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# Human Subject Research: International and Regional Human Rights Standards

ANDRÉS CONSTANTIN

## Abstract

This article will place the discussion of human subject research within the larger context of human rights law, both at the international and regional level, and examine existing normative human rights frameworks that can be used to protect research subjects. The traditional approach has commonly focused on the ethical aspects of human subject research and little has been said about the implications of human experimentation on the enjoyment of basic rights. The difference between ethical principles and human rights is clearly determined by the non-enforceability of ethical norms and the legally binding nature of human rights obligations. A human rights approach to bioethics, and particularly to human subject research, can bring about a defined system and universally accepted set of rules in a field where sociocultural and religious diversity come into play.

Andrés Constantin, LLM, is an institute associate at the O'Neill Institute for National and Global Health Law, Georgetown University Law Center, Washington, DC, USA.

Please address correspondence to Andrés Constantin. Email: ac1781@georgetown.edu.

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## Introduction

During the Second World War and the Holocaust, Nazi researchers committed mass-scale atrocities against Jews and other prisoners under the name of medical research. The largest German Nazi concentration camp, Auschwitz, witnessed Josef Mengele's egregious experiments performed on Gypsy children, twins, dwarfs, and people with abnormalities. When the research came to an end, they were killed and their organs autopsied and analyzed.[1]

It took two years after the end of the war for 16 German physicians to be found guilty of nefarious crimes against humanity. The Nazi doctors' trial exposed torture, deliberate mutilation, sterilization, and murder.[2] Their trial led to the 1947 drafting of the Nuremberg Code, a set of guidelines governing research on humans, which included 10 principles focused on patient consent and autonomy. The Nuremberg Code, the first of its kind, was created to prevent a recurrence of the horrors committed in Nazi Germany, and it paved the way for the development of medical ethics and greatly influenced the evolution of human rights law.[3] The later Declaration of Helsinki, adopted in 1964, reaffirmed the need for informed consent in all research and warned that the "interest of science and society should never take precedence over considerations related to the wellbeing of the subject."[4] In 1978, the Belmont Report framed these issues into "broader ethical principles [to] provide a basis on which specific rules may be formulated, criticized, and interpreted," and focused on three main principles: respect for persons, beneficence, and justice.[5]

While experimentation with human subjects is widely practiced, it is often done without due regard to the human rights of participants. For example, recent cases include oxygen experiments conducted on premature babies without the parents' knowledge, and studies on whether cooling kidneys before a transplant would result in fewer complications, conducted without adequate assessment of the risks to transplant recipients.[6] With the advent of new technologies, the links between ethical principles and human rights in research involving human participants become particularly relevant. For instance, new gene editing technologies, such as CRISPR-Cas9, pose serious risks and challenges to the protection of peoples' human rights and basic ethical principles in terms of, for instance, human dignity, informed consent, and the rights of future generations.[7] Some companies have already sought permission from European regulators and are planning to seek approval from the US Food and Drug Administration to begin CRISPR clinical trials in humans for metabolic, autoimmune, and neurogenerative diseases, among others.[8]

This article will place the discussion of human subject research within the larger context of human rights law, at both the international and regional level, and examine existing normative human rights frameworks that can be used to protect research subjects. The traditional approach has commonly focused on the ethical aspects of human subject research and little has been said about the implications of human experimentation on the enjoyment of basic rights. With the Nuremberg Code, the Helsinki Declaration, the Belmont Report, and the International Ethical Guidelines for Biomedical Research Involving Human Subjects as the instruments to be followed, there is a noticeable need for legally enforceable norms to protect the rights of research participants. The difference between ethical principles and human rights is clearly determined by the non-enforceability of ethical norms and the legally binding nature of human rights obligations. A human rights approach to bioethics, and particularly to human subject research, can bring about a defined system and universally accepted set of rules in a field where sociocultural and religious diversity come into play.[9] In the era of the Sustainable Development Goals (SDGs), health research is a primary and vital goal. Target 3.b supports "the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries."[10] In this context, human subject research is necessary and even desirable to achieve Universal Health Coverage (UHC) and the full realization of the right to health.[11] The enjoyment of the right to health is recognized in core human rights treaties as a fundamental human right.[12]

Nonetheless, human research is not exempt from restrictions necessary to guarantee respect for human rights. States must protect people from potential harms arising from and during scientific research. States have the obligation to protect people from being used or exploited in harmful scientific experiments, as well as the obligation to set safeguards to prevent harm caused by research or experimentation.

