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# COVID-19 VACCINES AND THEIR PITFALLS IN INFORMED CONSENT

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## ABSTRACT

The World Health Organization declared the coronavirus (COVID-19) pandemic as a global health crisis. The search for a coronavirus vaccine escalated to a global competition. Drugs for other diseases as well as new formulations are proposed as potential candidates for the treatment or intervention of coronavirus. Almost all pharmaceutically able countries are pursuing potential vaccines. At the time of writing this article, two vaccines are already marketed and tested with promising interim results. Both vaccines use messenger RNA (mRNA) encapsulated in a lipid nanocarrier. Under ordinary circumstances, clinical trial authorizations oblige sponsors to disclose all risks to volunteers in order to formulate an informed knowledgeable decision. This however has been subject to exceptions during the pandemic. The mRNA-based vaccine has been rushed in unprecedented record speed to human clinical efficacy evaluation. This raises a number of questions related to the validity of volunteers' free and informed consent. The present article argues that informed consent of all risks as well as the protection of volunteers' personal data constitute concrete obligations under human rights law that cannot be derogated from in times of emergency – such as the COVID-19 pandemic. Furthermore, it suggests a risk governance framework through blockchain for international vaccine testing clinical trials.

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## I. INTRODUCTION

The novel Coronavirus (Covid-19) is one of the deadliest viruses of the recent past. It was first reported in December 2019, in the city of Wuhan, which is situated in the province of Hubei in Central-East China. The virus is a "newly identified pathogen,"[1] most likely transmitted by human-to-human contact[2] and has been associated with products and visitors of the Huanan seafood market.[3] Its spread has been facilitated by the fact that Wuhan is a "major air and train transportation hub of central China," and arguably also because the initial spread of the disease coincided with the festivities of the Chinese C*hunyun* (i.e. the celebration of the lunar year Spring festival).[4] On 11 March 2021, the World Health Organization ("WHO") officially named Covid-19 a pandemic,[5] as the number of Covid-19 cases outside China increased 13-fold since January 2020, and the number of affected countries tripled.[6] The overall growth rate is worryingly high. By way of illustration, on 25 January 2020, a total of 75,815 individuals had been infected in Wuhan, the outbreak epicenter,[7] whereas at the same time, only 581 were reported globally to the WHO.[8]

Scientists and pharmaceutical companies have been racing to develop vaccines. The Kaiser Permanente Washington Health Research Institute in the United States was the first to develop a vaccine. Its first Phase 1 clinical

[1] *Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19)* (Feb. 28, 2020), https://www.who.int/docs/default-source/coronaviruse/who-china-joint-mission-on-covid-19-final-report.pdf.

[2]Joseph T. Wu, Kathy Leung & Gabriel M. Leung, *Nowcasting and Forecasting the Potential Domestic and International Spread of the 2019-nCoV Outbreak Originating in Wuhan, China: A Modelling Study,* 395 LANCET 689, 689 (2020) (provisionally named 2019 novel coronavirus (2019-nCoV) and now severe acute respiratory syndrome SARS CoV2).

[3] *Id.* at 689, 691.

[4] *Id.* at 690 (stating that the festivities began Jan. 10, 2020 and lasted for forty days).

[5] *WHO Director-General's Opening Remarks at the Media Briefing on Covid-19*, WORLD HEALTH ORG. (Mar. 11, 2020), https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.

[6]*Id.*

[7] *See* Wu, *supra* note 2, at 689, 693.

[8] *See Novel Coronavirus (2019 n-CoV): Situation Report - 3*, WORLD HEALTH ORG. (Jan. 23, 2020), https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200123-sitrep-3-2019-ncov.pdf.

trial[9] was conducted on March 16, 2020.[10] ModernaTX, Inc also developed a vaccine. It is a mRNA-based[11] vaccine encapsulated in a lipid nanoparticle, tested at an open-label trial.[12] The trial, which was scheduled to take place at only one location in the United States,[13] aimed at recruiting forty-five healthy volunteers over 6 weeks and ultimately designed to test the vaccine (mRNA-1273).[14] Pfizer, too, the largest global vaccine maker, teamed with the German company BioNTech to start clinical trials on another mRNA experimental vaccine that was developed at Fosun Pharma.[15] This mRNA vaccine, which emerged as a promising technology for vaccine development due to its non-infectious characteristics, activates the immune system to produce immune shields against the coronavirus.[16]

Many of these vaccines have been already tested, approved, and marketed.[17] The ones that have circulated in the market have proved to be

[9] *See generally* LAWRENCE M. FRIEDMAN, CURT D. FURBERG, DAVID L. DEMETS, DAVID M. REBOUSSIN & CHRISTOPHER B. GRANGER, FUNDAMENTALS OF CLINICAL TRIALS, 4-10 (Springer Int'l Pub. Switz., 5th ed. 2015) (explaining the four phases of clinical studies in which human subjects are administered a new drug: Phase 1 is performed on healthy volunteers to evaluate the risk of the new drug formulation; Phases 2 to 4, tests are done on patients to evaluate the therapeutic effect, confirm the therapeutic effect and market approval, respectively).

[10] *See NIH Clinical Trial of Investigational Vaccine for COVID-19 Begins*, NAT'L INST. OF ALLERGY AND INFECTIOUS DISEASES, (Mar. 16, 2020), https://www.niaid.nih.gov/news-events/nih-clinical-trial-investigational-vaccine-covid-19-begins.

[11] *See generally* Alexandre Jose Christino Quaresma, Rachel Sievert & Jeffrey A. Nickerson, *Regulation of mRNA export by the PI3 kinase/AKT signal transduction pathway,* 28 MBOC 1208, 1208 (2013) (explaining that mRNA messenger ribonucleic acid is the single-stranded intermediary that transfers genetic information from the DNA to the cytoplasm).

[12] *See generally supra* note 9, at 241-242, 501 (stating that open label trial is a type of clinical trial where both the researcher and the volunteer are aware which drug is being administered to volunteers).

[13] Safety and Immunogenicity Study of 2019-nCoV Vaccine (mRNA-1273) for Prophylaxis of SARS-CoV-2 Infection (COVID-19), U.S. NAT'L LIBR. OF MED. (Feb. 25, 2020), https://clinicaltrials.gov/ct2/show/NCT04283461.

[14] U.S. Patent No. 10,577,630 (issued Mar. 3, 2020).

[15] *Clinical trials for COVID-19 vaccine start, millions of dollars at stake*, LIVEMINT, https://www.livemint.com/news/world/clinical-trials-for-covid-19-vaccine-start-millions-of-dollars-at-stake-11584618436860.html (last updated Mar. 19, 2020, 05:45 PM).

[16] *The Pfizer-BioNTech COVID-19 Vaccine U.S. Distribution Fact Sheet*, PFIZER.COM (Nov. 20, 2020), https://www.pfizer.com/news/hot-topics/covid_19_vaccine_u_s_distribution_fact_sheet.

[17] Benjamin Mueller, *U.K. Approves Pfizer Coronavirus Vaccine, a First in the West*, N.Y. TIMES (Dec. 2, 2020), https://www.nytimes.com/2020/12/02/world/europe/pfizer-coronavirus-vaccine-approved-uk.html#:~:text=LONDON%20%E2%80%94%20Britain%20gave%20emergency%20authorization,than%201.4%20million%20people%20worldwide.

relatively successful, even against reported mutations of the virus.[18] And yet, a number of scientists have been expressing fears about the potential adverse effects of these vaccines. Potential risks associated with vaccines containing nano-carriers are generally greater than common vaccines. Clinical trials employing nano-carriers are characterized by unknown efficacy, tolerability and safety, thus posing uncertain and ambiguous risk assessment. The uncertain nature of new mRNA vaccines loaded in nano-carriers poses potential risks for volunteer participants.[19] In addition, complications on volunteers have already been reported at a trial stage. [20] By way of illustration, shortly after the marketing of the first vaccines, the CDC reported that healthy receivers of the Pfizer vaccine suffered from severe allergic reactions.[21] A case of a trial volunteer who presented a number of symptoms including inflammation of the spinal cord was also reported.[22]

This paper explores the legal issues pertinent to these vaccinations containing nanoparticles, especially trial participants' rights in relation to informed consent, and pharmaceutical companies' obligations. It further discusses ambiguous practices during the Covid-19 pandemic, such as those related to fast-tracking approval processes ('speedy trials') and conducting the vast majority of trials in the developing world. The following four sections discuss more specifically: first, the extent to which unknown side effects of unauthorized vaccines administered in clinical trials are covered by individual consent (section 2). As this paper argues, a dynamic interpretation of consent[23] cannot overcome constraints emerging from international human rights law and subsequent State obligations in relation to the right to health. Secondly, we explore whether dilution of informed consent is permissible during a state of emergency, such as the Covid-19 pandemic through speedy trials under the so-called regime of derogations

[18] Apoorva Mandavilli, *The Coronavirus Is Mutating. What Does That Mean for Us?*, N.Y. Times (Dec. 20, 2020), https://www.nytimes.com/2020/12/20/health/coronavirus-britain-variant.html.

[19] *Question and Answers on the interplay between the Clinical Trials Regulation and the General Data Protection Regulation*, EURO. COMM. DIR.-GEN. FOR HEALTH AND FOOD SAFETY (2014), https://ec.europa.eu/health/sites/health/files/files/documents/qa_clinicaltrials_gdpr_en.pdf.

[20] Rebecca Robbins et al., *AstraZeneca Covid-19 vaccine study put on hold due to suspected adverse reaction in participant in the U.K.*, STATNEWS (Sept. 8, 2020), https://www.statnews.com/2020/09/08/astrazeneca-covid-19-vaccine-study-put-on-hold-due-to-suspected-adverse-reaction-in-participant-in-the-u-k/.

[21] *COVID-19 Vaccines and Allergic Reactions*, CTR. FOR DISEASE CONTROL (last updated Jan. 22, 2021), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html.

[22] Alle, *supra* note 20.

[23] Jane Kaye et al., *Dynamic Consent: A Solution to a Perennial Problem?*, BRIT. MED. J.142 (2011).

(section 3). Thirdly, we go on to examine whether and which remedies are available to volunteers who suffer from those risks, both territorially as well as extra-territorially in the case of outsourced trials (section 4). Last, the paper examines whether the triggering of a State of emergency and the so-called derogation regime can serve as justification for the non-applicability of human rights obligations related to clinical trials. In this respect, the paper suggests that States do not have the right to derogate from the right to the enjoyment of the highest attainable standards of health, even in situations of emergency, such as Covid -19 (section 5). Ultimately, the paper suggests a blockchain-based governance model for managing risks arising from clinical trials involving new pharmaceutical technologies (section 6).

## II. THE SCOPE OF INFORMED CONSENT IN CLINICAL TRIALS UNDER HUMAN RIGHTS LAW

Informed consent manifests itself as a doctrine stemming from individual autonomy and privacy. It has been crucial in the development of medical ethics theories concerning liability in English and early American law, including in tort and negligence.[24] In the wording of the Appellate Court of California as far as back as 1957:

> A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment… In discussing the element of risks a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to informed consent. [25]

For claims alleging lack of informed consent in overseas clinical trials, US courts distinguish situations where lack of consent may be treated as a battery claim not requiring injury, from situations where lack of informed consent is best treated as a form of negligence requiring causation and actual injury. *Shloendorff v. Society of New York Hospital*[26] established the root premise of true consent. It was stated that: "Every human being of adult years and sound mind has a right to determine what shall be done with his own

[24] Ruth R Faden & Tom L Beauchamp (eds), *A History and Theory of Informed Consent* 24ff (1986).

