveira, 2001). On the other hand, the Brazilian researchers responsible for the protocol signaled difficulties in including subjects in the research, given the inclusion criteria of subjects without symptomatic manifestations and “treatment naïve” (Folha de S. Paulo, 1995). The initial enthusiasm of HIV/AIDS activists cooled off, however, when changes in the international scientific scenario on antiretrovirals were identified as elements that put the design and ethics of the study under suspicion.

*Protocol 028* was organized in three parallel experimental arms, in which the allocation of research subjects was randomized and double-blind, i.e., neither they nor the research team knew to which group they would be assigned. In one arm, subjects received Indinavir and Zidovudine (AZT), and in the other two, these same drugs were administered in isolation. When, in late 1995, study results were published indicating therapeutic superiority of combined antiretroviral drugs when compared to AZT alone, Brazilian bioactivists started demanding MSD and researchers to change the protocol (Oliveira, 2001). Considering that the maintenance of monotherapies in the research groups would be unethical, the bioactivists pressured the company and got the research design to include an additional antiretroviral, 3TC, in two arms of the research (Scheffer, 2000).

The company, however, refused to change the administration arm from Indinavir alone to a placebo, in order to guarantee the double-blind design of the trial. The MSD and the Brazilian researchers in charge of the study resisted the addition of an antiretroviral in this arm of the study, under allegations of harm to the trial methodology and lack of sufficient evidence for the combined use of antiretrovirals (Folha de S. Paulo, 1996). Of the nearly one thousand subjects in the study, about 300 were kept on monotherapy (Oliveira, 2001). In face of the impasse, debates quickly became heated: researchers refuted the criticism, affirming that “ethical-scientific questions aimed at affecting the competence and probity of the Brazilian researchers”, and that the study did not contain any error, because its protocol and consent form had been approved by the appropriate instances, and all patients signed the document (Motti, 1996). Bioactivists, on the other hand, insisted that it was unethical to keep hundreds of people under-treated. At the same time, representatives of these groups participated in the process of building the ethical norms that would soon be published, together with other social movements in health (Scheffer, 1999, 1996).<sup>12</sup>

The disputes reached their highest point when the research was denounced by bioactivists to the newly founded Conep in the second half of 1996. The commission accepted the denouncement, and designated as rapporteur the physician Fátima Oliveira, a member of the Black and feminist movements who had integrated the WG for the elaboration of Resolution 196/1996 as representative of the National Feminist Network for Health and Reproductive Rights. As detailed by the activist herself in her column in the newspaper *O Tempo* (Oliveira, 2014a), her opinion was the first ever issued by Conep and recommended the closure of *Protocolo 028*: “In March 1996, monotherapy with AZT was abolished from the public network, but research insisted on it!” (Oliveira, 2014a,

11 The scarce care for people with HIV at that time is related to the neglect vectored by the stigmatizing association of the infection with homosexuality. On the other hand, in this context of complex struggle for rights, the Brazilian HIV/AIDS bioactivism, as in other countries, was mainly led by gays and lesbians (Longhi, Franch and Neves, 2015; Valle, 2015).

12 According to Oliveira (2001), ethical debates had been raised by AIDS NGOs between 1991 and 1992, in the context of the controversy involving Brazil's participation in clinical trials with anti-HIV vaccines.

free translation).<sup>13</sup> The document was unanimously approved on December 7, 1996; however, by unclear routes, it reached the hands of the laboratory before being released. According to the physician, her opinion was “leaked,” as a ploy by the company to “shield the laboratory’s shares in the Stock Exchange” (Oliveira, 2014a). In March 1997 the Brazilian press published that the study had been closed by MSD itself, after the recommendation of an ethics committee hired by the company (Pivetta, 1997).