This article proceeds as follows. First, I describe the international standards for human subject research in the light of norms enshrined in human rights treaties. Next, I briefly examine the regional standards in the Inter-American System of Human Rights, the European System of Human Rights, and the African System of Human Rights, with particular references to cases and relevant normative frameworks. Then, I present core issues regarding human subject research and delve into the crucial question of derogations of human rights obligations in the context of public health emergencies, and the implications for human subject experimentation. I conclude with a brief reflection on the potential of using international human rights law to protect human research subjects.

## International standards for human subject research

The Universal Declaration of Human Rights (UDHR) was adopted in 1948, proclaiming that "All human beings are born free and equal in dignity and rights…endowed with reason and conscience" and recognizing that "No one shall be subjected to torture or to cruel, inhuman or degrading treatment."[13] While not legally binding, the UDHR set the ground for the adoption of the International Covenant on Civil and Political Rights (ICCPR) and the International Covenant of Economic, Social and Cultural Rights (ICESCR).[14]

The ICCPR provides that "no one shall be subjected without his free consent to medical or scientific experimentation."[15] When analyzing its drafting history, one can clearly identify that Article 7 was the result of the broad consensus of participants to explicitly include the prohibition as a response to the atrocities committed in concentration camps during the Second World War.[16] The UN Human Rights Committee later interpreted Article 7 as requiring "special protections" and provided that the prohibition in article 7 relates not only to acts that cause physical pain but also to acts that cause mental suffering to the victim. Moreover, the prohibition extends to corporal punishment, including excessive chastisement ordered as punishment for a crime or as an educative or disciplinary measure.[17]

On the other hand, Article 12 of the ICESCR calls states to prevent, treat, and control epidemic, endemic, occupational, and other diseases to achieve the full realization of the highest attainable standard of physical and mental health.[18] This, in turn, requires "the promotion of medical research and health education" and "fostering recognition of factors favoring positive health results, e.g., research."[19] However, this obligation is not limitless. The right to health is intimately related to and dependent upon the realization of other human rights, such as the "right to be free from torture, non-consensual medical treatment and experimentation."[20]

As will be examined later, the Convention on the Rights of the Child (CRC) requires States parties to ensure that the views of the child are given "due weight… in all matters affecting the child" and that parents and guardians act in the "best interests of the child."[21] Moreover, particularly relevant when it comes to the selection of vulnerable groups as research participants, the Convention on the Elimination of all forms of Discrimination Against Women (CEDAW) establishes the obligation of States parties to "establish legal protection of the rights of women…and to ensure…the effective protection of women against any act of discrimination."[22] The Committee on the Elimination of Discrimination Against Women recognized that women "have the right to be fully informed, by properly trained personnel, of their options in agreeing to treatment or research, including likely benefits and potential adverse effects of proposed procedures and available alternatives."[23]

The Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Pun-

ishment (CAT) defines "torture" as "any act by which severe pain or suffering, whether physical or mental, is intentionally inflicted on a person for such purposes as obtaining from him or a third person information or a confession."[24] Certainly the phrase "for such purposes as obtaining from him or a third person information" may be considered as including human subject research and likewise, as will be shown later, the lack of informed consent for research participation may be seen as a form of coercing the participant, in the terms outlined in Article 1.1. Moreover, Article 16 sets the state's obligation to prevent cruel, inhuman, or degrading treatment which do not amount to torture as defined in Article 1, under its jurisdiction.

It is true, however, that to be considered a violation of Article 1.1 or Article 16, the research must be conducted "by or at the instigation of or with the consent or acquiescence of a public official or other person acting in an official capacity," which is often not the case. Still, even in cases where government officials are not involved, an argument could be made that a state has a due diligence duty to prevent torture or other ill-treatment that occurs within its territory or under its jurisdiction, even when it is not conducted by persons under its direct control or public authorities.[25]

With regards to persons with disabilities, the Convention on the Rights of Persons with Disabilities (CRPD) recognizes that States must provide them with equal recognition of legal capacity and protection against non-consensual experimentation, as well as prohibit exploitation and respect physical and mental integrity.[26]

Lastly, in the field of humanitarian law, the legal framework includes the Geneva Conventions that specify the prohibition of biological experiments on wounded or sick members of armed forces and the ban on medical or scientific experiments on prisoners of war not justified by the prisoner's need. Moreover, its Additional Protocols applicable to victims of armed conflict forbid experiments on wounded, sick, or shipwrecked persons even with their consent, and on persons who are interned, detained, or held.