[25] Salgo v. Leland Stanford Board of Trustees, 154 Cal. App. 2d 560, 578 (1957).

[26] *Schloendorff v. Soc'y of New York Hosp*., 211 N.Y. 125, 105 N.E. 92 (1914), abrogated by *Bing v. Thunig*, 2 N.Y.2d 656, 143 N.E.2d 3 (1957)

body." True consent is "the informed exercise of a choice, which entails an opportunity to evaluate knowledgeably the options available and risks."[1] In *Helling v. Carey,*[27] the Court went on to note that the health care provider's compliance with the standards of protection as established by a reasonable, prudent professional is necessary to shield him from negligence claims. The average volunteer for evaluating the efficacy of a new mRNA vaccine nano-carrier has little to no understanding of the associated uncertainties and risks, and only the developer of such vaccine "*may*" have the highest possible knowledge of said risks. Thus, for the volunteers to reach an intelligent informed decision they must necessarily rely on the expertise of the developer.

Due to the difficulty to predict the potential adverse effect of mRNA vaccine and its-nanocarrier constituents, informed consent is crucial. The major technological challenges for wide spread application of encapsulated mRNA are its instability, high innate immunogenicity and ineffective delivery.[28] These challenges were addressed by loading the vaccine into a nano-carrier due to their small size (about 100-150 nano-meters), which allows for free circulation and avoidance of the immune system.[29] Under human rights law, the right to informed consent in relation to medical treatment and medical experimentation is implied in a variety of treaty provisions, including the right to physical integrity;[30] the right to private life, specifically health information privacy;[31] the right to health;[32] freedom from

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[27] *Helling v. Carey*, 83 Wash. 2d 514, 519 P.2d 981 (1974), disapproved of by *Barton v. Owen*, 71 Cal. App. 3d 484, 139 Cal. Rptr. 494 (Ct. App. 1977)

[28] Norbert Pardi et al., *mRNA Vaccines - A New Era in Vaccinology,* NAT. J. 261-279 (2018), https://www.nature.com/articles/nrd.2017.243.pdf.

[29] *See* Elvin Blanco et al., *Principles of Nanoparticle Design for Overcoming Biological Barriers to Drug Delivery*, NAT. J. 941-951 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4978509/pdf/nihms805388.pdf.

[30] International Covenant of Civil and Political Rights Article Seven, March 23, 1976.

[31] International Covenant of Civil and Political Rights Article Seventeen, March 23, 1976; Cf. also, ECtHR, X and Y v. the Netherlands*,* 26 March 1985, § 22, Series A No. 91 (noting that Article Eight of the Convention and the concept of "private life" encompasses the physical integrity).

[32] International Covenant of Economic, Social, and Cultural Rights Article Twelve, January 3, 1976 guarantees the enjoyment of the highest attainable standard of physical and mental health. Similarly worded provisions are found also in the International Convention on the Elimination of All Forms of Racial Discrimination Article Five; Convention on the Elimination of All Forms of Discrimination against Women Article Twelve; Convention on the Rights of the Child Article Twenty-Four; San Salvador Protocol Article Ten; African Commission of Human People's Rights Article Sixteen; European Social Charter Article Eleven.

inhuman and degrading treatment (IDT);[33] and the protection of the integrity of the person, especially persons with disabilities.[34] All these provisions shed light on the legality of treatment without fully informed consent. The International Covenant on Civil and Political Rights (ICPPR) was adopted following the sore experiences of Nazi Germany and experiments on prisoners and detained persons,[35] referring specifically to the right to free and informed consent for any medical experiments.[36]

References in the jurisprudence of UN treaty bodies, however, are still scarce. The most relevant case before the CESCR to date is arguably *Merino Sierra v Spain,*[37] which was found to be inadmissible due to the facts having taken place prior to the entry into force of the Optional Protocol to the ICESCR. The complaint was based on article 12 of the International

[33] International Covenant of Civil and Political Rights Article Two, March 23, 1976; European Court of Human Rights Article Three. See N. v. the United Kingdom [GC], no. 26565/05, § 29, ECHR 2008 (regarding the suffering flowing from a naturally occurring illness 'exacerbated by treatment stemming from measures for which the authorities can be held responsible.'

[34] See Convention on the Rights of Persons with Disabilities Article Fifteen: "No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his or her free consent to medical or scientific experimentation" and Article Seventeen; Phil Fennell, 'Article 15' *in: The UN Convention on the Rights of Persons with Disabilities: A Commentary* (Ilias Bantekas, Stein, Anastasiou eds, OUP 2019). Also, indicatively, Committee on the Rights of Persons with Disabilities, Concluding observations on the initial report of South Africa, CRPD/C/ZAF/CO/1, 23 October 2018, paragraph 32 (regarding forced sterilization and the administration of experimental or new drugs and treatments on girls and women with disabilities without their free and informed consent).

[35] *See* The Nuremberg Code Article One, October 1946, See Art. 1 of Nuremberg Code, which was emphasized in the context of: "Permissible Medical Experiments," in Trials of War Criminals before Nuremberg Military Tribunals under Control Council Law.

[36] International Covenant of Civil and Political Rights Article Seven, March 23, 1976: "No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation."

[37] Imelda Merino Sierra and Juan Luis Merino Sierra v. Spain, International Committee on Economic, Social and Cultural Rights, App. No. 4/2014. Views adopted by the Committee under the Optional Protocol to the International Covenant on Economic, Social and Cultural Rights, UN Doc E/C.12/59/D/4/2014 (24 November 2016) para. 7 (regarding a lawsuit for medical negligence, failure to provide treatment and lack of informed consent for medical tests medical tests on a patient diagnosed with pancreatic cancer). Likewise, in *LML*, a complaint relevant to lack of informed consent about the potential risks of a spinal surgery, was found to be inadmissible. See, LML v. UK. Decision adopted by the Committee under Article Two of the Optional Protocol, concerning communication No. 27/2015 (24 March 2017) (inadmissible) (regarding a patient subject to spinal surgery without having received comprehensive information about the subsequent risks).

Covenant on Economic Social and Cultural Rights (ICESCR) and the right to health.[38]

The jurisprudence of the European Court of Human Rights (ECtHR)in a number of cases related to medical procedures involving pharmaceutical companies could also provide some guidance on the way informed consent should be understood. Vaccination without informed consent is generally considered by the ECtHR as a form of compulsory medical intervention 'even if it is of a minor importance'.[39] As such it amounts to an interference with the right to respect for one's private life 'which includes a person's physical and psychological integrity, as guaranteed by Article 8(1)of the Convention'.[40] Yet, the question of the legitimacy of interference with individual rights is subject to the usual balancing exercise undertaken by the Court, including the necessity and proportionality tests. These tests typically amount to the benefit of the State as public health considerations are generally considered adequate justifications for an infringement to the right to private life under article 8 of the Convention. In addition, the jurisprudence of the Court in a number of cases related to persecution of individuals who refused to undergo compulsory vaccination[41] does not support the suggestion that State authorities have an obligation to justify how a particular vaccine is detrimental to one's health. In *Solomakhin,* for example, an individual was vaccinated for diphtheria while at the last stage

[38] *Id.* at paragraph 8. The Committee on ESCR has expanded to include the right to be free from medical experimentation and treatment without the patient's consent. See also, CESCR, General Comment 14: The Right to the Highest Attainable Standard of Health (Article 12), UN Doc E/C.12/2000/4 (11 August 2000) para. 8–9 (noting that the Covenant recognises the right to enjoy high standards of health, which represents a proposition that is largely dependent on a series of positive obligations. These obligations are of a twofold nature: on the one hand they require the provision of adequate health care services, while on the other they oblige the authorities to satisfy the underlying determinants of health, including basic shelter, food, water, sanitation, safe working environment, freedom from pollution, disease prevention and others. This definition of the right to health with its two corresponding components is broader than the definition of 'health' in the preamble to the Constitution of the World Health Organization (WHO), which defines health as a 'state of complete physical, mental and social well-being and not merely the absence of disease or infirmity').

[39] See for example, *Y.F. v. Turkey,* no. 24209/94, ECHR 2003-IX at para 33 ('a person's bodily integrity concerns the most intimate aspects of one's private life, and that compulsory medical intervention, even if it is of a minor importance, constitutes an interference with this right').

[40] Salvetti v. Italy (dec.), no. 42197/98, 9 July 2002, and Matter v. Slovakia, no. 31534/96, § 64, 5 July 1999.

[41] *Solomakhin v. Ukraine,* App No 24429/03 (15 March 2012) para 38. Cf also, Boffa and 13 others v. San Marino, application no. 26536/95, Commission decision of 15 January 1998, DR 92; also, Vavřička v. the Czech Republic, App Nos. 47621/13, 3867/14, 73094/14 et al (relinquishment); *Aleksandra Skerlevska against the former Yugoslav Republic of Macedonia,* Application no. 54372/15, lodged on 26 October 2015, Communicated on 12 June 2017 (pending).

of an illness, following the spread of an epidemic in Eastern Ukraine.[42] The applicant claimed that the doctors had not sought his informed consent for this particular vaccine, nor had they properly checked potential side effects. According to the Court, 'the applicant's physical integrity could be said to be justified by the public health considerations and necessity to control the spread of infectious diseases'.[43]

Two safeguards seem to be applicable in this respect. Firstly, the Court maintains that access to unauthorized vaccinations and experimental products must be regulated, precisely because of the absence of European consensus among European States on the matter. [44] Secondly, any interference with individual health and the right to private life under article 8 should be accompanied by relevant precautions 'to ensure that the medical intervention would not be to the applicant's detriment to the extent that would upset the balance of interests between the applicant's personal integrity and the public interest of protection of the health of the population'.[45] Such precautions clearly should encompass precise information about all potential risks. As emphasized by Judge Zupančič: "Informed" consent implies that the patient in such circumstances must be instructed as to all the potential risks of administering any kind of medical treatment, which he must thereafter consent to in a genuinely informed way. Failing that, we cannot speak of a full consent […].[46] This is a particularly important obligation in speedy trials. By way of example, Sinopharm's vaccine was tested on approximately a million people, as part of an 'emergency-use program authorized by Beijing'.[47] Such 'fast track'

[42] Solomakhin, *supra* note 39 at para 30 (regarding patients who were vaccinated 'vaccinated during the acute stage of an illness and that the doctors had not checked all relevant contraindications to vaccination in his case'. In particular , the patients claimed that they had been administered an expired vaccine of poor quality , as well as that this was done against their will.

[43] Solomakhin, *supra* note at para 36. The individual died subsequently from a heart attack.

[44] *Hristozov and others v. Bulgaria*, App No. 47039/11 and 358/12 (13 November 2012) para 122 – 125 (regarding vaccination of an unauthorized vaccine on cancer patients, allowed exceptionally for "compassionate use"). The ECtHR noting that national courts should strike a 'balance between the public interest and personal autonomy, sought to protect the health and life of those concerned by preventing abuses and the risks accompanying the use of untested products').

[45] *Hristozov, supra* note 42 at para 122 – 125

[46] Solomakhin, *supra* note (concurring opinion of Judge Zupančič).