Resolution 196/1996 and the work of Conep were positively received as a sign that public institutions were aware of abusive conduct by scientists and pharmaceutical companies. For activists, the publication of Resolution 196/1996 established a new era in the regulation of scientific activities, in which Brazil stopped being a “no man’s land” (Oliveira, 2014b), and launched a “new ethical culture” (Scheffer, 1999, p. 2). This had as some of its fundamental components, notably present in Resolution 196/1996, elements raised by bioactivists, such as the guarantee that research subjects would receive the best treatment available during the studies; that the research project would be reviewed by a CEP with the participation of representatives of the study subjects; and that the benefits of the research would become available in the Brazilian health system and not only in the sponsors’ country of origin (Scheffer, 2000).

## Ethical limits, state accountability and right to health

The national debate on research ethics sparked in the context of Brazilian re-democratization did not occur in a complete normative vacuum nor by a tautological search for proposing ethical parameters for scientific practices. On the contrary, the norms in force at the end of the 1970s and beginning of the 1980s indicate that some attention to the regulation of scientific practices in the biomedical field already occurred in the governmental sphere, although apparently limited in their implementation. The scientific conduct of studies with Norplant

and *Protocolo 028* were characterized by the determination of scientific parameters and assistance by the sponsoring laboratories and local researchers. Indeed, research procedures usually were not monitored or supervised by governmental or social control agencies, and scientists showed resistance in moments of contestation, claiming there were undue limitations or “patrolling” of scientific freedom (Folha de S. Paulo, 1997; Pimentel et al., 2017).

One of the most significant political demands mobilized by feminist movements in the 1980s around clinical research was for the involvement of the Brazilian state in scientific processes, a fact that confronted the ambiguities between the mechanisms provided by the legal provisions in force (Brazil, 1978; Brazil, 1981). By attempting to assign a role for the State in the supervision, authorization and oversight of medical experimental practices, an ethical agenda was configured, whose fundamental purpose was to hinder abusive conducts and affirm the rights of women in a context of diverse population control policies. In the midst of an intense debate on family planning and sexual and reproductive rights, an agenda of ethics in research was collaterally imprinted within a broad set of feminist and anti-racist struggles of social movements. In the CNDSM, it was thus stated among the demands concerning “Black women’s identity”: “That any form of controlling intervention, indiscriminate distribution of contraceptives, *experiments on women* and surgical sterilization, female or male, aimed at limiting the number of children of the Black race be prohibited” (Brasil, 1987, p. 31, free translation - emphasis added). These groups also fought for representatives of women’s movements to have a seat in decision-making processes involving scientific research, especially those related to reproductive and contraceptive processes. In this context, the construction of an ethical agenda is inseparable from social struggles against racism and sexism in the medical-scientific context.

Already in the mid-1990s, the political agendas articulated as a result of research involving people

13 Fátima Oliveira detailed that she and her family were threatened in anonymous phone calls, and that she even received an attempt at bribery during the preparation of her opinion (Oliveira, 2014a).

with HIV took up again not only the role of the State and social participation in the regulation of clinical research activities, but also reinforced attention to issues involving geopolitical and economic asymmetries between Brazil and countries of origin of multicenter clinical trials, the use of suboptimal technologies in controlled studies, and the perspectives of access to treatment during and at the end of the research. Thus, in addition to proposing barriers to malpractice, a propositional agenda on the subject was also established under the rubric of **research ethics**. Both in the 1980s and in the following decade, the outcomes of the episodes gained greater repercussion, signaling that the critical underlying idea in the actions reviewed here was that: “when it comes to clinical research, Brazil is a no man’s land. Laboratories dictate the rules and test whatever they want, on whoever they want, with the connivance of the most renowned professionals and institutions” (Scheffer, 1997, p. 18, free translation). The association between the institutionalization of ethics in research and the establishment of limits to abusive practices emerged, thus, as fundamental marks of the contexts of release of Resolution 01/88, and of the creation of the CEP/Conep System.