## Regional standards for human subject research

### *Inter-American system of human rights*

While there is no specific Inter-American instrument devoted to human subject research, the protection of research participants is ensured through other norms. Under the Inter-American system of human rights, the American Declaration of the Rights and Duties of Man (ADHR) and the American Convention on Human Rights (ACHR) are the two most relevant instruments. Although not a legally binding instrument, the Inter-American Court of Human Rights held in its Advisory Opinion OC-10/89 of 1989 that recognizing the ADHR not being a treaty "does not, then, lead to the conclusion that it does not have legal effect" on members of the Organization of American States (OAS).[27]

The ADHR recognizes the right to the preservation of health and to well-being, as well as the equality of all persons before the law "without distinction as to race, sex, language, creed or any other factor."[28] For its part, the ACHR establishes the right of every person "to have his physical, mental and moral integrity respected." It also establishes that no one shall be subjected to torture or to cruel, inhuman, or degrading punishment or treatment."[29]

The ACHR, while raising most of the principles contained in the ADHR to a treaty-level protection, reduced the ESC rights to a single provision recognizing that

> *States Parties undertake to adopt measures… with a view to achieving progressively, by legislation or other appropriate means, the full realization of the rights implicit in the economic, social, educational, scientific and cultural standards set forth in the Charter of the Organization of American States.*[30]

The ESC rights were later captured in the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights, which provides that everyone "shall have the right to health, understood to mean the enjoyment of the highest level of physical, mental

and social well-being."[31]

However, according to Article 19(6) of the Protocol, only violations of the right to unionization and the right to education may give rise to individual petitions before the Inter-American Court of Human Rights, meaning that other rights, such as the right to health, were practically excluded from the scope of protection of the Inter-American human rights system. For years, the justiciability of ESC rights within the Inter-American system was the subject of scholarly debate regarding whether Article 26 of the ACHR allows for circumvention of Article 19(6) and opens up the door for the direct justiciability of ESC rights.[32]

Until 2017, the Inter-American Court had examined the indirect violation of ESC rights under provisions of the ACHR that enshrine civil and political rights. One clear example of this "indirect violation analysis" relevant to the ambit of human subject research concerns a 2016 decision from the Inter-American Court, wherein it addressed the question of informed consent in relation to forced sterilization as a violation of the right to humane treatment (Article 5), right to personal liberty (Article 7), right to privacy (Article 11), and right to freedom of expression (Article 13) and established that obtaining consent must derive from a communication process, through which qualified personnel present clear information without technicalities, impartial, accurate, truthful, timely, complete, adequate, reliable and informal.[33]

In August 2017, the court declared the direct violation of Article 26 for the first time.[34] And almost seven months after *Lagos del Campo*, the court clarified and expanded its interpretation of Article 26 in the context of the right to health.

In *Poblete Vilches v. Chile*, the Inter-American Court unanimously declared the international responsibility of Chile for not guaranteeing Poblete Vilches' right to health. The court ruled for the first time on the right to health as an autonomous right, in accordance with Article 26 of the Convention. In turn, although in the context of the provision of health services, the court recalled its previous decision in *I.V. v. Bolivia* and recognized the relationship between obtaining free and prior informed consent, and the autonomy and self-determination of the individual, as part of the respect and guarantee of the dignity of every human being. Moreover, the court considered obtaining informed consent as a fundamental mechanism to achieve respect and to guarantee different human rights recognized by the ACHR, which may have relevant implications for human subject research.[35]

Box 1. Example 1 of human rights violations in human subject research: US syphilis experiment in Guatemala

Between 1946 and 1953, researchers from the United States and Guatemala conducted, with the support of public institutions, non-consensual medical experiments on some of the most vulnerable populations in Guatemala under the excuse of contributing to the advancement of science.