[47] Ben Westcott & Sophie Jeong, *Almost a Million People Have Been Given an Experimental Chinese Coronavirus Vaccine, Pharmaceutical Giant Claims*, CNN (Dec. 7, 2017), at 1, https://www.cnn.com/2020/11/20/asia/china-sinopharm-vaccine-test-intl-hnk/index.html.

approvals have sparked intense debate in medicine more generally[48] and medical ethics more specifically,[49] as well as the media, [50] and are arguably in contradiction with human rights standards on vaccine authorization and informed consent due to the rapidity of procedures.

## III. OUTSOURCING CLINICAL TRIALS: PITFALLS FOR INFORMED CONSENT OBLIGATIONS

Before circulating in the market, vaccines are tested in different segments of populations. This is not necessarily problematic – rather, it is a necessary requirement to ensure a vaccine's effectiveness against 'all diverse populations of the world.'[51] A recent trend, however, has emerged involving the outsourcing of clinical trials in locations outside the home state of large multinational pharmaceutical companies. Both home states and foreign states typically participate in the outsourced trials. The foreign state accepts to participate in the outsourced trials as part of their healthcare obligations to provide medications that is otherwise unavailable without such participation ('outsourcing trials'). The home state accepts to participate in outsourced trials to have a pool of volunteers residing in other countries ('cross-border clinical trials'), particularly Brazil, China, India, South Africa, the Middle East, and Eastern Europe.[52] This raises a number of

[48] *See generally*, Robert Steel, Lara Buchak & Nir Eyal*, Why Continuing Uncertainties are no Reason to Postpone Challenge Trials for Coronavirus Vaccines*, 46 J MED ETHICS 808, 808 (2020), https://jme.bmj.com/content/medethics/46/12/808.full.pdf; *contra* Arnon Keren & Ori Lev, *Uncertainty, Error and Informed Consent to Challenge Trials of COVID-19 Vaccines*, 46 J. MED. ETHICS 808, 813 (2020), https://jme.bmj.com/content/medethics/46/12/813.full.pdf.

[49] Jennifer O'Neill*, The COVID-19 vaccine, informed consent and the recruitment of volunteers*, J. OF MED. ETHICS: BLOG (Nov. 3, 2020), https://blogs.bmj.com/medical-ethics/2020/11/23/the-covid-19-vaccine-informed-consent-and-the-recruitment-of-volunteers/.

[50] Sui-Lee Wee & Elsie Chen, *Vaccine Unproven? No Problem in China, Where People Scramble for Shots*, N.Y. TIMES (Nov. 11, 2020), https://www.nytimes.com/2020/11/17/business/china-coronavirus-vaccine-safety.html /.

[51]*See 172 countries and multiple candidate vaccines engaged in COVID-19 vaccine Global Access Facility*, WHO (Aug. 24, 2020), https://www.who.int/news/item/24-08-2020-172-countries-and-multiple-candidate-vaccines-engaged-in-covid-19-vaccine-global-access-facility.

[52] By way of example, see, Seth W. Glickman et al., *Ethical and Scientific Implications of the Globalization of Clinical Research,* 360 NEW ENG. J. OF MED. 2792, 2793 (2009); see also, Carolijn Terwindt, *Health Rights Litigation Pushes for Accountability in Clinical Trials in India*, 16 HEALTH AND HUM. RTS. J. 84, 83 (2014); Benjamin Kagina, *COVID-19 vaccine*

issues, including the lack of available and effective legal remedies in volunteers' own countries. In fact, cross-border clinical trials are often viewed by volunteers as access to medical treatment that is otherwise unavailable in their home states. Patient volunteers are less likely to question the treatment procedure or the medication provided to them at no cost.[53] It is estimated that more than 50 percent of all clinical trials is conducted outside the producers' country of incorporation or headquarters.[54] The US Federal Drug Administration (FDA) approved over forty formulations of drugs[55] that employ nanotechnology either in its making of the active ingredient (e.g., sirolimus[56]) or encapsulating the active ingredient with a protective shell to improve the efficacy and reduce side effects (e.g., liposomal formulation of doxorubicin).[57] The nano-enabled products that are approved by the FDA receive wide international recognition and acceptance. For example, only 49 percent of Doxil,Ò known internationally as Caelyx,Ò and its family of similar products are sold in the US market.[58] In Saudi Arabia alone, there are to date ten clinical trials utilizing DoxilÒ.[59]

Many actors are involved in a clinical trial of a new drug and in the various phases of its administration. These include the drug-producing company, the researchers, the research organizations conducting the trial (which may be a public or private academic institution or a private

*trials in Africa: what's promising, and what's problematic*, THE CONVERSATION (Dec. 2, 2020), https://theconversation.com/covid-19-vaccine-trials-in-africa-whats-promising-and-whats-problematic-150967; and Jeffrey Mphahlele, *COVID-19 vaccine: the challenges of running a trial in the middle of a pandemic*, THE CONVERSATION (July 7, 2020), https://theconversation.com/covid-19-vaccine-the-challenges-of-running-a-trial-in-the-middle-of-a-pandemic-141728.

[53] Samiran Nundy et al., *A New Colonialism? -- Conducting Clinical Trials in India*, 352 NEW ENG. J. OF MED. 1633, 1634-6 (2005).

[54] Wemos Foundation, *The Clinical Trials Industry in South Africa: Ethics Rules and Realities* (Amsterdam: Wemos Found., July 2013), https://www.wemos.nl/wp-content/uploads/2016/06/Clinical_Trials_Industry_South_Africa_2013.pdf.

[55] C. Lee Ventola, *Progress in Nanomedicine: Approved and Investigational Nanodrugs*, 42 PHARMACY & THERAPEUTICS 742, 744 (2017).

[56] Sirolimus is a target of the rapamycin inhibitor with immunosuppressive properties. Its clinical application is limited due to its poor solubility. The FDA approved the nano-formulation of the drug and is marketed as RapamuneÒ.

[57] Doxorubicin is an anti-cancer drug that is widely used for the treatment of numerous tumors, including breast, ovarian, and lung. However, due to its irreversible cardiotoxicity a liposomal shell was designed to protect the untreated tissue and organs from its toxicity. The FDA-approved liposomal Doxorubicin products are DoxilÒ, LipodoxÒ, and MyocetÒ.

[58]Available at: https://www.grandviewresearch.com/industry-analysis/liposomal-doxorubicin-market.

[59] *See* https://clinicaltrials.gov/ (enter "Doxil" into "Other terms" search box; choose "Saudi Arabia" from "Country" dropdown; then click "Search" button).

organization), public and private hospitals, as well as healthcare providers. The legal obligation/liability towards volunteers of a clinical trial depends on the role of these actors and their interaction with volunteers. Regulatory agencies, as agents of states, are required to ensure adequate protection. To shield the individuals and entities implementing crisis measures from targeted liability, authorized emergency measures need to be instituted. For example, the US Federal Public Readiness and Emergency Preparedness (PREP) Act[60] protects entities that implement health countermeasures approved for emergency use by the FDA from liability. The PREP Act provides limited tort liability protections, among others, to vaccine manufacturers, pharmacists, and medical professionals. A compensation fund is established for injured volunteers. The immunity provided by the PREP Act, however, is limited and faced legal challenges on the basis of inadequate informed consent.[61]

The US Food and Drug Administration (FDA) issued guidance to assist clinical trial sponsors assuring the safety of the trial volunteers, maintaining compliance with good clinical practice, and minimizing the risks to the integrity of clinical trials during the pandemic.[62] The FDA deviated from the required public notice[63] and allowed for the guidance to be applied immediately. However, the FDA made it clear that the guidance is not establishing a set of legally binding responsibilities. This is a major deviation from the normal practice of FDA,[64] which restrict waving or the appearance of waving of any legal right against the investigator or the sponsor of a clinical trial.[65]

Claims may be advanced at the producer's home state, or place of headquarters, as was the case with suits against the producers of the Torvan drug,[66] even though the clinical trial in question (from which the suit arose)

[60] 42 U.S.C. § 247d-6d (2020).
[61] Parker v. St. Lawrence County Pub. Health Dept., 102 A.D.3d 140 (2012).
[62] FDA, *Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency* (2021), *https://www.fda.gov/media/136238/download.*
[63] According to the FDA regulations, a public notice is required pursuant to 701(h)(1)(C)(i) of the FDA Act and 21 CFR 10.115(g)(2). When public participation is not feasible, the Act could be implemented without notice or comment period.
[64] *See A Risk-Based Approach to Monitoring of Clinical Investigations Questions and Answers Guidance for Industry,* https://www.regulations.gov/document?D=FDA-2019-D-0362-0002
[65] *See* 46 FR 8951, Jan. 27, 1981, *as amended at* 64 FR 10942, Mar. 8, 1999.
[66] Trovan is a drug produced by Pfizer, which was found to result in long-term brain damage and death for some of the participants. *See* Harpreet K. Pannu, *Acute Liver Failure due to Trovafloxacin: CT Findings*, 8 EMERGENCY RADIOLOGY 108 (2001); Joe Stephens, *Pfizer to Pay USD 75 Million to Settle Nigerian Trovan Drug-Testing Suit*, THE WASHINGTON POST, July 31, 2009.

was conducted in Nigeria.[67] That courts in developed states apply (or not) the *forum non conveniens* principle in order to assert jurisdiction over conduct committed in the (outsourced) country where a clinical trial took place, is an integral part of the notion that multinational corporations (MNCs) are responsible for their direct impact on people and communities in their countries of operation,[68] so long as they had a directing role in the conduct in question.[69]This is usually difficult to ascertain and prove.

The administration of nano-enabled drugs is governed by policies and laws specific to the jurisdiction in which the clinical trials are performed. Informed consent obligations conferred on the investigator in a clinical trial are well entrenched.[70] However, there is no internationally recognized risk governance framework for informed consent whereby participants can critically review and agree to its terms ahead of volunteering to the treatment. Jurisdictions that are not fully equipped with sufficient scientific know-how concerning the formulation of vaccines enabled with nano-carriers lack the expertise to assess the risks associated with the complexity, uncertainty and ambiguous nature arising from the administration of mRNA vaccines and its nano-carriers. Further, there is no international regulatory framework for admitting nano-enabled drugs or vaccines to the clinical trial markets.

The outsourcing of clinical trials in developing countries has led to a string of cases where volunteers questioned the propriety of informed consent. In a case heard in Argentina, the judge rejected GlaxoSmithKline's defense that complying with informed consent requirements was a mere formality, the absence of which did not pose an actual risk to the volunteer participants. The court went on to explain that: "even minor deficiencies in the procedure could become relevant later on as certain health effects may

[67] Abdullahi v. Pfizer, Inc. 562 F.3d 163 (2d Cir. 2009).

[68] *See e.g. Chandler v Cape PLC* [2012] EWC. Civ 525; *See also* Landgericht Dortmund weist Klage gegen KIK wegen Verjährung [*Jabir v KiK Textilen und Non-Food GmbH* 7 O 95/15 decision of 10 January 2019], available at: http://www.lg-dortmund.nrw.de/behoerde/presse/Pressemitteilungen/PM-Urteil-KIK.pdf . *See* Vivian G. Curran, *Harmonizing Multinational Parent Company Liability for Foreign Subsidiary Human Rights Violations*, 17 CHI. J. OF INT'L L. 403 (2016).

