WHO IHR Revisions & Pandemic Agreement

Urgent Legal Notice

Free and Informed Consent for Medical Countermeasures March 2024

GLOBAL HEALTH RESPONSIBILITY
GHR.AGENCY

Author: Dr. Amrei Müller

Urgent Legal Notice: Free and Informed Consent for Medical Countermeasures. March 2024, Agency for Global Health Responsibility

Please direct inquiries to:
The Global Health Responsibility Agency
5020 Salzburg
www.ghr.agency

Contents

Executive Summary

This Urgent Legal Notice calls on States and the WHO to integrate an unconditional and express commitment to the protection of the human rights of every individual not to be subjected to medical treatment or medical or scientific experiments without free and informed consent in both the amended International Health Regulations (IHR) and the new Pandemic Agreement.

Directions of WHO's Pandemic Law-making

Proposed amendments to the IHR and draft provisions in the Pandemic Agreement aim to ensure rapid global mass vaccination with investigational products during a PHEIC/pandemic

Many proposed amendments[1] to the 2005 International Health Regulations (IHR) and draft provisions of the new WHO Pandemic Agreement[2] aim to address future Public Health Emergencies of International Concern (PHEICs) and/or pandemics by globally administering emergency-licensed, investigational vaccines, generally referred to as *medical countermeasures,* to every individual as fast as possible.

Among these proposed amendments to the IHR and the draft Pandemic Agreement provisions are:

a) those that aim to oblige States and the WHO to build, strengthen and sustain capacities and institutions for research on pathogens with PHEIC/pandemic potential as well as the development of PHEIC-/pandemic-related medicinal products like vaccines;[3]

b) those that aim to ensure that States have the regulatory framework in place to grant fast-track emergency authorisation of investigational medicinal products during a PHEIC/pandemic to allegedly address these PHEICs/pandemics,[4] and those that aim to strengthen the legal basis for the WHO's own Emergency Use Listing (EUL) programme through which it issues so-called emergency listings for investigational medicinal products during a PHEIC/pandemic that are allegedly needed to address the PHEIC/pandemic[5] (referred to as 'relevant diagnostics, therapeutics or vaccines' in the draft Pandemic Agreement (revised negotiating text)[6]); and

c) those that aim to oblige both States[7] and the WHO to ensure the rapid production, procurement and distribution of PHEIC/pandemic-products which the WHO considers are required to address a PHEIC/pandemic ('relevant diagnostics, therapeutics and vaccines'[8]), including through the setting up of the Global Pandemic Supply Chain and Logistics Network[9] that is to be convened by the WHO.[10]

Global mass vaccination strategy during the Covid-19 PHEIC

During the Covid-19-PHEIC, where this strategy of global mass vaccination was already followed, the WHO Covid-19 Emergency Committee recommended States to vaccinate an ever-increasing percentage[11] of their populations against SARS-CoV-2 with various emergency-licensed or emergency-listed investigational DNA- and modRNA-based vaccines. The legal basis for this was allegedly Article 18(1) IHR.[12] WHO also advertised and continues to recommend these vaccines as 'safe and effective'.[13]

The WHO issued *de facto* global emergency authorisations – so-called 'emergency use listings' (EUL) – for all known investigational vaccines against Covid-19.[14] The WHO Director-General can activate the EUL procedure during a PHEIC or in a pre-public health emergency (PHE)

situation that does not meet the criteria of a PHEIC yet. In the words of the WHO, the EUL is a special procedure for [assessing and listing] unlicensed vaccines, medicines and *in vitro* diagnostics in the event of a PHE when the community/public health authorities may be willing to tolerate less certainty about the efficacy and safety of products, given the morbidity and/or mortality of the disease and the lack or paucity of treatment, diagnosis/detection or prevention options.[15] Its aim is to 'expedit[e…] the availability of these [medical] products to people affected by public health emergency'[16] on a 'time limited [preliminary] basis while further data is being gathered and evaluated'.[17] The EUL mirrors at the global level the Emergency Use Authorisation (EUA)[18] and Conditional Marketing Authorisation procedures of respectively the US' Food and Drug Administration and the European Medical Agency,[19] and enables the WHO to distribute investigational medical countermeasures worldwide during a PHEIC particularly for countries lacking this regulatory pathway.

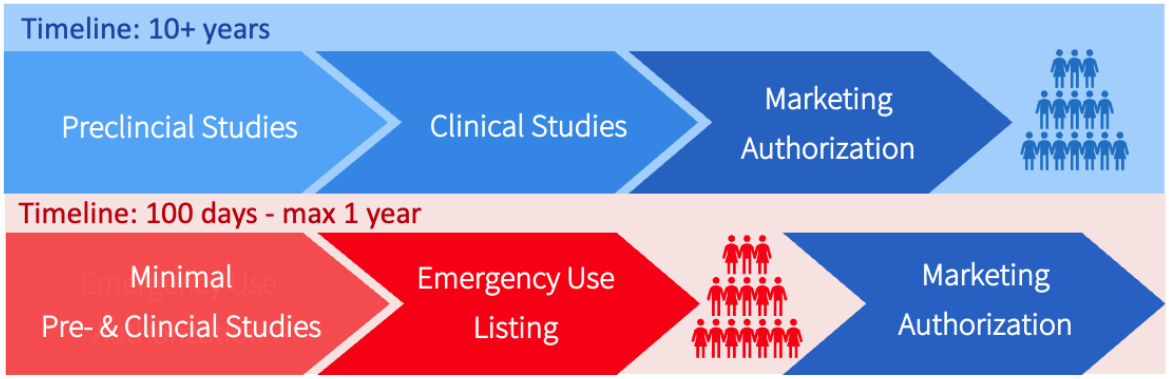

Figure 1 Comparison between Marketing Authorization & Emergency Use Listing

An increasing body of scientific literature as well as the lived experience of people around the world show, however, that the vaccines against Covid-19 have not been as 'safe and effective' as promised,[20] causing a wide range of adverse effects, including death.[21] Individuals were never informed about the investigational (that is, experimental) character of the Covid-19 vaccines – since these vaccines only had an emergency authorisation / WHO EUL – and were therefore by definition unable to give their informed consent to these medical treatments. Many were also (indirectly) coerced into vaccination by their governments as they found themselves faced with the choice of either taking the investigational vaccines or of losing their job, being prohibited to travel, and/or being otherwise excluded from economic, social, political, spiritual and cultural life of their countries. Whilst this was due to many States going beyond the recommendations of the WHO Covid-19 Emergency Committee, directly or indirectly mandating investigational Covid-19 vaccinations for their populations, the vaccine-focused recommendations of the WHO's Covid-19 Emergency Committee as well as WHO's active promotion of these vaccines as 'safe and effective' did not discourage this.