After the release of Resolution 196/1996, the adherence of Brazilian scientists to the normative predictions and the creation of CEPs in diverse institutions only grew. Currently, Brazil has CEPs in all states, with more than 860 by the end of 2021.<sup>14</sup> This scenario, however, was not free of tensions: issues such as the time to decide on authorizations, the need for additional ethical evaluation of international clinical trials by Conep, and the impacts of regulatory processes on the influx of clinical trials to Brazil were problematized by researchers and pharmaceutical companies over the following decades (Castro, 2020). Moreover, the fact that the document rules any type of research, despite being notably based in the universe of biomedicine, mobilized broad and pertinent criticism from researchers in the Human and Social Sciences (Duarte, 2015).

When Resolution 196/1996 was revised and replaced by Resolution 466/2012 (Brasil, 2012), the context of debates also made visible a series of criticisms interposed by people with rare diseases, who understood that the guarantee of access to post-study treatment advocated by the CNS drove off clinical studies involving possible therapies for these groups (Castro, 2018). Thus, new meanings of **research ethics** were highlighted, in which protection was not necessarily linked to the prevention of abuses by scientists and pharmaceutical companies, but to the defense of better regulatory conditions that would guarantee the inflow of clinical trials and, consequently, the participation of rare disease patients in studies with experimental treatments. In this context, the 2012 regulation marked the emergence of new elements that guide the practices of Conep, making the commission’s understanding of its role in ethical regulation more complex with the idea of promoting scientific activity in the country as a way to protect the interests of research participants in search of treatments (Castro, 2020).

In the genealogical notes proposed here, we denote how various aspects participated in the constitution of a public agenda of social movements in the 1980s and 1990s around the institutionalized regulation of biomedical practices. Not all the elements were equally contemplated in the regulations published in these decades, pointing out to the complexity of the correlations of forces present in the elaboration of these documents and explains that the social demands around the subject went beyond the terms foreseen in the CNS resolutions. The resolutions, therefore, do not entail directly from intrinsic values or ethical dispositions or automatically acquired from international dialogues; nor are they immediate effects of the actions of the Brazilian activists. The actions of these groups, and the events occurring on the national scene should, however, be taken into account in efforts to historicize the history of **research ethics** in Brazil.

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14 NATIONAL COMMISSION ON RESEARCH ETHICS - (COMISSÃO NACIONAL DE ÉTICA EM PESQUISA) CONEP. Committees of Ethics in Research in Brazil. Retrieved from: <<http://conselho.saude.gov.br/comites-de-etica-em-pesquisa-conep?view=default>>. Accesses on Jan 17, 2022.

## Final considerations

In October 2021, the CEP/Conep System turned 25 years old. Despite the landmark date, the anniversary of the system came discreetly given the context in which it was celebrated. The country was still living under the shadow of the irreparable losses from the Covid-19 pandemic, although in October 2021 vaccination was advancing more effectively, unlike the first months of that year. Additionally, during the work of the Parliamentary Inquiry Commission (*Comissão Parlamentar de Inquérito*) established to investigate crimes committed by the Federal Government in the context of the pandemic, unforeseen facts came to light: outrageous cases of conduct of pharmaceutical experiments on hospitalized patients with Covid-19, several times without their consent or even knowledge. The debate on **research ethics** then took the attention of society in general, and certain biomedical practices were the focus of critical attention.

New elements have permeated the field of **research ethics**, such as the circulation of fake news, the use of scientifically ineffective drugs in clinical trials, and the role of the CEP/Conep System in the oversight of medical research. Therefore, considering ways in which political, social, economic, and health contexts update **research ethics** and its issues and priorities is fundamental. In this essay, I have tried to highlight episodes that denote the Brazilian history of participation of social movements in this field, critically articulating for the guarantee of rights and reinforcement of the role of the State and civil society in the regulation of scientific practices. In this pandemic setting, in which clinical research has taken on a prominent place in national life, it is especially relevant to remember and update this Brazilian record of social struggles around **research ethics**, articulated to the broad defense of the right to health.

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