[69] See *Okpabi and others v Royal Dutch Shell Plc* (2018) EWCA Civ 191 and as approved by the UK Supreme Court. The Court of Appeal effectively denied jurisdiction over claims by victims oil spills in the Niger Delta. *Okpabi* is somewhat in contrast to *Lungowe and Others v Vedanta Resources Plc* [2017] EWCA Civ 1528 where the Court of Appeal delivered had held a year earlier that environmental tort claims, such as those raised in *Okpabi*, could proceed in English courts, arguing that the UK parent company owed a duty of care to the overseas claimant.

[70]Stacey B. Lee, *Informed Consent: Enforcing Pharmaceutical Companies' Obligations Abroad*, 12 NATL. LIBR. OF MED. 15 (2010).

only occur in the future."[71] That drug manufacturers, whether sponsoring international clinical trials or not, have legal obligations arising from such processes has been made abundantly clear. The Indian Supreme Court reasoned that manufacturers have a duty of care towards clinical trial volunteers in accordance with the Caparo test of foreseeability, proximity and fairness.[72]

One of the legal side effects of transnational clinical trial outsourcing is the presumption that informed consent is at best a non-conducive (i.e. not an essential condition for the volunteer/offeree) contractual term, or a tort, assuming that some harm occurs. In the first case the breach of contract arising from the absence of appropriate informed consent does not lead to significant damages and is not a cause for the termination of contract. On the other hand, tort-based liability will arise where local laws require a duty of care (i.e. concerning informed consent) and harm is caused to the participant. It is clear that both contractual and tort-based mechanisms, although useful, should only be used residually and not as the primary source of obligations by drug manufacturers.

At present, most clinical trials on novel COVID-19 vaccines are domesticated in the home state where the vaccine is being developed. The most successful reported vaccine efficacy tests concern the two vaccines by ModernaTX and Pfizer. The ModernaTX vaccine Phase 3 clinical trial was administered on 30,000 participants at 100 different locations in the United States.[73] Pfizer tested its vaccine on over 40,000 trial participants.[74] Johnson and Johnson announced its Phase 3 transboundary clinical trial for its COVID vaccine to include 60,000 participants in Argentina, Brazil, Chile, Colombia, Mexico, Peru, South Africa and the United States.[75] In the case of the EU alone, volunteers may be subject to vaccination treatment with a product that is not available in the market of a member State, which

[71] Andrea Gerlin, *Glaxo to Appeal Fines in Argentina Case Over Synflorix Trial*, BLOOMBERG BUSINESSWEEK (Jan. 3, 2012), https://www.bloomberg.com/news/articles/2012-01-03/glaxo-to-appeal-fines-in-argentina-case-over-synflorix-trial.

[72] Karine Morin, *The Standard of Disclosure in Human Subject Experimentation*, 19 J. OF LEGAL MED. 157 (1998).

[73] 'Safety and Immunogenicity Study of 2019-nCoV Vaccine (mRNA-1273) for Prophylaxis of SARS-CoV-2 Infection (COVID-19)' available at: https://clinicaltrials.gov/ct2/show/NCT04283461

[74] 'Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals', available at: https://clinicaltrials.gov/ct2/show/NCT04368728.

[75] *Johnson & Johnson Initiates Pivotal Global Phase 3 Clinical Trial of Janssen's COVID-19 Vaccine Candidate,* Johnson & Johnson (Sept. 23, 2020), https://www.jnj.com/johnson-johnson-initiates-pivotal-global-phase-3-clinical-trial-of-janssens-covid-19-vaccine-candidate.

nonetheless has been authorized in another member State 'where it is not possible to treat a disease with medicinal products available in the country'.[76] In all other circumstances, however, States should have accrued State obligations for the protection of the right to health, both extra-territorially and vis a vis private corporations.

A surge in the number of transnational clinical trials for nano-enabled vaccine carriers is anticipated. At present, a sizeable number of clinical trials are running to evaluate the efficacy of nano-enabled drug carriers.[77] International clinical trials of nano-enabled drugs may provide a benefit to volunteers and governments in the developing world, as nano-enabled drugs provide access to medical treatment that is otherwise unavailable; At the same time, it saves costs for producers. The cost of clinical trials in developed countries is almost 90 per cent cheaper than in developing countries.[78] However, the delegation to third parties to conduct such trials does not release the manufacturer from its own liability.[79] International medical professional organizations[80] require that informed consent be properly obtained, and adequate monitoring systems be implemented for all clinical trials.

Speedy clinical trials pose additional complexities with regard to receiving adequate information and monitoring the results. In many cases, volunteers are either denied crucial information about the phase of testing, the dangers associated with the particular drug, or the available data relating to the financial needs and expectations of the volunteer. In October 2020, for example, the NY Times reported that US-based Eli Lilly and the National Institutes of Health were among the first to conduct clinical trials with

[76] COMM. FROM THE COMM'N TO THE EURO. PARL., THE EURO. COUNCIL, THE COUNCIL AND THE EURO. INVEST. BANK: EU Strategy for COVID-19 VACCINES, COM/2020/245 final (Jun 17, 2020) (available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0245).

[77] *See* www.clinicaltrials.gov (search with keyword "nano") (showing that as of December 30, 2020, there were 345 studies of nano-enabled products being experimented in 101 trials in Europe, 83 in the US, 35 in the Middle East, 29 in East Asia, 27 in Africa, 14 in South America, 9 in Australia, 13 in Canada, 3 in Japan, 5 in Russia, 2 in India and 2 in Mexico).

[78] Joanne Nicholas, *Outsourcing Clinical Trials*, 104 J. OF THE NAT'L CANCER INST. 1043 (2012).

[79] *See* 21 CFR 50.20 (emphasizing that "No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.").

[80] *See, e.g.*, the EC Commission Directive 2005/28/EC of 8 April 2005 (laying down principles and detailed guidelines for good clinical practice for investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products).

monoclonal antibodies in nursing homes.[81] Many of the residents in these homes "have dementia, or have difficulty seeing and hearing."[82] Therefore, trial managers are obliged to properly obtain informed consent from volunteers, which itself may be traced as far back as Article I of the Nuremberg Code: "The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity."[83]

## IV. HUMAN RIGHTS VIOLATIONS BY STATES AND NON-STATE ACTORS DURING THE COVID-19 PANDEMIC

What remains to be examined, therefore, is whether the emergence of the pandemic is a factor that influences human rights obligations of States. In other words, the question is whether the dilution of obligations related to seeking informed consent is justified due to the application of a special regime during the pandemic.

This is hardly the first pandemic in recent history. The International Sanitary Convention,[84] which initially dealt only with cholera, was adopted in 1892, following the Cholera Epidemic of 1873. These conventions followed worldwide efforts towards international health cooperation, beginning with the first International Sanitary Conference in Paris, which opened on 23 July 1851, and followed by another Convention dealing with the plague in 1897.[85] Their objective was to "harmonize and reduce to a safe

[81] Gina Kolata, *An 'Unprecedented' Effort to Stop the Coronavirus in Nursing Homes*, N.Y. TIMES (Aug. 20, 2020), https://www.nytimes.com/2020/08/20/health/coronavirus-nursing-homes.html.

[82] *Id.*

[83] 11 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10, 181-182 (1949) (available at https://www.loc.gov/rr/frd/Military_Law/pdf/NT_war-criminals_Vol-II.pdf) (noting that the Nuremberg Code resulted from Trials of War Criminals before Nuremberg Military Tribunals under Control Council Law No 10: Nuremberg, October 1946-April 1949, in which Nazi doctors were put on trial for experimenting on humans in concentration camps. The Code establishes principles for human subject research protection).

[84] International Sanitary Convention, PAN AMERICAN HEALTH ORGANIZATION (1892), https://www.paho.org/hq/index.php?option=com_content&view=article&id=13878:iv-international-sanitary-convention&Itemid=2261&lang=en.

[85] Lawrence O. Gostin, *World Health Law: Toward a New Conception of Global Health Governance for the 21st Century*, 3 YALE J. HEALTH, POL. & ETHICS 413, 414 (2005) (also giving an account of instruments pre-dating the Charter) (noting that in 1903, the International Sanitary Convention replaced the conventions of 1892 and 1897).

minimum the conflicting and costly maritime quarantine requirements of different European nations."[86] The effectiveness of these treaties, however, has been limited, aiming at international cooperation rather than the establishment of a special regime. As a result, the legal regime applicable in situations of pandemics, akin to disasters, remains the regime of derogations.

### A. BRIEF OVERVIEW OF THE GENERAL DEROGATION REGIME UNDER THE ICCPR

The right to declare a State in a situation of emergency and subsequently take derogatory measures from some human rights obligations is a right that States possess. The ICCPR, the primary instrument guaranteeing rights that are traditionally perceived as "civil and political," allows derogations in exceptional circumstances. Such circumstances have been defined as a "time of public emergency which threatens the life of the nation, the existence of which is officially proclaimed" under article 4.[87] This provision is central to the exercise of sovereign power, subsequent to executive orders and other types of extraordinary powers of the executive. "When the State is engaged in a life and death struggle, no one can demand that it refrain from taking special emergency measures: *salus rei publicae suprema lex est*".[88]

The first safeguard to of the article, is the second paragraph of article 4, which stipulates that some rights can never be derogated from, even in such times of emergency that threaten the life of a nation, as is the case with an epidemic – or pandemic. This list of rights is not subject to derogations.[89]

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[86] Global Health Histories, *Origin and development of health cooperation*, WHO, https://www.who.int/global_health_histories/background/en/ (explaining history of the conventions).

[87] Art 4 para 1 and 4 para 2. In time of public emergency which threatens the life of the nation and the existence of which is officially proclaimed, the States Parties to the present Covenant may take measures derogating from their obligations under the present Covenant to the extent strictly required by the exigencies of the situation, provided that such measures are not inconsistent with their other obligations under international law and do not involve discrimination solely on the ground of race, colour, sex, language, religion or social origin. See generally, D McGoldrick, *The Interface Between Public Emergency Powers and International Law*, 2 INT'L J. CONST. L. 380, 383 (2004).

[88] Lawless v. Ireland (1961), 1 EHRR 15 (the case concerned an IRA suspect detained under emergency legislation).

[89] *See* Dominic McGoldrick, *The Interface Between Public Emergency Powers and International Law*, 2 INT'L J. CONST. L. at 383 (2004) ("No derogation from articles 6, 7, 8 (paragraphs I and 2), 11, 15, 16 and 18 [religious freedom] may be made under this provision").

This list has been extensively discussed during the drafting of the ICCPR.[90] The Committee has stated several times that States cannot evade the obligations which they have undertaken by ratifying the Covenant."[91]

Under human rights law, several important safeguards apply.[92] First, such powers may be applied in exceptional circumstances only, like when the 'life of a nation' is threatened. If no such circumstance is present, the normal legal regime applies. Second, the right to take such measures is subject to notification requirements. This notification has the purpose of making the situation public and may take the form of a formal declaration to the relevant body – namely, the Secretary General of the United Nations (UN SG) or of the OAS – in the case of the ACHR.[93]

In some cases, therefore, as under the ECHR, emergency measures taken by States may not be lawful for the only reason that the pertinent notification requirement was not met.[94] The same applies in the context of the OAS and under the ACHR, which requires in addition that notification of derogations be made "immediately."[95] Third, it can only apply for a

[90] Marc Bossuyt, *Guide to the "travaux Préparatoires" of the International Covenant on Civil and Political Rights* (Martimus Nijhoff 1997) at 91ff; UN Human Rights Committee (HRC), CCPR General Comment No. 29: *Article 4: Derogations during a State of Emergency*, 31 August 2001, CCPR/C/21/Rev.1/Add.11, para 9 in fine. In the adopted version of the ICCPR non- derogable rights include fundamental civil rights such as the right to life, freedom from torture, freedom from slavery and curiously also religious freedom. In relation to religious freedom (which is clearly derogable under other instruments, such as the ECHR for example), most States, seemed to agree that even if religious freedom under 18 is non- derogable, this is not the case also with article 18 paragraph 3 in relation to the manifestation of a religion. This means therefore that States have the right to close down places of warship, yet these limitations should be only as a measure of last resort, and only if this does not fully deny religious freedom. This point is also made by the HRC which highlights that 'even in times of most serious public emergencies, States that interfere with the freedom to manifest one's religion or belief must justify their actions by referring to the requirements specified in article 18, paragraph3'.