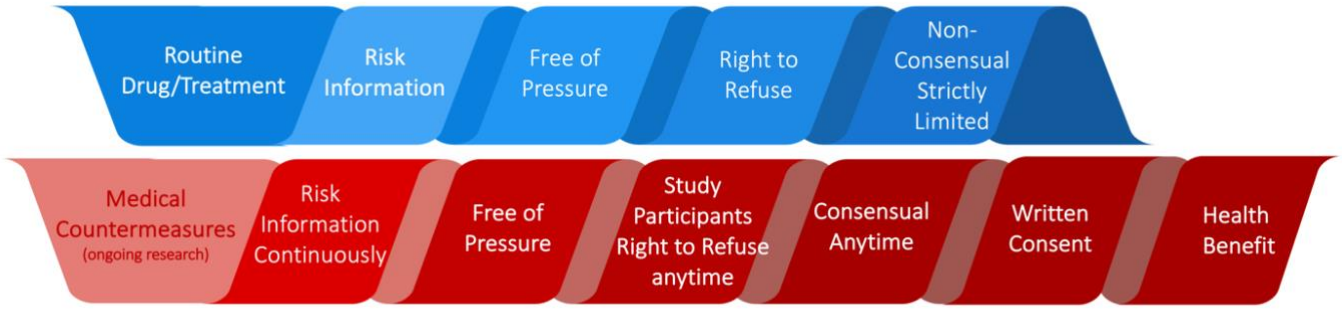

Figure 2 Prior Informed Consent Comparison between Routine Drug & Medical Countermeasures with ongoing research

The Human Rights Dimension

The human rights not to be subjected to medical treatment or medical or scientific experimentation without free and informed consent

Against the background of these two developments, both the WHO and its Member States should re-iterate their unconditional commitment to the protection of the human rights not to be subjected to medical treatment or medical or scientific experiments without free and informed consent in both the amended International Health Regulations and the new Pandemic Agreement. These rights must be upheld even during PHEICs/pandemics. Otherwise, the WHO and its Member States run the risk of violating these fundamental rights that have been enshrined in international human rights law, international humanitarian law and international criminal law, among other in response to the painful experiences with the horrendous medical and scientific practices of the National Socialists and various colonial powers.[22] The principle of free and informed consent to medical treatment and participation in medical or scientific experiments is furthermore firmly included in national legal orders.[23]

International human rights law encompasses the human right to physical and mental integrity, which includes the right not to be subjected to medical and scientific experimentation[24] or to medical treatment[25] without free and informed consent.[26] Under the right to life, States are prohibited from arbitrarily depriving individuals of their lives.[27] This includes duties to regulate activities that may result in the deprivation of life, such as the administration of new drugs,[28] and not to expose individuals to such activities e.g. by subjecting them to medical experiments or medical treatments without their free and informed consent. Free and informed consent can only be given after individuals have been informed objectively about the purpose and nature of a medical procedure, its benefits, risks and adverse effects, about reasonable alternatives, and what will happen if the treatment is

not carried out.[29] This must be done without any coercion, deception, inducement, or exerting any kind of other pressure.[30] When participating in medical experiments, the information process must be a continuous one, i.e. participants must continuously receive information about new risks, possible negative consequences and uncertainties,[31] and consent must be given in writing.[32] Free consent also includes the right to refuse medical treatment or participation in medical experiments[33] and to withdraw consent at any time.[34]

Mandatory or even coercive medical treatments without informed consent are permitted under international human rights law in strictly limited circumstances only, summarised by the UN Human Rights Committee in 2014:

> 'Non-consensual […] treatment may only be applied, if at all, in exceptional cases as a measure of last resort where absolutely necessary for the benefit of the person concerned, provided that he or she is unable to give consent, and for the shortest possible time without any long-term impact and under independent review.'[35]

Coerced participation in medical experimentation is prohibited *at all times* as it forms part of the absolute and non-derogable right not to be subjected to torture or inhuman or degrading treatment or punishment.[36] In this context, it can be recalled that the UN Human Rights Committee called on the United States in 2006 to abide by its non-derogble duties under the second sentence of Article 7 of the International Covenant on Civil and Political Rights (ICCPR), noting that

> '(a) waivers of consent in research regulated by the U.S. Department of Health and Human Services and the Food and Drug Administration may be given in case of individual and national emergencies; (b) some research may be conducted on persons vulnerable to coercion or undue influence such as children, prisoners, pregnant women, mentally disabled persons, or economically disadvantaged persons; (c) non-therapeutic research may be conducted on mentally ill persons or persons with impaired decision-making capacity, including minors; and (d) although no waivers have been given so far, domestic law authorizes the President to waive the prior informed-consent requirement for the administration of an investigational new drug to a member of the U.S. Armed Forces, if the President determines that obtaining consent is not feasible, is contrary to the best interests of the military members, or is not in the interests of U.S. national security.'[37]

If subjecting individuals to medical or scientific experiments or to medical treatment without their free and informed consent amounts to torture, this can constitute not only a violation of a non-derogable human rights obligation but also of a *jus cogens* norm,[38] as the prohibition of torture falls into the category of peremptory *jus cogens* norms.[39] The prohibitions of torture or inhuman or degrading treatment, including the prohibition to subject individuals to medical or scientific experiments or medical treatment without their consent are also enshrined in international humanitarian law applicable in times of international and non-international armed conflict,[40] as well as in international criminal law.[41]

Under the right to life, States' duties not to expose an unknown number of individuals to reasonably foreseeable threats to their lives by subjecting them to new medical treatments or participation in medical experiments without their informed consent are non-derogable too.[42] Utilitarian considerations – referring to the necessity that the right to life of a certain number of people can be disregarded in a global vaccination campaign with investigational products that will inevitably lead to a number of deaths – to allegedly uphold the right to life of others are thus not permitted and will amount to an arbitrary deprivation of life.[43]