People from Guatemalan marginalized populations were subjected to non-consensual experiments, including intentional exposure to syphilis, gonorrhea, and chancroid, which caused them permanent damage. The experiments specifically targeted prisoners, soldiers, patients in a state-run psychiatric hospital, children in orphanages, and sex workers, among others. With the exception of sex workers, who were included in the experiments to have intercourse with prisoners and soldiers, the groups of individuals that were targeted lacked mobility and could be kept in an area that would facilitate observation for the duration of the experiments.[36]

The experiments, funded by a grant from the US National Institutes of Health (NIH) to the Pan American Sanitary Bureau, involved multiple Guatemalan government ministries and a total of about 1,500 study subjects. The findings were never published. During the experiments, sex workers were infected with venereal diseases and then provided for sex to subjects for intentional transmission of the disease; subjects were deliberately inoculated by injection of syphilis into the spinal fluid that bathes the brain and spinal cord, under the skin, and on mucous membranes; an emulsion containing syphilis or gonorrhea was spread under the foreskin of the penis in male subjects; the penis of male subjects was scraped and scarified and then coated with the emulsion containing syphilis or gonorrhea; a woman from the psychiatric hospital was injected with syphilis, developed skin lesions and wasting, and then had gonorrheal pus from a male subject injected into both of her eyes and; children were subjected to blood studies to check for the presence of venereal disease.[37]

Susan Mokotoff Reverby, a professor at Wellesley College, discovered information about these experiments in 2005 while researching the Tuskegee syphilis study and shared her findings with United States government officials.[38] In October 2010, the US government apologized formally, observing that the violation of human rights in that medical research was to be condemned, regardless of how much time had passed.[39]

### *European system of human rights*

Europe has pioneered human subject research and clinical trials. In 1997, the Council of Europe adopted the Convention for the Protection of Human Rights and Dignity of the Human Beings with regard to the Application of Biology and Medicine ("Oviedo Convention") in Oviedo, Spain, which brought together the bioethics and the legal realms for the first time on a single legally binding instrument.[40] The Oviedo Convention lays out minimum basic norms governing biomedical activities and does not exclude the possibility of granting wider protections.[41]

The notion of dignity is the cornerstone of the Oviedo Convention and, as such, primacy is afforded to the interests and welfare of the human being over the interests of society or science.[42] Moreover, as a general rule, any intervention in the health field "may only be carried out after the person concerned has given free and informed consent to it."[43] In relation to scientific research, Chapter 5 of the Convention delineates the standards that must be followed to ensure protection of persons undergoing research.[44]

The Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research, adopted in 2005, further expands the protection of human beings involved in research activities. It reaffirms the primacy of the human being over societal or scientific interests, and outlines the need for having an independent ethics committee in place "to protect the dignity, rights, safety and well-being of research participants."[45] Moreover, it describes the information that must be provided to the research participants, and the obligation to secure prior, free, and informed consent from each participant.[46]

Other instruments may also be invoked to protect the rights of research participants. The European Convention on Human Rights prohibits torture, or inhuman or degrading treatment.[47] The European Social Charter recognizes the right to protection of health, and the right to special protection of children and young persons.[48] The Charter of Fundamental Rights of the European Union recognizes the inviolability of human dignity and the right of everyone to have his/her physical and mental integrity respected. In particular, the Charter of Fundamental Rights of the European Union acknowledges that in the fields of medicine and biology the free and informed consent of the person concerned must be respected.[49]

### *African system of human rights*

Under the African System, the African Charter on Human and Peoples' Rights recognizes that "human beings are inviolable [and] every human being shall be entitled to respect for his life and integrity of his person." In 1996, the Organization of African Unity adopted a Resolution of Bioethics in which it pledged to promote within the continent "the obligation to obtain the free and enlightened consent of any one to submit himself/herself to bio-medical research."[50]

Vulnerable populations that may become research subjects are afforded special protection in Africa. For instance, the Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa ("Maputo Protocol") recognizes the right to dignity of every woman and, particularly relevant to the context of human subject research, prohibits "all medical or scientific experiments on women without their informed consent."[51] With regards to children, the African Charter on the Rights and Welfare of the Child protects children's right to survival and development, their right to health, and their right to protection against abuse and torture.[52]

## Core issues regarding human subject research

Basic ethical principles such as respect for persons, beneficence, and justice are common to most ethical codes in the world, and in turn inform and are linked to (1) the notion of informed consent, (2) the assessment of risks and benefits, and (3) the selection of human subjects and discrimination. I will examine these three core issues in the next section.