[91] McGoldrick, *The Interface Between Public Emergency Powers and International Law*, 2 INT'L J. CONST. L. at 390 (2004).

[92] *Id.* at 383 (defining derogations as "complete or partial elimination as an international obligation.").

[93] Constitutional Rights Project, Civil Liberties Organisation and Media Rights Agenda (1994), ("[T]he African Charter does not contain a derogation clause. Therefore, the limitations on the rights and freedoms enshrined in the Charter cannot be justified by emergencies and special circumstances. The only legitimate reasons for limitations to the rights and freedoms of the Charter are found in article 27(2).").

[94] The European Commission for instance has found that derogations are not valid in the absence of notification, as the situation has not become officially public. *See* on *Greece v. UK,* ECHR Commission report, para 158; *Cyprus v. Turkey,* Commission report of 4 October 1983 para 68; *Silva v. Uruguay,* Communication No. R.8/34, U.N. Doc. Supp. No. 40 (A/36/40) at 130 (1981).

[95] McGoldrick, *supra* note 90.

limited period time and for limited rights only. Most international human rights instruments provide such specific conditions for the lawfulness of such ”derogations”, while at the same time set out a minimum ensemble of rights that can be never derogated from irrespective of circumstances. Human rights bodies, subsequently, have had the opportunity to elaborate on the legality of such derogations' regimes – which have indeed in the past been subject to abuse.

### B. APPLICABILITY OF THE DEROGATION REGIME DURING PANDEMICS SUCH AS COVID-19

Most states have instituted extreme quarantine measures and declared a state of emergency.[96] As of December 2020, according to the latest version of statistics by the WHO, there were globally over 75 million confirmed cases and over 1.6 million deaths (about 2.2 per cent), with numbers rising worldwide.[97] This prompted many countries to declare themselves in a state of public health emergency. In response, states adopted measures heavily restricting fundamental rights and freedoms such as freedom of movement. Restrictions have been less in line with the numbers of infections, and rate of mortality (see Fig.1), and more the product of political choices.[98] Undoubtedly, the pandemic has exemplified the huge gap between developed and safe countries as well as between developing and fragile countries,[99] in the same way that it has exemplified the divide between rich and poor or low-income families.[100]

[96] *Eg.,* the U.S. declared a national emergency concerning the coronavirus on March 13, 2020. https://www.ncsl.org/ncsl-in-dc/publications-and-resources/president-trump-declares-state-of-emergency-for-covid-19.aspx.

[97] WHO, *Weekly epidemiological update-15* (Dec. 20, 2020) available at: https://www.who.int/publications/m/item/weekly-epidemiological-update-15-december-2020.

[98] *See e.g.,* Manuela Andreoni, *Coronavirus in Brazil: What You Need to Know*, https://www.nytimes.com/article/brazil-coronavirus-cases.html.

[99] Yemen and Vietnam's death rates are among the highest worldwide (29 people die for every 100 reported infection cases in Yemen). *See* Weekly Epidemiological Update, WORLD HEALTH ORG. (Dec.15, 2020), https://www.who.int/publications/m/item/weekly-epidemiological-update---15-december-2020. Only Vietnam was able to adopt effective measures. *See, e.g.,* Anna Jones, *Coronavirus: How 'overreaction' made Vietnam a virus success*, BBC NEWS (15 May 2020), https://www.bbc.com/news/world-asia-52628283. On Yemen on the contrary, see Coronavirus Data: Yemen Situation, WORLD HEALTH ORG., https://covid19.who.int/region/emro/country/ye (last updated Feb. 8, 2021).

[100] Derek Thompson, *The Coronavirus Will Be a Catastrophe for the Poor*, THE ATLANTIC (Mar. 20, 2020), https://www.theatlantic.com/ideas/archive/2020/03/coronavirus-will-supercharge-american-inequality/608419/.

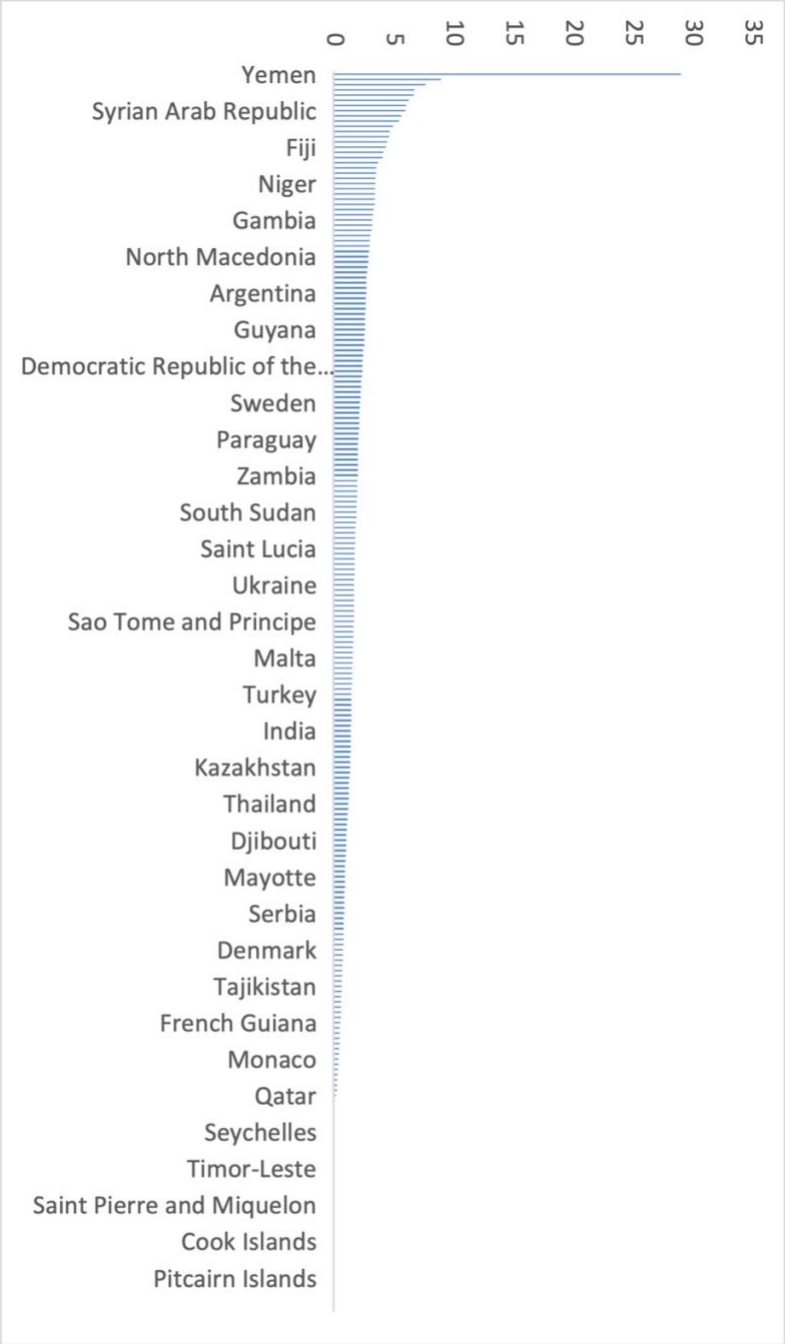


*Figure 1*: Percentage of mortality relative to reported infection cases

The first rights that are typically suspended in a pandemic, such as the Covid-19 outbreak, would be Article 12 (right to liberty of movement), Article 19 (right to freedom of expression) and Article 21 (right of peaceful assembly) of the ICCPR.[101] The Human Rights Committee has specifically underlined that "not every disturbance or catastrophe qualifies as a public emergency which threatens the life of the nation, as required by Article 4, paragraph 1". This is the case of both national and international armed conflict, for instance – whereby human rights may still be applicable even though humanitarian law applies as *lex specialis*.[102] In relation to other situations, not covered by the definition of an armed conflict (as in an epidemic, or *a fortiori* a pandemic), the Human Rights Committee does not warrant unlimited power to States in relation to derogable rights. On the contrary, under the Covenant, any measures derogating from a State party's obligations must be limited "to the extent strictly required by the exigencies of the situation."[103]

The HRC, in addition, highlights that "if States parties consider invoking Article 4 in situations other than armed conflict, they should carefully consider the justification and why such a measure is necessary and legitimate in the circumstances" and that "on a number of occasions, the Committee has expressed its concern over States' parties that appear to have derogated from rights protected by the Covenant, or whose domestic law appears to allow such derogation in situations not covered by Article 4".[104] This means that States do not have unlimited powers to impose exceptional regimes of unlimited derogations, even in relation to non-derogable rights. On the contrary, derogations are subject to necessity and proportionality requirements, whereby necessity' should be defined as a measure of last resort. According to the Committee, geographical coverage, duration, and material scope of the state of emergency are the main requirements in defining both necessity and proportionality. [105] Travel bans, for example, should not exceed the duration that is absolutely necessary to fight the diffusion of a pandemic (and inversely, that the geographical coverage of the

[101] *Cf.* analytically, Alessandra Spadaro, *COVID-19: Testing the Limits of Human Rights*, 11 EUR. J. OF RISK REG. 317, 320–21 (2020).
[102] U.N. Human Rights Comm., General Comment No. 29: State of Emergency (Art. 4) para 3, CCPR/C/21/Rev.1/Add.11 (July 24, 2001). This comment is an improvement of previous General Comment no 5. *See* Sarah Joseph, *Human Rights Committee General Comment No. 29,* 2 HUM. RIGHTS L. REV. 81 (2002).
[103] UN HRC, *supra* note 100, para 5.
[104] *Id.* at para 3.
[105] *Id.* at para 4.

measures taken should follow the rhythm of spread of a pandemic and should not be as strict as in the epicenter or its surroundings). It also follows logically that necessity and proportionality are the necessary requirements in the actions of those ensuring compliance with quarantine measures such as national police authorities, armed forces and the military and immigration authorities.

In addition, the Committee specifically highlights that even though some articles have been listed as non-derogable, States have "a duty to conduct a careful analysis under each article of the Covenant based on an objective assessment of the actual situation."[106] These findings are extremely pertinent in pandemics, whereby States may typically derogate without carefully balancing the interests at stake. Hence, rights commonly derogated from pandemics, as in Covid 19, are typically the liberty of movement and freedom to choose one's residence (article 12 para 1); the right to leave or enter one's own country under article 12, para 2, and 12 para 4; and the 'right to liberty and security of person', and the right to private and family life (Article 17), in case of separation of family members in view of confining individuals affected. This means, for instance, that separation of families may be, at its face, a violation of Article 17 and the right not to interfere with one's privacy and family life unlawfully, especially if home-confinement is an alternative. The same applies to prisoners – solitary confinement or visitations and restrictions to prisoners[107] are, in principle, in breach of Article 17 of the ICCPR.