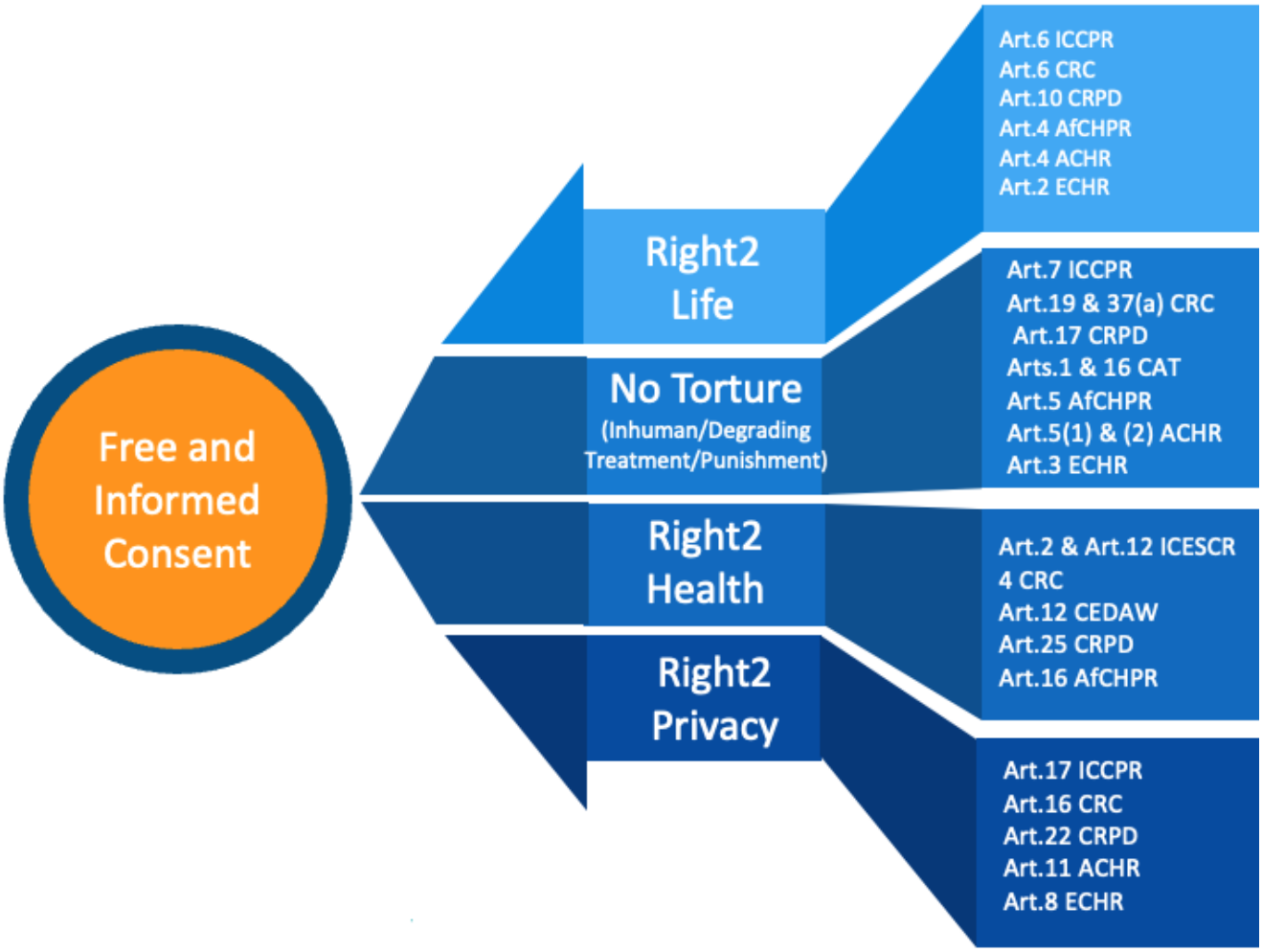

Figure 3 Human Rights Architecture of Informed Consent

Relevant Human Rights Treaties (international and regional)

International

CAT – Convention Against Torture, 1984
CEDAW – Convention on the Elimination of all Forms of Discrimination Against Women, 1979
CRC – Convention on the Rights of the Child, 1989
CRPD – Convention on the Rights of Persons with Disabilities, 2006
ECHR – European Convention on Human Rights, 1950
ICCPR – International Covenant on Civil and Political Rights, 1966
ICESCR – International Covenant on Economic, Social and Cultural Rights, 1966
UNESCO Declaration – UNESCO Universal Declaration on Bioethics and Human Rights

Regional

ACHR – American Convention on Human Rights, 1969
AfCHPR – African Charter on Human and Peoples' Rights, 1981
ECHR – European Convention on Human Rights, 1950
Oviedo Convention – Convention on Human Rights and Biomedicine, 1997
Additional Protocol to Oviedo Convention – Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, 2005

Obligations of States and WHO

States' obligations to secure these rights in the negotiations

As state parties to various international and regional human rights treaties, Member States of the WHO are clearly obliged to ensure that neither the amendments to the IHR nor any provisions in the new Pandemic Agreement conflicts with their duties under these treaties not to subject individuals to medical or scientific experimentation or medical treatment without their free and informed consent.

States cannot, in addition, escape their human rights duties by transferring competences to the WHO which does not have equivalent human rights duties on its own. States may not incur responsibility for such acts by their mere membership in the WHO.[44] But the potential for abuse of membership in an international organisation like the WHO has led to a regime for the attribution of international responsibility of States for the intentional circumvention of their human rights duties through their membership in an international organisation and the conduct of the latter.[45] This applies even if the act in question is not an international wrongful act for the international organisation itself. Conversely, this indicates that States have positive duties under international human rights law to ensure that their membership in international organisations like the WHO as well as the activities of such organisations do not prevent them from protecting human rights, and that human rights protection provided by international organisations is equivalent to their own duties under international human rights law.[46]

Moreover, it should be recalled that any amendment or new treaty that goes as far as that it conflicts with *jus cogens* norms – e.g. when violating the prohibition of torture by way of subjecting individuals to medical or scientific experimentation or medical treatment without informed consent under Article 7 ICCPR – will be void, as provided for in Article 53 Vienna Convention on the Law of Treaties (VCLT).[47]

Obligations of the WHO to secure these rights in the negotiations

As an international organisation, WHO is bound by 'any obligations incumbent upon [… international organisations] under general rules of international law, under their constitutions or under international agreements to which they are parties.'[48] This includes human rights obligations deriving from treaties and customary law, including *jus cogens* norms, though these human rights obligations of WHO differ in character from States' human rights duties under international human rights law.[49] The current IHR binds the WHO and requires it to abide by international human rights law when implementing the IHR,[50] and WHO obligations for the human right to health in particular flow from its Constitution.[51] The Universal Declaration of Human Rights (UDHR),[52] as well as some provisions in the ICCPR and the International Covenant on Economic, Social and Cultural Rights (ICESCR) may have attained customary status binding the WHO too.[53] As highlighted by the UN Committee on Economic, Social and Cultural Rights (CESCR), WHO's human rights duties have a more negative dimension not to undermine the ability of States to implement their human rights obligations that these States owe to everyone coming under their respective jurisdiction through functioning (democratic) institutional frameworks;[54] and a more positive dimension

to (pro-actively) enable and assist States of jurisdiction to implement their human rights duties.[55]

This includes WHO duties not to undermine States' capacities to secure the human rights not to be subjected to medical treatment and to medical or scientific experimentation without free and informed consent of the individuals who come under the respective States' jurisdiction, and to (actively) support States in complying with these human rights duties, many of which are non-derogable. The *jus cogens* character of the norms under which some of these obligations arise – i.e. those duties that prohibit subjecting individuals to medical treatment/medical or scientific experimentation in forms that amount to torture – give peremptory strength to these WHO duties.