### *Respect for persons: Informed consent*

The ethical principle of *respect for persons* demands that subjects enter into the research voluntarily and with adequate information.[53] To be operative, this ethical principle has often been articulated under the notion of "informed consent," usually formulated in terms of rights.[54] The requirement of informed consent is critical to protecting people unfamiliar with medicine or research protocols from manipulation and exploitation.[55]

In the context of human subject research, consent is considered to be free and informed when it is given on the basis of objective information from the researcher and includes not only the nature of the research, but also its potential consequences and risks involved, as well as its alternatives. Free and informed consent is also given in the absence of any type of pressure or coercion from anyone who may influence the participants' independent decision.[56] In order to enable potential subjects to make reasoned decisions on matters that will greatly affect them, informed consent must be obtained prior to any experimentation. In addition, the information must be sufficiently clear and suitably worded for the proposed subject.[57] This requirement is crucial and may be difficult to satisfy when seeking to obtain consent from persons with limited education or those unfamiliar with science.[58]

From a human rights standpoint, informed consent is a fundamental aspect of the respect for autonomy and human dignity of the person and is the very first criterion by which to assess the lawfulness of any experimentation. As such, the principle of autonomy is crucial as it represents the decision-making power of the research participant and the recognition of her/him as an autonomous moral subject.

By formulating the notion of *respect for persons*—as well as other ethical principles—using the terminology of rights recognized in legally binding human rights instruments, rights holders and duty-bearers benefit from clarity on the legal responsibility and the scope and content of the right to informed consent.

### *Beneficence: Maximizing benefit and minimizing harm—the case of public health emergencies*

The principle of *beneficence* requires the best interests of the research subject to be front and center in order to do no harm, or at least to minimize the possibility of harm while maximizing benefits.[59] Emergency response is the most challenging and sensitive area in the beneficence debate: where the need for immediate governmental action against an imminent health threat must be balanced against possible risks and harms to research participants.[60] Human rights law offers a solution in these cases under the notion of "derogation under state emergency."

Oftentimes, disease outbreaks can pose major risks to countries, which in turn may lead governments to declare a public health emergency. A public emergency has been defined as one that is imminent or already occurring, whose effects involve the entire nation and threaten the continued organized life of the community, and where normal measures or restrictions for the maintenance of public safety or health are inadequate.[61]

Several human rights treaties, as well as general principles of law, recognize the right of States to derogate from human rights norms during a national emergency.[62] Non-compliance with certain human rights obligations is permitted during a grave emergency under the principle of exceptional threat.[63] However, a series of limitations must be observed in order to prevent abuse when declaring an emergency, in particular when such emergency may require human subject research to be conducted.

A derogation is only acceptable if necessary and proportional to the emergency at hand. Therefore, the first limitation to the derogation from human rights is the necessity of said measure.[64] Moreover, the derogations must be proportional to the factual circumstances. In other words, the duration, severity, and geographic scope of derogations is limited to measures strictly required by the situation.[65] States shall demonstrate the proportionality by linking the emergency and the derogations and proving that no less restrictive measure is available.

However, certain rights are non-derogable. For instance, the principle of non-discrimination is considered "functionally non-derogable in the sense that it is never strictly necessary to violate the ban on arbitrary discrimination in order to meet an actual threat."[66] In that sense, the Human Rights Committee has considered that even in situations of public emergency such as those referred to in article 4 of the [ICCPR], no derogation from the provision of article 7 [prohibiting medical or scientific experimentation without free consent, as well as torture or other cruel, inhuman or degrading treatment] is allowed and its provisions must remain in force.[67]

### *Justice: Selection of human subjects and non-discrimination*

Justice requires that vulnerable people should not be inappropriately targeted as experimental subjects and "gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects."[68] In practice, this principle relates to the fundamental principle of non-discrimination, since "all human beings are born free and equal in dignity and rights."[69]

In selecting human participants for research, respect is necessary for people who may not be able to choose freely or who have diminished capacity. Some people may have diminished autonomy due to mental illness or age. Others may find it difficult to voluntarily and freely consent because they are subject to authority (for example, prisoners, members of the military), or because their condition may place them at increased risk (for example, pregnant women).[70] Vulnerable populations might also include marginalized populations, such as indigenous peoples, people living in extreme poverty, racial minorities, or people living with HIV/AIDS.