State practice in relation to derogations in relation to epidemics until now has been rather scarce. It is arguably the first time that States notify the UN SG that they will be imposing a regime of derogations from their human rights obligations under the ICCPR. The same has happened with derogations under the ECHR. To date, the UN SG has received 12 notifications under Article 4 of the ICCPR.[108] Guatemala has issued four notifications from February 19 to March 31, 2020. Guatemala is, in fact, one of the States that have made maximum use of this procedure. Guatemala used this procedure in 2010 to notify the SG about derogations due to natural disasters such as Hurricane Mitchand Hurricane Stan in 2005, as well as in relation to the eruption of the Pacaya volcano in 2010, to the devastations caused by tropical storm Agatha, and because of a 7.8 (on the Richter scale)

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[106] *Id.* at para 6.

[107] Luke Barr and Christina Carrega, *State prisons prepare for coronavirus but federal prisons not providing significant guidance, sources say*, ABC NEWS (Mar. 11, 2020, 12:42 PM), https://abcnews.go.com/US/state-prisons-prepare-coronavirus-federal-prisons-providing-significant/story?id=69433690.

[108] Notifications under Article 4 of the ICCPR, UNITED NATIONS TREATY CTR., https://treaties.un.org/Pages/CNs.aspx?cnTab=tab2&clang=_en.

earthquake in 2012.[109] Likewise, in 2009, Guatemala deposited a derogation in light of the 'swine flu' pandemic. On that occasion, a 'public health emergency' was declared throughout the national territory for a period of thirty days. The 2009 swine flu pandemic or swine flu was an influenza pandemic that lasted from January 2009 to August 2010.[110]

The most recent notification is that dated 20 March by Peru, which has imposed extensive quarantine orders due to the COVID 19 health emergency, resulting in 'total closure of borders, suspending therefore international passenger transport' under an emergency degree dated 20 March 2020, which imposed necessary confinement at home from 8.00 p.m. to 5.00 a.m. and compulsory isolation for those who travelled the days prior to the issuance of the degree. Hence Peru notified that it will be suspending articles 9, 17, 21 and 12 of the ICCPR, allowing individuals [to] move around only to provide and avail themselves of the food products, pharmaceuticals and staple goods and in order to attend health centers and to perform their work.[111] The only services allowed by the authorities are those 'ensur[ing] water, sanitation, electricity, gas, fuel, communications, solid waste collection and funeral services' and 'assistance and care for elderly persons, children, adolescents, dependents, persons with disabilities or vulnerable persons'; 'financial, insurance and pension entities, as well as complementary and related services that ensure their proper functioning'; 'production, storage, transport, distribution and sale of fuel' hotels and other facilities providing accommodation, only for the purpose of complying with the quarantine order; 'media and telephone call centers'; and public sector workers who, exceptionally, provide services.

In all situations, non-discrimination and human dignity should be the yardsticks. This may happen in a scenario arising from obligatory placement in confinement centers to stop spreading of a disease as in the case of pandemics. Conditions in such centers should be consistent with minimum dignity standards. In this respect, freedom from cruel, inhuman or degrading treatment or punishment, including also the right to be free from 'medical or scientific experimentation without one's *free* consent' is part of non-derogable contents of article 6. Likewise, the right to privacy may also be especially susceptible to abuses in case States pass new laws warranting compulsory testing and the automatic identification of former COVID-19

[109] *See* Emanuele Sommario, *Limitation and Derogation Provisions in International Human Rights Law Treaties and their Use in Disaster Settings*, *in* ROUTLEDGE HANDBOOK OF HUMAN RIGHTS AND DISASTERS 21(Flava Zorzi Giustiniani et al. eds., 2018).

[110] *Id.*

[111] C.N.123.2020. TREATIES-IV.4 (Depositary Notification), ICCPR notification under 4 (3), Peru, dated 20 March 2020.

patients by the authorities on the basis of the so-called digitized 'immunity passports', as suggested by the UK and US.[112] Such identification may have an impact of privacy and increase stigmatization, and ultimately, discrimination – especially in the case of young individuals and in relation to the right to work.

### C. DEROGATIONS FROM THE RIGHT TO HEALTH DURING THE COVID-19 PANDEMIC?

Social and economic rights are also affected during the pandemic, especially the right to health and the right to a healthy environment. The interrelation between types of rights necessarily encompasses the preservation of the right to health through limitation of other rights – such as the right to personal freedom, or freedom of movement.[113] Contrary to the ICCCPR, however, the ICESCR does not contain a comprehensive provision on derogations. It only contains a provision on possible limitations 'solely for the purpose of promoting general welfare in a democratic society' and insofar as 'this may be compatible with the nature of these rights' (article 4). It is also explicitly stated in the ICCPR that 'no restriction upon or derogation from any of the fundamental human rights recognized or existing in any country in virtue of law, conventions, regulations or custom shall be admitted on the pretext that the present Covenant does not recognize such rights or that it recognizes them to a lesser extent' (article 5).

In reality, the legitimacy of derogations to economic, social and cultural (ESC) rights cannot be easily distinguished from the exact scope of these rights and subsequent obligations.[114] The reason is that ESC rights are intrinsically related to the management of scarce resources.[115] This entails

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[112] *COVID-19 Information*, U.S. EMBASSY & CONSULATES IN THE UNITED KINGDOM, (Jan. 27, 2021, 3:00 PM), https://travel.state.gov/content/travel/en/traveladvisories/ea/passport-covid-19.html.

[113] Spadaro, *supra* note 99, at 319 (noting that 'public health measures consisting in the enforcement of social distancing, which are deemed effective in reducing the spread of certain influenza-like diseases, including COVID-19, clash with a number of individual rights. It is worth giving a few examples, based on some of the most commonly adopted measures, with no pretence of providing an exhaustive overview').

[114] Amrei Müller, *Limitations to and Derogations from Economic, Social and Cultural Rights,* HUM. RTS. L. REV. (2009) 9(4): 557, 558 (arguing that the legitimacy of derogations to economic, social and cultural (ESC) rights cannot be easily distinguished from the exact scope of these rights and subsequent obligations).

[115] U.N. Human Rights, Office of the High Commissioner, *International Covenant on Economic, Social and Cultural Rights*, Art 2.1, ("Each state party to the present Covenant

the adaptation of public health strategies, such as the mean non-denial of materials that are vital for non-contamination, such as soap and sanitizers, especially to the most vulnerable and needy. Those should continue being available, accessible and affordable at all times,[116] even if this means for the State dispensing additional resources. In cases of pandemics, violations against the right to health may, therefore, include denial of treatment due to conflicting obligations in treating patients who are more in need; or even denial of basic healthcare material for specific groups of the population, especially when States find that this may have adverse circumstances, such as, for instance, refusing or not providing hand sanitizers in prisons for fear of intoxication.[117]

The non-discrimination principle seems to be again the guideline in relation to socio-economic rights,[118] especially in relation to vulnerable segments of the population. Sacrifice of one's life over another will unavoidably take place in pandemic scenarios, where tough choices will need to be made. Most States in Covid-19 management have been prioritizing treatment of children and youths with underlying conditions, for instance, over the elderly, and this is something that most people find morally justified. While it may be possible to prioritize certain groups in need, non-discrimination entails that other segments of the population cannot consistently and persistently be excluded from access to healthcare, medicine and treatment. This does not apply only to the elderly, but also to persons with disabilities, health workers, human rights activists and other people with needs. In the event of increased risk of infection, increased rather than core obligations[119] should be applicable to those residing in refugee camps and shelters, homeless persons or undocumented migrants, those confined in prisons and also those found in battlefields and in situations of armed conflict during the outbreak of the pandemic, both combatants and civilians. In such cases, humanitarian law and primarily the obligation to provide humanitarian aid applies in parallel to the international human rights regime, similar to the international disaster framework.[120]

undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realisation of the rights recognised in the present Covenant by all appropriate means, including particularly the adoption of legislative measures").

[116] Id.

[117] UN Commission on Human Rights, *Limburg Principles on the Implementation of the ICESCR* 8 January 1987, E/CN.4/1987/17.

[118] International Covenant on Economic, Social and Cultural Rights, *supra* note 113.

[119] Limburg Principles, s*upra* note 115.

[120] Sommario, *supra* note 107.

## D. PHARMACEUTICAL COMPANIES' OBLIGATIONS DURING THE COVID-19 PANDEMIC

The obligation to seek trial participants' informed consent as well as the obligation to protect personal data under human rights law are both tackled under the right to privacy, which 'protects individuals against arbitrary interference by public authorities'.[121] As discussed in the previous section, during pandemics, States are obliged to conform to necessity and proportionality requirements to protect this right, even during pandemics. In reality, however, the question is more complex, since typically testing is done by pharmaceutical companies – i.e. private actors – rather than state authorities. Two aspects of pharmaceutical companies' duties will be discussed in this section, first, the duty to seek clinical trial participants' informed consent in relation to all possible risks, and secondly, the obligation to protect trial participants' personal data.

### i. Clinical Trial Participants' Informed Consent

Pharmaceutical companies and corporations are not exempt from the obligation to conform with human rights law and from seeking trial participants' informed consent, especially when conducting clinical trials abroad. The interpretation of human rights standards by international and regional bodies has expanded to encompass States obligations to regulate private actors. General Comment 14 of the CESCR in particular indirectly links the right to health with healthcare services provided by private corporations, which typically arise in situations where the State has outsourced part of its healthcare obligations to private providers.[122] This means that both the manufacturer and the host State are under strict obligations to conduct clinical trials in a manner that is human rights-compliant and in addition States must regulate such activities under sanction of law.

Pharmaceutical companies' duties have arisen primarily in relation to access to medicine and intellectual property rights. More recently, however, UN bodies and particularly the UN Special Rapporteur on the right to the highest attainable standard of health have been referring gradually also to clinical trials. According to the UN GA guidelines for Pharmaceutical companies (2008) 'a company's clinical trials should observe the highest ethical and human rights standards, including non-discrimination, equality and the requirements of informed consent', a requirement that is 'especially

[121] Solomakhin, *supra* note 39.
[122] Human Rights Committee, *General Comment No.14: The Right to the Highest Attainable Standard of Health (Art. 12),* at ¶36, Aug. 11, 2020.

vital in those States with weak regulatory frameworks.[123] According to the guidelines, these companies should equally conform to medical ethics, in particular 'to the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, as well as the World Health Organisation Guidelines for Good Clinical Practice'.[124] Also, in its guiding principles on corporate responsibility, the OHCHR notes that 'pharmaceutical companies should be able to communicate how they ensure that drug trials are conducted safely and with adequate information and consent'.[125] Individuals, therefore, should have the right to challenge strategies by pharmaceutical companies and corporations that are not in conformity with these standards. In its "General Comment on the nature of State obligations", the Human Rights Committee emphasizes the significance of providing effective remedies against *any* perpetrator of human rights violations.[126]

Assuming that the pandemic constitutes a national emergency, and that the derogations regime is applicable, the prescription drug developer owes a duty of care to disclose all known and anticipated risks to participants. The duty of care cannot be diminished due to the emergency. Since the regulatory authority probably reduces its "oversight", the duty on the developer, as the foremost expert on the potential risks, increases. For example, the FDA allowed in its guidance of clinical trials during Covid-19 for the sponsor to have the flexibility to adjust the protocol of clinical trials depending on the specific circumstances and by consultation with the Institutional Review Board (IRB).[127] Allowing for the IRB review to substitute the FDA review is a substantial change under the crisis condition that would not have been permitted under normal circumstances. The guidance allowed for alternative methods for safety assessment that are consistent with the clinical trial protocol "*to the extent possible*." Consultation with the FDA is recommended but not mandatory.[128] The FDA through a high level of flexibility is shifting the burden to the sponsor of clinical trials.