If WHO disregards these duties, it may incur international responsibility for their violations (wrongful acts) under the Draft Articles on the Responsibilities of International Organisations (DARIO)[56] (see Articles 3-5), if these wrongful acts can be attributed to the WHO (Articles 6-9). Articles 28-40 DARIO deal with the consequences of responsibility.

Summary and Urgent Call for Express Codification

The strategy to address PHEICs and/or pandemics primarily through global mass vaccination with investigational, emergency-licensed or emergency-listed vaccines will likely be entrenched in international health law through the adoption of IHR amendments and the new Pandemic Agreement. At the same time, the responses to the Covid-19-PHEIC exposed the willingness of States and the WHO to allegedly neglect and violate the human rights not to be subjected medical treatment or vaccination, or to medical or scientific experimentation, without free and informed consent on the assumption that only a rushed global vaccination campaign can end the Covid-19-PHEIC.

To prevent a repetition of such violations and neglect, and to ensure that both the amended IHR and the new Pandemic Agreement are in line with international human rights law, States should include an express obligation on States and the WHO to ensure that medical countermeasures can only be administered to individuals after they have given their free and informed consent. This is all the more important for vaccines which have a preventive function and are given to healthy persons; and would include an obligation not to resort to direct or indirect coercion – for example by employing administrative or regulatory powers or behavioural science techniques like nudging – to make individuals taking up investigational vaccines during a PHEIC/pandemic.

Neither the current drafts of the IHR amendments nor of the provisions of the Pandemic Agreement include such explicit obligations. Suggestions as to how this can be achieved follow.

Annex 1 Concrete Drafting Proposals for the Pandemic Agreement

The current legal draft misses an express obligation on States to guarantee that medical countermeasures, particularly vaccines, can only be administered to individuals if they have given their free and informed consent.

As an emerging binding instrument of international law, the obligations in the draft address States, binding them internally to implement the relevant provisions towards their citizens in accordance with their national constitutional legal regimes, and externally, in relation to other State parties. The new Pandemic Agreement should not undermine States' and the WHO's capacities to comply with their obligations under international human rights law.

Proposals for the INB based on the Revised draft of the negotiating text of the WHO Pandemic Agreement, A/INB/9/3, 13 March 2024

NEW Article 3. Principles

To achieve the objective of the WHO Pandemic Agreement and to implement its provisions, the Parties ~~will be guided~~, shall be guided and are obliged to adopt, inter alia, relevant legislation if necessary, by the following:

1. full respect for the dignity, human rights and fundamental freedoms of all persons, particularly the human rights to bodily integrity and not to be subjected to medical treatment or medical or scientific experimentation without free and informed consent, including the right to refuse any medical treatment and vaccination at all times, and the enjoyment of the highest attainable standard of health of every human being;
2. the sovereign right of States to adopt, legislate and implement legislation, within their jurisdiction, in accordance with the Charter of the United Nations and the general principles of international law, and their sovereign rights over their biological resources;
3. equity as the goal and outcome of pandemic prevention, preparedness and response, ensuring the absence of unfair, avoidable or remediable differences among groups of people;
4. common but differentiated responsibilities and respective capabilities in pandemic prevention, preparedness, response and recovery of health systems;
5. solidarity, transparency and accountability to achieve the common interest of a more equitable and better prepared world to prevent, respond to and recover from pandemics; and
6. the best available science and evidence as the basis for public health decisions for pandemic

Annex 2 – Concrete Drafting Proposals for the IHR Amendments

Article 23(3) of the current version of the IHR (2005) includes an explicit obligation on States Parties that '[n]o medical examination, vaccination, prophylaxis or health measure under these Regulations shall be carried out on travellers without their prior express informed consent or that of their parents or guardians.' Although no final draft of the IHR Amendments have been made public by the WGIHR, an informal document dated 9th February 2024 indicates that Article 23 and the related provisions might remain unchanged.

This guarantee is a unique safeguard for individuals, particularly travellers, ensuring that no domestic health authority can subject them to non-consensual treatment. For this reason, Article 3(1) IHR should be revised to integrate an unconditional free and informed consent guarantee for individuals. This would have the effect that free and informed consent serves as a guiding principle of IHR implementation, securing States' and the WHO's commitment to abide by *jus cogens* and binding customary and human rights treaty law at all times.

In addition, the flaws in Article 23(3) and Article 31 in the current version of the IHR must be corrected.

As regards Article 23(3) IHR, the text appears to permit an exception from the prohibition to subject travellers to non-consensual medical treatment, vaccinations or other health measures through a cross-reference to Article 31(2) IHR. If the current textual version remains that upholds this exception, individuals crossing borders may have difficulties to invoke their rights not to be subjected to medical treatments without their free and informed consent.

The exception in Article 31(2) reads:

> '[i]f a traveller for whom a State Party may require a medical examination, vaccination or other prophylaxis under paragraph 1 of this Article **fails to consent to any such measure**, or refuses to provide the information or the documents referred to in paragraph 1(a) of Article 23, the State Party concerned may, subject to Articles 32, 42 and 45, **deny entry to that traveller**. If there is **evidence of an imminent public health risk**, the State Party may, in accordance with its national law and **to the extent necessary to control such a risk**, compel the traveller to undergo or advise the traveller, **pursuant to paragraph 3 of Article 23**, to undergo:
>
> (a) the least invasive and intrusive medical examination that would achieve the public health objective;
>
> (b) vaccination or other prophylaxis; or
>
> (c) additional established health measures that prevent or control the spread of disease, including isolation, quarantine or placing the traveller under public health observation.' (emphasis added)

The limited scope of Article 31(2) IHR makes it clear that it was not the intent of the drafters of Article 31(2) to undermine or weaken the guarantee in Article 23(3) IHR that travellers shall not be subjected to medical treatment or other health measure without their 'prior express informed consent'. The narrow issue regulated by Article 31 IHR is the question about the conditions under which a State Party can deny access to its territory on the grounds that a traveller does not consent to medical treatment or vaccination. The wording of Article 31 indicates a very high threshold: a State Party can only lawfully deny entry to a traveller if there

is evidence of an imminent public health risk. Consequently, according to the current version of the IHR, the State Party is not allowed to deny entry by default but only in highly exceptional situations and on a case-by-case basis. This is ensured by the phrase 'to the extent necessary to control such a risk', indicating that a State Party may deny the right of entry only as an *ultima ratio* if the imminent risk is concrete and evident. In addition, given the scope and purpose of the IHR regulating and coordinating international responses to PHEICs, denying entry can only be based on the traveller refusing to undergo a medical treatment or vaccination recommended in a temporary or standing recommendation of a relevant WHO Emergency Committee during a PHEIC. In other words, it is excluded that States invoke the exception to deny entry to travellers on the basis of *any* disease.

During the Covid-PHEIC, however, many States Parties and particularly the EU Member States denied travellers the right to enter a country if they did not present a vaccine certificate to the custom borders. This was despite the fact that Covid-19 vaccination was never required for international travel under the relevant temporary recommendations of the WHO Covid-19 Emergency Committee.