In the case of prisoners, for instance, given their imprisonment, they are usually subject to human rights abuses and are unable to refuse experimentation. In light of this situation, protections against the use of prisoners for medical experimentation have been widely established under international law.[71] Children are also protected as a vulnerable group for cases of research and experimentation. Children "shall in all circumstances be among the first to receive protection and relief" and "be protected against all forms of exploitation."[72] Also, medical experimentation on mothers is subject to special care and assistance, since it can endanger their health and that of their child.[73]

The recognition of the principle of non-discrimination as a cornerstone in human subject research is grounded on the notion of the unequal power dynamic between the researcher and the individual subject, which may be exacerbated in cases of structural inequality that are the "consequence of a situation of social exclusion or "subjugation" of [vulnerable groups] by others, in a systematic way and due to a complex set of social practices, prejudices and beliefs."[74] In this line, both the Special Rapporteur on the right to health and the Special Rapporteur on torture have recognized that structural inequalities may be exacerbated by social and economic factors, stigma, and discrimination, which could impair the informed consent of vulnerable groups.[75] In cases involving vulnerable populations, careful scrutiny is necessary to ensure that they are not involved in the research merely because their vulnerability makes them easier to manipulate.

The principle of non-discrimination is violated when differential treatment lacks an objective and reasonable justification. In the context of human subject research, the selection of groups of people according to their level of exposure to certain disease vectors—as may be bodily fluids—would be considered "objective and reasonable justification." Restricting the experiments to vulnerable populations—prisoners, women, children, people living in poverty—without a rational link between them and the factors contributing to the spread of a disease may violate the principle of non-discrimination, as these populations are often powerless, impoverished, or politically underrepresented, leaving them unable to question the methods or procedures or challenge the project.

Framing the selection of research participants as a human rights issue protects vulnerable populations as it clarifies freedoms, entitlements, and duties in this realm, provides a normative foundation for claims, and facilitates the accountability process.[76]

Box 2. Example 2 of human rights violations in human subject research: Postobon lab testing on Colombian children

On February 13, 2018, the *Liga contra el Silencio*—an alliance of journalists and media that fights censorship in Colombia—reported that Colombia's largest beverage company, Postobon, distributed drinks containing uncertified chemical supplements to more than 3,000 children from La Guajira, one of the poorest departments of Colombia, and conducted lab tests on some of the children to evaluate the effects of their products.[77]

According to sources from the company, the objective was "to determine the physical changes of the development and the biochemical changes derived from the consumption of this drink fortified with vitamins and minerals, in a representative sample of children who receive the drink." Postobon said its intention was "to evaluate the acceptance, use and consumption of the drink in its two presentations, as well as training in nutrition to parents of the 220 children of educational institutions."[78]

Colombia's Ministry of Health requested information from Postobon about the authorization protocol for the research, but it has not been provided. It is unclear whether the company requested parental/guardian consent for conducting this research. It is also unclear whether the company took steps to minimize harms and maximize benefits to the participating children, and whether the company had obtained consent for the scientific experimentation.

## Conclusion

International and regional human rights law offers many normative foundations for the protection of human subject research. International and regional human rights treaties explicitly provide for rights—such as the right not to be subjected to torture or other forms of cruel, inhuman, or degrading treatment—that may be used to better protect the rights of research participants.

Human rights law promotes states' accountability on the adoption of positive measures ensuring the protection of research participants. Moreover, it obliges states to adopt legislative and administrative measures and, in cases of violations, it gives the research participant the ability to claim the enforcement and protection of those rights through judicial recourse.

Moreover, human rights standards provide a perfect avenue to address structural injustice and institutional and national responsibility in cases of human experimentation. Bringing ethical principles and human rights standards together can help bring compensation and relief to surviving participants or family members. Such standards can also serve to advance a reconciliation process at the national and international levels in cases of abominable experiments on humans, such as those that occurred in Nazi Germany, and to prevent future misconduct.

This article demonstrates the different ways in which the current state of international human rights law affords protection to research participants both at the international and regional level and reinforces principles and guidelines long enshrined in documents delineating ethical principles.

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29. American Convention on Human Rights (ACHR), O.A.S. Treaty Series No. 36 (1969), art. 1 and 5.

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