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[123] U.N. GAOR, HUMAN RIGHTS GUIDELINES FOR PHARM. COS. IN RELATION TO ACCESS TO MEDS. 21 (A/63/263, 2008).
[124] *Id.* at 22.
[125] U.N HUMAN RTS., OFF. OF THE HIGH COMM'R, THE CORP. RESP. TO RESPECT HUMAN RTS. 58 (2012).
[126] U.N HUMAN RTS., OFF. OF THE HIGH COMM'R, THE CORP. RESP. TO RESPECT HUMAN RTS. 58 (2012).
[127] *See* FDA, CONDUCT OF CLINICAL TRIALS OF MED. PRODUCTS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY 27 (2021).
[128] *Id.* at 3-4.

### ii. Clinical Trial Participants' Personal Data

A clinical trial for a new drug takes, in the United States, on average six to seven years to complete. The number of volunteers may number in the thousands. There are several actors that are involved in clinical trials (drug developers, trial sponsors, researchers, etc.). Due to the nature of clinical trials and the increasing number of actors involved therein, data obtained from clinical trials is transferred horizontally among the different actors.

In the United States, the legal protection of clinical trial data is set forth in the FDA regulations and the FDA Common Rule.[129] The U.S. Department of Health and Human Services (HHS) is responsible to promulgate regulations for the privacy of individuals' health data.[130] The privacy rule under the Health Insurance Portability and Accountability Act (HIPAA) ensures individual health data is protected when transmitted between healthcare providers and health insurance providers. Pharmacists and drug manufacturers are not identified as a covered entity within the scope of the HIPAA privacy rule. The US Supreme Court in *Sorrell v. IMS Health Inc*[131] held that a Vermont statute that restricts the communication of health information collected from patients is unconstitutional.[132] The privacy rule, however, extends to clinical trial sponsors' study teams.[133] Under the HIPAA protected health information is defined as individually identifiable health information that is maintained or transmitted in any medium. This "information" in the definition includes all oral, recorded, past, present or future physical or mental health or conditions of an individual. For the purpose of research, protected health information, could be disclosed.[134] In clinical trials any information obtained from volunteers would be classified as health information and would be protected under the HIPAA privacy rule. If the information obtained in a clinical trial is anonymized, it would not be subject to HIPAA protection.[135] HIPAA requires consent from the individual to disclose or share his/her data.[136] The individual should be notified of the name/entity to whom the information is disclosed, the purpose of the disclosure, an expiry date for the disclosure and the signature of the individual authorizing the disclosure.[137] The individual has the right to

[129] *See* 45 C.F.R § 46.101 and 21 C.F.R. § 314.126.
[130] U.S. DEP'T OF HEALTH AND HUMAN SERVS., SUMMARY OF THE HIPPA PRIV. RULE 1 (2003).
[131] *Sorrell v. IMS Health*, 564 U.S. 552 (2011).
[132] *Id.*
[133] 45 C.F.R. §160.103 (2013).
[134] 45 C.F.R. §164.152(i)(1)(iii) (2013).
[135] 45 C.F.R. §164.502(d)(1) (2013).
[136] 45 C.F.R. §164.508(a) (2013).
[137] 45 C.F.R. §164.508(c)(1) (2013).

revoke the authorization at any time.[138] In 2011, the HHS sought to amend the Common Rule to incorporate the HIPAA privacy rule to strengthen the privacy protection of data obtained from human subjects during a clinical trial.[139]

Under the European Union legal framework, clinical trials and data protection regulations are generally governed by two distinct standards. The volunteer's informed consent to participate in a clinical trial is different from the volunteer's consent for lawful processing of his/her personal data. For example, Article 56 of the European Clinical Trials Regulation (CTR)[140] requires the clinical trial sponsor to record, store and handle data of the clinical trial protocol while preserving the confidentiality of the records to protect personal data. The CTR legally obliges the clinical trial sponsor to report all results of the trial, perform safety reporting and archive the clinical trials in a master file for twenty-five years. The clinical trial protocol must define the purpose and conditions under which data collected from clinical trial participants will be processed. The volunteers should be properly informed on the processing of their personal data. The sponsor of the clinical trial is the data controller and is obliged to institute measures to ensure that the data is processed in accordance with the rules of the General Data Protection Regulation (GDPR).[141] Processing of clinical trial data for the purpose of reliability and safety must be in compliance with Article 9(2)(i) of the GDPR, which provides that:

> Processing is necessary for reasons of public interest in the area of public health such as ensuring high standards of quality and safety of health care and medicinal products or medical devices, on the basis of Union or member State law, which provides for suitable measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy.

The legal obligation of the clinical trial sponsor is that expressed in the CTR relating to the safety reporting under Articles 41-43 and archiving

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[138] 45 C.F.R. §164.508(b)(5) (2013).

[139] Human Subjects Research Protection: Enhancing Protection for Research Subjects and Reducing Burden, Delay and Ambiguity for Investigators, 76 Fed. Reg. 143, 44515 (July 26, 2011).

[140] Council Regulation 536/2014 of Apr. 16, 2014, on Clinical Trials on Medicinal Products for Human Use, 2014 O.J. (L 158) 41.

[141] Council Regulation 2016/679 of Apr. 27, 2016, on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data (GDPR), 2016 O.J. (L 119) 30, 46.

under Article 58. The legal basis for data processing related to reliability and safety purposes under the GDPR, states that processing of data collected from clinical trials is lawful if it is "*necessary for compliance with a legal obligation to which the controller (sponsor of the clinical trial) is subject*." Processing of clinical trial data for research activities is derived from a legal obligation in accordance with Article 9(2) in conjunction with Article 6(1) of the GDPR for either public interest, legitimate interest or under specific circumstances.

There is a fundamental distinction concerning the definition of informed consent in view of data processing between the CTR and the GDPR. The CTR considers informed consent as a safeguard, not a legal basis, for data processing while under the GDPR informed consent is a legal obligation. Thus, under the GDPR, consent must be: freely given, specific, informed and unambiguous; hence processing of data under specific circumstances requires an explicit consent from the participant. This difference between the CTR and GDPR requirements has a substantial effect on data collected from a participant in a clinical trial in the event that the participant decides to withdraw. Under Article 28(3) of the CTR withdrawal from a clinical study does not affect the data obtained on the basis of the informed consent before the withdrawal. On the contrary, under the GDPR when the individual participant withdraws its consent all data obtained must be deleted by the controller.[142]

The GDPR applies to clinical trial sponsors established in the European Union (EU) and outside the EU where the processing is related to data subjects of the EU.[143] Thus, both HIPAA and the GDPR will impact clinical trials conducted in the EU and sponsored by US companies (e.g. Pfizer testing of mRNA in Germany). Although HIPAA and the GDPR regulate the collection and transfer of clinical trial participants' data these regulations differ in several areas. HIPAA obtains the authorization to collect, process and transfer data in the informed consent to participate in the clinical trial while the GDPR through an informed consent process specifically designed for the data to be collected, processed and transferred between entities. The HIPAA authorization must include details of the purpose and the entities that will use the data, but HIPAA does not specify exactly how much detail must be communicated with a clinical trial volunteer. The GDPR, however, requires that volunteers are provided with sufficient information to make a knowledgeable decision. The GDPR provides an absolute right to clinical trial volunteers to revoke data processing, whereas the HIPAA provides a

[142] *See* GDPR art. 3, 17(1)(b), 2016 O.J. (L 119) 32, 43.
[143] *See* GDPR arts. 3, 27, 2016 O.J. (L 119) 32, 48.

volunteer the right to revoke an authorization, albeit it permits a limitation if the authorization has been relied upon.[144]

Exceptional deviation from data protection regulations (e.g. HIPAA in the US and the GDPR in the EU) under a state of emergency provides some, but not unlimited authority, to relax protections concerning privacy of information.[145] Governments operating under a state of emergency possess the legislative means to use clinical data to restore public health without acquiring individual consent. For example, the UK enacted a special law entitled: "The Health Protection (Coronavirus) Regulation 2020",[146] which granted powers to health care providers, among other entities, to confine, treat and transmit personal information of Covid-19 infected individuals without their consent. The powers become effective upon a declaration by the Secretary of State declaring an imminent threat to public health. In similar manner, Germany promulgated a Coronavirus Notification Regulation,[147] governing the use of personal data associated with the virus infection. Health care providers are permitted to transmit personal information to a competent authority to allow for coronavirus outbreak analysis without the consent of the individual.

## V. BLOCKCHAIN AND RISK GOVERNANCE REGISTRY

Blockchain is a form of digital information stored in a public database. Blockchain is based on the ledger keeping method that is distributed across many stations, through a peer-to-peer network, which functions on the basis of a cryptographic communication scheme to ensure the security of its records.[148] All connected peers hold identical copies of the ledger machine consensus.[149] While bitcoin (or cryptocurrency) is the most recognized application of blockchain, many other applications are being advanced,

[144] 45 C.F.R. §164.508(b)(5) (2013).

[145] *See Disclosures for Public Health Activities*, OCR HIPAA PRIVACY (Apr. 3, 2003), https://www.hhs.gov/hipaa/for-professionals/special-topics/public-health/index.html.

[146] *See* The Health Protection (Coronavirus) Regulations 2020, SI 2020/129, (Eng.), http://www.legislation.gov.uk/uksi/2020/129/made.

[147] *See Coronavirus and Basic Rights: What is the German State Allowed to do?,* DW, https://www.dw.com/en/coronavirus-and-basic-rights-what-is-the-german-state-allowed-to-do/a-52835004.

[148] A. Cohn, T. West, & C. Parker, *Smart After All: Blockchain, Smart Contracts, Parametric Insurance, and Smart Energy Grids*, 67 Defense L.J. 57 (2018).