It was a hard fact for individuals around the globe who exercised their right to refuse the WHO-recommended, emergency-listed Covid-19 vaccinations that they were denied international travel. Beyond that, at the national level, many were precluded from exercising their fundamental rights, impacting their lives and livelihoods, and constituting severe pressure to take the vaccines.

This evidence and experience of unvaccinated individuals during the Covid-19-PHEIC must lead to a stronger commitment of the international community to free and informed consent, including the right to refuse vaccination. Therefore, free and informed consent should become an explicit guiding principle of the IHR, reinforcing the human rights not to be subjected to medical treatment or medical or scientific experimentation under international human rights law also in the context of international travel.

Proposals for the WGIHR to consider

NEW Article 3 Principles

1. The implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons and no medical treatment or vaccination undertaken without the free and informed consent of persons. This includes the right to refuse medical treatment or vaccination without undue negative consequences.

2….

NEW **Article 23** Health measures on arrival and departure

….

3. No medical examination, vaccination, prophylaxis or health measure under these Regulations shall be carried out on travellers without their prior express informed consent or that of their parents or guardians, ~~except as provided in paragraph 2 of Article 31~~, and in accordance with the law and international obligations of the State Party. If a traveller refuses consent to medical examination, vaccination, prophylaxis or health measure, the requirements of paragraph 2 of Article 31 shall be considered by the State Party.

NEW **Article 31** Health measures relating to entry of travellers

1. Invasive medical examination, vaccination or other prophylaxis and relevant certificates shall not be required as a condition of entry of any traveller to the territory of a State Party pursuant to Article 3 paragraph 1. Only non-invasive medical diagnostic testing of the health status of travellers in accordance with the advice of a temporary or standing recommendation can be required if the following conditions are met:
~~subject to Articles 32, 42 and 45, these Regulations do not preclude States Parties from requiring medical examination, vaccination or other prophylaxis or proof of vaccination or other prophylaxis:~~
(a) when necessary to determine whether a public health risk exists;
(b) as a condition of entry for any travellers seeking temporary or permanent residence;
(c) as a condition of entry for any travellers pursuant to Article 43 or Annexes 6 and 7; or
(d) which may be carried out pursuant to Article 23.
2. If a traveller for whom a State Party requires a medical examination, vaccination or other prophylaxis under paragraph 1 of this Article fails to consent to any such measure, or refuses to provide the information or the documents referred to in paragraph 1 of Article 23, the State Party concerned may, subject to Articles 32, 42 and 45, deny entry to that traveller only if the following conditions are met:
- the traveller poses an imminent public health risk through an evident infection, i.e. has clinical signs of symptoms and has been clinically tested positive for a disease for which a temporary or standing recommendation has been issued.

3. If a traveller poses an imminent public health risk through an evident infection for which a temporary or standing recommendation has been issued, the State Party shall offer the traveller in accordance with paragraph 2 of Article 23,
(a) the least invasive and intrusive medical examination that would achieve the public health objective;
(b) vaccination or other prophylaxis; or
(c) additional established health measures that prevent or control the spread of disease, including isolation, quarantine or placing the traveller under public health observation.

List of Abbreviations

ACHR – American Convention on Human Rights, 1969

Additional Protocol to Oviedo Convention – Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, 2005

AfCHPR – African Charter on Human and Peoples' Rights, 1981

CAT – Convention Against Torture, 1984

CEDAW – Convention on the Elimination of all Forms of Discrimination Against Women, 1979

CEDAW Committee – UN Committee on the Elimination of Discrimination against Women

CESCR – UN Committee on Economic, Social and Cultural Rights

CRC – Convention on the Rights of the Child, 1989

CRPD – Convention on the Rights of Persons with Disabilities, 2006

DARIO – Draft Articles on the Responsibilities of International Organisations, 2011

ECHR – European Convention on Human Rights, 1950

ECtHR – European Court of Human Rights

EUL – Emergency Use Listing

HRC – UN Human Rights Committee

ICCPR – International Covenant on Civil and Political Rights, 1966

ICESCR – International Covenant on Economic, Social and Cultural Rights, 1966

ICJ – International Court of Justice

ICTY – International Criminal Tribunal for the Former Yugoslavia

IHR – International Health Regulations, 2005

INB - Intergovernmental Negotiating Body

Oviedo Convention – Convention on Human Rights and Biomedicine, 1997

PHEIC – Public Health Emergency of International Concern

UDHR – Universal Declaration of Human Rights, 1948

UNESCO Declaration – UNESCO Universal Declaration on Bioethics and Human Rights

VCLT – Vienna Convention on the Law of Treaties, 1969

WHO - World Health Organization

WHOC – Constitution of the World Health Organisation, 1946

Endnotes

[1] This document relies on the Article-by-Article Compilation of Proposed Amendments to the International Health Regulations (2005), submitted in accordance with decision WHA75(9) (2022), issued in November 2022 by the Working Group on the Amendments of the International Health Regulations (WGIHR), available at: https://apps.who.int/gb/wgihr/pdf_files/wgihr1/WGIHR_Compilation-en.pdf (in the following referred to as 'Article-by-Article-Compilation'). Since then, no updated amendments have been made accessible to the public, despite on-going intense negotiations and heightened public interest in the process.

[2] This document relies on the recent Revised Draft of the Negotiating Text of the WHO Pandemic Agreement, A/INB/9/3, 13 March 2024 (in the following referred to as Draft Pandemic Agreement (revised negotiating text)).

[3] Art. 9 Draft Pandemic Agreement (revised negotiating text). Whilst most of the Article addresses States, Art. 9(2)(f) envisages a central role for the WHO in promoting 'international collaboration and coordination, including with the private sector, to set common objectives, research goals and priorities, to develop pandemic-related products for diverse populations and settings'. This will likely link into WHO's current Research and Development Blueprint for Emerging Pathogens (R&D Blueprint) Programme (https://www.who.int/teams/blueprint/who-r-and-d-blueprint-for-epidemics).

[4] Art. 14 Draft Pandemic Agreement (revised negotiating text); Article-by-Article Compilation, proposed new Art. 13A 'Access to Health Products, Technologies and Know How', para. 6(c), p. 14.

[5] Arts. 1(l), 12(10) and 14(1) and (4) Draft Pandemic Agreement (revised negotiating text).

[6] Art.1(l) Draft Pandemic Agreement (revised negotiating text).

[7] Arts. 10 and 13*bis* Draft Pandemic Agreement (revised negotiating text); Article-by-Article Compilation, proposed new Art. 13A 'WHO Led International Health Response', paras. 4 and 5, p. 13, and proposed new Art. 13A 'Access to Health Products, Technologies and Know-How', para. 4, p. 14; and proposed amendments to Art. 13, new para. 7, p. 12.