[149] J Yli-Huumo et al. 'Where Is Current Research on Blockchain Technology?—A Systematic Review' (2016) 11(10) PloS 1. J. Yli-Huumo et al., *Where Is Current Research on Blockchain Technology?—A Systematic Review*, 11(10) PloS 1 (2016).

particularly in the context of sharing inter-organizational data, digital asset registration or integrity, and identity management.[150] To simplify the concept of blockchain in risk registry of nano-carriers in transnational clinical trials, consider the blockchain of risk registry as a computer file. The file is stored in a computer in the network, say a location where the clinical trial is being carried out. The file is broadcasted to other locations on the network of transnational clinical trials for risk register sharing and updates. The risk registry generated from one transnational clinical trial location will be shared with all on users (e.g. other locations and regulators of foreign and domestic). The blockchain ensures the integrity and security of the information because it is built on a system of distributed consensus. This does not allow changes unless all participants agree to the change.[151]

There are three main categories of blockchains, which are largely public blockchain where access to join the network is granted to anyone with an intent to join the network. Upon joining, the participant is enabled to add information, approving tasks or make new additions to the ledger.[152] Private or permissioned blockchains exist where a new user can only join a network through an invitation scheme that checks whether the new user meets a set of conditions established by the peer-to-peer network. Once access is granted, the new user will be provided with authentication, access control and privileges.[153] Consortium blockchain exists where a semi-decentralized data structure is controlled by a single organization in the same fashion as that of the permissioned blockchain. This scheme is utilized to manage the growth of the data file that is distributed across the network and act as a consensus system for any new information to the ledger being handled by the network.[154]

The distribution of data from a single database to distributed databases increases decentralized control and storage of records that have the potential to increase the trust and give rise to the collaborative system. By using blockchain, the efficiency of the risk registry system will be increased and result in better synchronization and countering the security issues and availability of information.

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[150] M. Memon et al., *Blockchain Beyond Bitcoin: Blockchain Tech. Challenges and Real-World Applications*, 29 IEEE (Aug. 2018).

[151] C. Mann et al., *Two-Factor Authentication for the Bitcoin Protocol*, 16 INT. J. INF. SECUR. 213 (2017).

[152] N. K. Ostern, *Blockchain in the IS Research Discipline: A Discussion of Terminology and Concepts*, 30 Electronic Markets 195 (2019).

[153] T. I. Kiviat, *Beyond Bitcoin: Issues in Regul. Blockchain Transactions*, 65 DUKE L.J. 569 (2015).

[154] M. Latha Nandi et al., *Blockchain Technology-Enabled Supply Chain Sys. and Supply Chain Performance: A Resource-Based View*, 25 SUPPLY CHAIN MGMT. 841 (2020).

Permissioned blockchain recording system provides protective access to include new risk registries from clinical trial conductors from around the globe. It also allows the producers to have a platform to gather all risk data generated from all participants, thus subsequently improve the risk governance which subsequently improves the informed consent. The distributed feature of the blockchain ledger allows for collaborative sharing of risk data by all of those sharing the data in a network consisting of all participants of the outsourced clinical trials. Distributed ledgers allow all clinical trials monitoring personnel (onsite or remotely) within the network to access and visualize changes to the ledger as they occur while maintaining the information safe from unauthorized access via cryptographic keys and signatures.[155] The technology represents an opportunity for evolution in various fields of clinical trials risk governance given its adaptability to all elements of risk governance. Transparency and disclosure are at the base of good risk governance models in that they enable clinical trials participants to make informed decisions.

Tracking risk governance registry for international clinical trials of nano-enabled vaccines provides substantial advancement to materializing new treatment regiments around the globe. It allows for robust and standardized electronic trials data record-keeping that can be inspected by regulators remotely. It allows for the identification of problems at the early stage of the trial. The risk governance registry enables the recruitment of volunteers and at the same time enables regulatory oversight for new vaccine approvals.

### A. BLOCKCHAIN AND RISK GOVERNANCE OF INFORMED CONSENT

Vaccine testing and approval process proceeds at different time-controlled and efficacy stages. The first stage in the development cycle is the exploratory stage followed by pre-clinical stage then clinical stage that is followed by regulatory review and approval. Subsequently the vaccine will be manufactured under quality control measures.

Clinical trials of the same vaccine could be running simultaneously at different locations by different conductors. For example, efficacy clinical trial for the mRNA-1273 vaccine, which was developed by ModernaTX, Inc. is conducted at 100 different locations involving more than 30,000

[155] A. Hughes et al., *Beyond Bitcoin: What Blockchain and Distributed Ledger Technologies Means for Firms,* 62 BUSINESS HORIZONS 273 (2019).

participants.[156] It is well known that drugs could be tested at different locations, often cross boundary from the manufacturer's home state. For example, Thermodox, is currently under twelve clinical trials testing efficacy against liver, breast and bone cancer at different locations (United States, United Kingdom, Netherland, China, and Canada).[157] Johnson and Johns just initiated its Phase 3 testing on its COVID-19 vaccine to include 60,000 participants from Argentina, Mexico, Chile, Colombia, South Africa and the United States. Massive data will be generated out of these clinical trials. Blockchain strategy for risk governance will enable collection of all data and making available globally and on-time.

The blockchain ledger of all five risk governance elements (pre-assessment, appraisal, evaluation and tolerability, management and communication) complies with recent ruling in the United States that requires for all clinical data to be made available to healthcare providers and patients. In *Seife and Lurie v. U.S. Department of Health and Human Services,*[158] the plaintiff claimed that "The basic reporting requirements deprived them as well as other researchers and advocates, of the data necessary to ensure transparency in research, promote better decision-making by clinicians and policymakers, eliminate bias in the medical literature, and to make patients, clinicians, and regulators aware of medical product safety and effectiveness." The basic requirement for vaccine approval under the FDA statues does not require that all data be made available. However, the possibility of producers to may only share data that in favor of their product is highly possible, leading to healthcare providers to prescribe vaccines that are ineffective or unsafe. Extending this ruling to pre-clinical data that is required for the recruitment of volunteers for clinical trials improves immensely the informed consent practice, particularly for nano-enabled mRNA COVID vaccine that definitely have higher uncertainty and ambiguity due to its instability and immunogenicity.

Risk governance for nano-enabled vaccines need to run in parallel with all stages of vaccine clinical trials. Blockchain ledgers associated with each element of the risk assessment. A block that consists of index, timestamp, list of risk data entry transactions, proof and a connector to other blocks.

The decentralized standard for transnational clinical trials risk registry allows for the disclosure of registered risks among all participating sites, thus

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[156] A. Hughes et al., *Beyond Bitcoin: What Blockchain and Distributed Ledger Technologies Means for Firms,* 62 BUSINESS HORIZONS 273 (2019).

[157] *Phase 1/2 Study of ThermoDox With Approved Hyperthermia in Treatment of Breast Cancer Recurrence at the Chest Wall,* Clinicaltrials, https://clinicaltrials.gov/ct2/results?cond=cancer&term=ThermoDox&cntry=&state=&city=&dist.

[158] Seife v. HHS, 1:18-cv-11462 (S.D.N.Y. 2020).

strengthening the components of informed consent and build trust between international pharmaceutical vaccine producers and the governments where the volunteers are recruited. Further it allows for the regulatory bodies to have access to all relevant data ahead of pre-marketing approval. The benefits of deploying blockchain technology of risk registry of vaccine nano-carriers could be summarized in the following points:

- **Transparency**: Every node on the network will have a complete documentation of the registered risk and holds history of the registry that can be visible to all permissioned to view anytime and from anywhere. Thus, clinical trials directors at all locations will be able to view the risk and inform potential volunteers or take actions to mitigate risks of currently participating volunteers. It also, allows for the regulators and government agents to review the risks as they registered from all participating locations. Thus, facilitating the administration of informed consent even at locations where the risks have not yet been registered.
- **Build trust:** Transnational clinical trials are painted with a dark record of unethical behaviour of a number of pharmaceutical key players. Regulatory bodies at different locations may have different requirements to authorize clinical trials in their territories, however, access of immutable risk registry record keeping and verification of data at multiple nodes facilitate trust building between transnational regulators and global pharmaceutical industry.
- **Risk predictability:** The risk history maintained at different nodes and generated from clinical trials at different locations facilitates prediction of risk at new clinical trials locations.
- **Reliability:** The risk registry is stored at multiple nodes through the blockchain system, the consensuses scheme assures change of information only when other relevant peers approve. Thus, tampering with risk registry is minimized.
- **Security:** Data are stored at multiple nodes using encryption which will prevent tampering with data without proper authentication.
- **Ease of access:** The availability of data at the distributed nodes on the net enhances the ease and speedy access of risk registry data.

The challenges that may arise of employing blockchain technology to risk governance of clinical trials that involve vaccine enabled with nano-carriers include:

- IP protection of the technologies, not only the blockchain platform, but also the vaccine and its nano-carriers. Volunteers of the clinical trials, particularly those at developing countries, are not concerned with IP infringements. The permission blockchain could mitigate this concern by restricting shared information to only those who are participating in the study and only information pertaining to informed consent.
- Confidentiality of the data, which includes the personal data of the volunteers as well as the research data obtained at the different phases of the trial. A new prescription drug value is backed by the scientific evidence supporting the product. Transparency of data ensures that all positive and negative implications of the vaccine and its nano-drug be made available to volunteers to make an informed decision. Confidentiality of data to sponsor could be managed by blockchain ledger to only allow for participants to view the data. This is probably the most problematic challenge that could face a producer, as it makes all of its data be potentially available to its competitors. However, the producers are legally bound by the informed consent doctrine to make all data available to volunteers so they can make an informed decision. The risk governance will ensure that only products that meet the safety threshold to reach to state of efficacy evaluation with human volunteers.
- Regulatory measures to catch up with the advancement in both the vaccine and its nano-carrier technology and that of the blockchain. This essay contends that new regulatory approaches are needed to address vaccine enabled with nano-carrier. Current regulatory measures are based on extrapolation of conventional regulatory instruments to rapidly address known concerns. However, those were developed for technologies that are not viable at the nanoscale. The risk governance provides a systematic approach for designing balanced regulatory measure that on one hand allows for new scientific discovery to progress and on the other mitigate unnecessary exploitation of vulnerable volunteers to unsafe drugs.

The blockchain management of risk governance of vaccine enabled with nano-carriers clinical trials provides a technological tool that increases transparency, mitigate the legal claims associated with informed consent and affirms the legal burden on both producers and host state to ensure that uncertainties and ambiguities are addressed ahead of instituting drugs to volunteers. Further, the approach helps all sites participating in clinical trials to have direct and immediate access to data to manage risks that were discovered at remotes sites.

## VI. CONCLUSION

The coronavirus outbreak forced governments to declare states of emergency. In search of a medical breakthrough that could either treat the infection or reduce its spread, pharmaceutical companies engaged in a race to identify vaccines that could be employed to reduce the effect of the outbreak. mRNA vaccines have been identified as potential candidates. To reduce the mRNA's harmful impact, the vaccine was encapsulated in a nano-shell. Clinical trials on human subjects commenced at record speed. Regulations that allow for fast tracking clinical trials have been enacted under the exceptional power of governments acting under states of emergency. A declared state of emergency must nonetheless account for the integrity of the human volunteers, while at the same time encourage development of a viable effective vaccine. The informed consent doctrine and rigorous monitoring mechanisms of clinical trials are only two vital elements among the many that are required to ensure the protection of participants in mRNA clinical trials. Human rights oblige States to respect, protect and fulfill the highest standards of health to clinical trials participants, whether conducted locally or internationally. This right is non-derogable even in a state of emergency. A risk governance framework mitigates ambiguous risks and provides more informed consent to prenatal participants, which on the one hand assists in recruiting informed volunteers, while on the other reduces potential liability. Laws concerning personal data protection are not immune from derogation during a national state of emergency. The protections under the HIPAA and GDPR are fragile therein.

What is abundantly clear is that efforts to prevent spread of Covid-19, as well as come up with a viable vaccine require not a relaxation of existing human rights standards, but the augmentation of solidarity and international cooperation. Blockchain technology would provide a registry ledger to document risks and benefits in a way that could facilitate cross boundary clinic trails for novel vaccine developers, government agencies and volunteers.

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