[8] Art.1(l) Draft Pandemic Agreement (revised negotiating text).

[9] Art.13 Draft Pandemic Agreement (revised negotiating text).

[10] Art.13(5) Draft Pandemic Agreement (revised negotiating text). Similarly: Article-by-Article Compilation, proposed new Art. 13A 'WHO Led International Health Response', and proposed new Art. 13A 'Access to Health Products, Technologies and Know-How', pp. 13-14.

[11] See e.g. WHO Covid-19-EC, Statement on the Eighth Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Coronavirus Disease (COVID-19) Pandemic, 15 July 2021, rec.3 to State parties (10%); Statement on the Ninth Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Coronavirus Disease (COVID-19) Pandemic, 26 October 2021, rec.3 to State Parties (40%); Statement on the Tenth Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Coronavirus Disease (COVID-19) Pandemic, 19 January 2022, rec.3 to State Parties (70%); Statement on Twelfths Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Coronavirus Disease (COVID-19) Pandemic, 12 July 2022, rec.3 to States Parties ('achieve the highest possible vaccination coverage among persons at highest risk of severe disease outcomes and among persons at highest risk of exposure, health workers, the elderly and other priority groups' including a 'booster dose'); Statement on the Fourteenth Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Coronavirus Disease (COVID-19) Pandemic, 30 January 2023, rec.1 ('achieve 100% [vaccination] coverage of high-priority groups').

[12] International Health Regulations, 2005.

[13] See e.g. https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines/advice, and https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines/explainers.

[14] During the Covid-19 PHEIC, WHO granted an EUL to all known investigational vaccines against Covid-19 and recommended them for worldwide administration: https://extranet.who.int/prequal/sites/default/files/document_files/Status_COVID_VAX_08AUgust2023.pdf

[15] WHO, Emergency Use Listing Procedure, Version of 9 August 2022, p. 7.

[16] WHO, Emergency Use Listing Procedure, https://extranet.who.int/prequal/vaccines/emergency-use-listing-procedure.

[17] WHO, Emergency Use Listing Procedure, Version of 9 August 2022, p. 7.

[18] US Food and Drug Administration, Emergency Use Authorization, https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

[19] EMA's conditional marketing authorisation process explained: https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/conditional-marketing-authorisation.

[20] Joseph Fraiman *et al*., 'Serious Adverse Events of Special Interest Following mRNA COVID-19 Vaccination in Randomized Trials in Adults' (2022) 40 *Vaccines* 5798, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9428332/; M. Nathaniel Mead, 'COVID-19 mRNA Vaccines: Lessons Learned from the Registrational Trials and Global Vaccination Campaign' (2024) 16(1) *Cureus* e52876; Dimitrios Bitounis *et al*., 'Strategies to Reduce the Risks of mRNA Drug and Vaccine Toxicity' *Nature Reviews Drug Discovery* (2024), https://www.nature.com/articles/s41573-023-00859-3; Stephanie Seneff *et al.,* 'Innate Immune Suppression by SARS-CoV-2 mRNA Vaccinations: The Role of G-quadruplexes, Exosomes, and MicroRNAs' (2022) 164 *Food and Chemical Toxicology* 113008, https://www.sciencedirect.com/science/article/pii/S027869152200206X; Aseem Malhotra, 'Curing the Pandemic of Misinformation on Covid-19 mRNA Vaccines through Real Evidence-based Medicine –

Part 1' (2022) 5(1) *Journal of Insulin Resistance* a71, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9557944/pdf/JIR-5-71.pdf; and Aseem Malhotra, 'Curing the Pandemic of Misinformation on Covid-19 mRNA Vaccines through Real Evidence-based Medicine – Part 2' (2022) 5(1) *Journal of Insulin Resistance* a72, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9557939/pdf/JIR-5-72.pdf ; Vladimir Uversky *et al.*, 'IgG4 Antibodies Induced by Repeated Vaccination May Generate Immune Tolerance to the SARS-CoV-2 Spike Protein' (2023) 11 *Vaccines* 991, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10222767/; Gretchen Vogel and Jennifer Couzin-Frankel, 'Studies Probe Covid-19 Shots' Link to Rare Symptoms. Details Emerge for Uncommon Cases of Neurologic Complications, Blood Pressure Swings, and Other Side Effects' (2023) 381 *Science* 18, https://www.science.org/content/article/rare-link-between-coronavirus-vaccines-and-long-covid-illness-starts-gain-acceptance; Fadi Nahab *et al*., 'Factors Associated with Stroke after Covid-19 Vaccination: A Statewide Analysis' (2023) 14 *Frontiers in Neurology* 1199745, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10337778/; Josef Finsterer, 'Neurological Adverse Reactions to SARS-CoV-2 Vaccines' (2023) 21(2) *Clinical Psychopharmacology and Neuroscience* 222, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10157009/; Peter Doshi, 'Will Covid-Vaccines Save Lives? Current Trials are not Designed to Tell Us' (2020) 371 *British Medical Journal* m4037, https://www.bmj.com/content/371/bmj.m4037 ; Peter Doshi, 'Pfizer and Moderna's "95% Effective" Vaccines – We Need more Details and the Raw Data', *thebmjopinion*, 4 January 2021, https://blogs.bmj.com/bmj/2021/01/04/peter-doshi-pfizer-and-modernas-95-effective-vaccines-we-need-more-details-and-the-raw-data/; Peter Doshi, 'Clarification: Pfizer and Modern's "95% Effective" Vaccines – We Need more Details and the Raw Data', *thebmjopinion*, 5 February 2021, https://blogs.bmj.com/bmj/2021/02/05/clarification-pfizer-and-modernas-95-effective-vaccines-we-need-more-details-and-the-raw-data/

[21] See e.g. adverse events reported at: Vaccine Adverse Event Reporting System (VAERS), https://vears.hhs.gov. Current and reformatted US data at *Openvears*, VAERS COVID Vaccine Adverse Event Reports, https://openvaers.com/covid-data; *EudraVigilance*, European Database of Suspected Adverse Drug Reaction Reports, https://www.adrreport.eu/en/index.html; and Data from WHO Database *VigiAccess*, concerning all Covid-19 vaccines, https://www.vigiaccess.org.

[22] See the historical overview by Mahmoud Cheriff Bassiouni *et al.,* 'An Appraisal of Human Experimentation in International Law and Practice: The Need for International Regulation of Human Experimentation' (1981) 72 *Journal of Criminal Law & Criminology* 1597, p. 1606; Jochen Vollman and Rolf Winau, 'Informed Consent in Human Experimentation before the Nuremberg Code', (1996) 313 *British Medical Journal* 1445; see also Parliamentary Assembly of the Council of Europe (PACE), Covid-19 Vaccines: Ethical, Legal and Practical Considerations, Reports of the Committee on Social Affairs, Health and Sustainable Development, Rapporteur: Ms Jennifer DE TEMMERMAN, France, Alliance of Liberals and Democrats for Europe, Doc 15212, 11 January 2021, para. 62.

[23] See e.g. Thierry Vansweevelt and Nicola Glover-Thomas (eds.), *Informed Consent and Health – A Global Analysis* (Edward Elgar, 2020).

[24] Art. 7 International Covenant on Civil and Political Rights (ICCPR), 1966; Art. 15 Convention on the Rights of Persons with Disabilities (CPRD), 1990; see also Art. 16 Convention on Human Rights and Biomedicine (1997), ETS No.164 (hereinafter Oviedo Convention); Art. 24 Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (hereinafter Additional Protocol to Oviedo Convention), CETS No. 195, 2005; Art. 6(2) UNESCO Universal Declaration on Bioethics and Human Rights (2005) (hereinafter UNESCO Declaration); and UN Special Rapporteur on the Right to Health, 'Report on Informed Consent', UN Doc A/64/272, 10 August 2010, para. 35.

[25] This right forms part of both the rights to health (Art. 12 International Covenant on Economic, Social and Cultural Rights (ICESCR), 1966; Art. 24 Convention on the Rights of the Child (CRC), 1989; Art. 12 Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW), 1979; Art. 25 CPRD; Art. 16 African Charter on Human and Peoples' Rights (AfCHRP), 1981); the right to privacy (Art. 17 ICCPR; Art. 16 CRC; Art. 22 CRPD; Art. 11 American Convention on Human Rights (ACHR), 1969; Art. 8 European Convention on Human Rights (ECHR), 1950); and the right not to be subjected to torture or inhuman or degrading treatment (Art. 7 ICCPR; Art. 19 and 37(a) CRC; Art. 15 CPRD; Arts. 1 and 16 Convention Against Torture (CAT); Art. 5 AfCHPR; Art. 5(1) and (2) ACHR; Art.3 ECHR). See also Arts. 1 and 5 Oviedo Convention; and Art. 6(1) UNESCO Declaration.

[26] See e. g. judgments of the European Court of Human Rights (ECtHR) and statements and 'Views' of UN human rights treaty bodies finding violations of these rights due to mandatory urine-, blood- or HIV/AIDS-tests (see ECtHR, *R.S. v Hungary*, No 65290/14, 2 July 2019; ECtHR, *M.A.K. and R.K. v The United Kingdom,* No 45901/05, 23 March 2010; UN Human Rights Committee (HRC), Views adopted by the Committee under Article 5(4) of the Optional Protocol, concerning Communication No 2273/2013 (*Andrea Vandom v Republic of Korea*), UN Doc CCPR/C/123/D/2273/2013, 10 August 2018); due to forced administration of medical products (ECtHR, *X v Finland*, No 34806/04, 3 July 2012); due to forced gynaecological examinations and sterilisations (ECtHR, *Juhnke v Turkey*, No 52515/99, 13 May 2008, paras. 81–82; ECtHR, *V.C. v Slovakia,* No 18968/07, 8 November 2011); due to invasive treatments during childbirth (see Committee on the Elimination of Discrimination against Women (CEDAW), Decision adopted by the Committee under Article 4(2)(c) of the Optional Protocol, concerning Communication No 138/2018 (*S.F.M v Spain*), UN Doc CEDAW/C/75/D/138/2018, 28 February 2020, para. 7.2); due to coercion to continue a non-viable pregnancy (see HRC, Views adopted by the Committee under Article 5(4) of the Optional Protocol, concerning Communication No 2425/2014 (*Siobhan Whelan v Ireland*), UN Doc CCPR/C/119/D/2425/2014, 17 July 2017, para. 7.8); due to forceful administration of anti-psychotic drugs (see HRC, 'Views adopted by the Committee under Article 5(4) of the Optional Protocol, concerning Communication No 1449/2006 (*Umarov v Uzbekistan*), UN Doc CCPR/C/1449/2006, 19 October 2010, para. 8.3); due to forced testing of antipsychotic drugs that were not authorised for general use (ECtHR, *Bataliny v Russia*, No 10060/07, 23 July 2015, para. 90); generally, see also

Committee on Economic, Social and Cultural Rights (CESCR), General Comment 14 – Right to Health', UN Doc E/C.12/2000/4, 11 August 2000, para.8.

[27] Art. 6(1) ICCPR; Art. 6 CRC; Art. 22 CPRD; Art. 4 AfCHPR; Art. 4 ACHR; Art. 2 ECHR.

[28] HRC, General Comment 36 – Right to Life, UN Doc CCPR/C/GC/36, 3 Sept 2019, para.16.

[29] Art. 5 Oviedo Convention and the Explanatory Report, ETS 164 – Human Rights and Biomedicine, 4 April 1997, para. 35; Art. 6 UNESCO Declaration; CESCR, General Comment 25 – Right to Science, UN Doc E/C.12/GC/25, 30 April 2020, para. 71; CEDAW, Views: Communication No 4/2004 (*A.S. v Hungary*), UN Doc CEDAW/C/36/D/4/2004, 29 August 2006, para. 11.3; CEDAW, General Recommendation 24 – Women and Health, contained in UN Doc A/54/38/Rev.1, chap. I (1999), para. 20; UN Special Rapporteur on the Right to Health, Report on Informed Consent, para. 15.

[30] See e.g. Nuremberg Code (1947), principle 1; Art. 5 Oviedo Convention and Explanatory Report, para.35; Art. 15(2) UNESCO Declaration; UN Special Rapporteur on the Right to Health, Report on Informed Consent, paras. 13 and 36; CESCR, General Comment 22 – Right to Sexual and Reproductive Health, UN Doc E/C.12/GC/22, 2 May 2016, para. 58; CEDAW, General Recommendation 24 – Women and Health, para. 22; CEDAW, *A.S. v Hungary*, para. 11.3.

[31] Art. 24 Additional Protocol to Oviedo Convention 2005; UN Special Rapporteur on the Right to Health, Report on Informed Consent, para. 35.

[32] Art. 16(v) Oviedo Convention; Art. 6(2) UNESCO Declaration; UN Special Rapporteur on the Right to Health, Report on Informed Consent, para. 35.

[33] Art. 5 Oviedo Convention; Art. 6(1) and (2) UNESCO Declaration; CESCR, General Comment 25 – Right to Science, para. 44; UN Special Rapporteur on the Right to Health, Report on Informed Consent, para. 28; John Tasioulas and Effy Vayena, 'Getting Human Rights Right in Global Health', (2015) 385(9978) *The Lancet* 42, at 42, referring to a human right not to participate in medical experiments.

[34] Art. 16(v) Oviedo Convention and Explanatory Report, para. 38; UN Special Rapporteur on the Right to Health, Report on Informed Consent, para. 35.

[35] HRC, 'Concluding Observations – United States of America', UN Doc CCPR/C/USA/4, 23 April 2014, para. 18.

[36] Arts. 7 and 4(2) ICCPR; HRC, 'General Comment 29 – State of Emergency', UN Doc CCPR/C/21/Rev.1/Add.11, 31 Aug 2001, para. 7.

[37] HRC, 'Concluding Observations – United States of America', UN Doc CCPR/C/USA/CO/3/Rev.1, 18 Dec 2006, para.31.

[38] Article 53 of the Vienna Convention on the Law of Treaties (VCLT) defines a peremptory norm of general international law as 'a norm accepted and recognized by the international community of States as a whole as a norm from which no derogation is permitted and which can be modified only by a subsequent norm of general international law having the same character.'

[39] International Court of Justice (ICJ), *Belgium v Senegal*, ICJ Reports 2012, pp. 449-50 and 457; and International Criminal Tribunal for the Former Yugoslavia (ICTY), *The Prosecutor v Anto Furundžija,* Trial Chamber, IT-95-17/1-T, 10 Dec 1998, paras. 144 and 153-157; International Law Commission, Commentary on Articles on State Responsibility, 2001, p. 85.

[40] Arts. 12 and 50 Geneva Convention (I) for the Amelioration of the Condition of Wounded and Sick in Armed Forces in the Field, 12 August 1949; Arts. 12 and 51 Geneva Convention (II) for the Amelioration of the Conditions of the Wounded, Sick and Shipwrecked Members of Armed Forces at Sea, 12 August 1949; Arts. 13 and 130 Geneva Convention (III) Relative to the Treatment of Prisoners of War, 12 August 1949; Arts. 32 and 147 Geneva Convention (IV) Relative to the Protection of Civilian Persons in Time of War, 12 August 1949; Art. 11 (2) (b) Protocol Additional to the Geneva Conventions of 12 August 1949, and relating to the Protection of Victims of International Armed Conflicts (Protocol I), 8 June 1977; and Art. 5 Protocol Additional to the Geneva Conventions of 12 August 1949, and Relating to the Protection of Victims of Non-International Armed Conflicts (Protocol II), 8 June 1977; Rules 90 and 92 Customary IHL.

[41] Art. 8 (2) (a) (ii), 8 (2) (b) (x) and 8 (2) (e) (xi) Rome Statute of the International Criminal Court.

[42] Art. 6(1) and Art. 4(2) ICCPR.

[43] Art. 6(1) ICCPR; HRC, General Comment 36 – Right to Life, paras. 16 and 17; and Art. 6 CRC; Art. 10 CPRD; Art. 4 AfCHPR; Art. 4 ACHR; Art. 2 ECHR.

[44] Art. 62 Draft Articles on the Responsibility of International Organisations (DARIO), 2011.

[45] Art. 61 DARIO.

[46] E.g. CESCR, General Comment 14 – Right to Health, para. 39; CESCR, General Comment 19 – The Right to Social Security, UN Doc E/C.12/GC/19, 4 Feb 2008, paras. 57-58; ECtHR, *Waite and Kennedy v Germany*, No 26083/94, 18 Feb 1999, para. 76; ECtHR, *Al-Dulimi and Montana Management v Switzerland*, No 5809/08, 26 Nov 2013, para. 144; and reiterated in the Maastricht Principles on Extraterritorial Obligations of States in the Area of Economic, Social and Cultural Rights, 2011, principle 15.

[47] Art. 53 VCLT reads: 'A treaty is void if, at the time of its conclusion, it conflicts with a peremptory norm of general international law. …'.

[48] ICJ, *Interpretation of the Agreement of March 1951 between the WHO and Egypt*, Advisory Opinion, ICJ Reports 1980 (73), para. 37; see also Arts. 2(b) and 10 of the Draft Articles on the Responsibilities of International Organisations (2011) and commentary, p. 63; and relevant academic literature, e.g. Gerhard Hafner, 'Accountability of International Organisations – A Critical View' in Ronald St John MacDonald and Douglas Johnston (eds), *Towards World Constitutionalism* (Nijhoff, 2005) 585, p. 629; August Reinisch, 'Governance Without Accountability?' (2001) 44 *German Yearbook of International Law* 207, pp. 281-82.

[49] For an explanation of these differences, see Samantha Besson, 'The Bearers of Human Rights' Duties and Responsibilities for Human Rights: A Quiet (R)evolution' (2015) 32(1) *Social Philosophy & Policy* 244.

[50] Art. 3(1) IHR.
[51] Preamble, Constitution of the World Health Organisation (WHOC) 1946; Art. 3(2) IHR, also cross-refers to the WHOC. IOs are bound by their constituent instrument, even if they are not parties to this instrument (see: ICJ, *Reparations for Injuries Suffered in the Service of the United Nations*, Advisory Opinion, ICJ Reports 1949 (147), para. 180).
[52] UDHR, 10 December 1948, avaialble at: https://www.un.org/en/about-us/universal-declaration-of-human-rights.
[53] See the recent analysis by William Schabas, *The Customary Law of Human Rights* (OUP, 2021); Ilias Bantekas and Lutz Otte, *International Human Rights Law and Practice* (CUP, 3rd ed, 2013), pp. 20-22 and 62; HRC, General Comment 24 – On Issues Relating to Reservations, UN Doc CCPR/C/21/Rev.1/Add.6, 11 Nov 1994, para.8.
[54] CESCR, General Comment 14 – Right to Health, paras. 42 and 64. Generally, concerning these more negative responsibilities for human rights of IOs see also CESCR, General Comment 21 – The Right to take Part in Cultural Life, E/C.12/GC/21, 21 Dec 2009, paras. 57 and 59; CESCR, General Comment 22 – Right to Sexual and Reproductive Health, para. 52; CESCR, General Comment 4 – The Right to Adequate Housing, 1991, contained in UN Doc E/1992/23, para. 19; CESCR, General Comment 7 – The Right to Adequate Housing (Forced Evictions), 16 May 1997, contained in UN Doc E/1998/22, annex IV, paras. 17-18; and the Maastricht Principles, principle 16.
[55] CESCR, General Comment 14 – Right to Health, paras. 42 and 64. Generally, concerning these more positive obligations of international organisations, including the WHO, see CESCR, General Comment 15 – The Right to Water, E/C.12/2002/11, 20 January 2002, para. 60 ('promotion of the right to water' through activities of international organisations); CESCR, General Comment 17 – The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of which He or She is the Author, UN Doc E/C.12/GC/17, 12 January 2006, para. 57 (UN agencies to take measures 'likely to contribute to the effective implementation of Art. 15(1)(c) ICESCR); CESCR, General Comment 2 – International Technical Assistance Measures, contained in UN Doc E/1990/23, 2 Feb 1990, para. 8(a) (addressing the UN and its agencies); General Comment 21 – Right to Take Part in Cultural Life, para. 75-76 (generally on 'policies' of IOs to be compliant with ICESCR).
[56] DARIO.